



KRUPANIDHI COLLEGE OF PHARMACY

(Approved by AICTE & PCI, New Delhi, Affiliated to RGUHS, Bengaluru)

Accredited with Grade 'A' by NAAC, Bengaluru | ISO 9001 – 2015 Certified

12/1, CHIKKA BELLANDUR, CARMELARAM POST, VARTHUR HOBLI, BANGALORE – 560 035

Number of courses offered by the Institution across all programs during the years 2019-2020

SI No	Program name	Course code	Name of the Course	Link The Document
B.PHARM				
1	B.Pharm - I Sem	BP101T	Human Anatomy and Physiology	Click Here
2		BP107P	Human Anatomy and Physiology – Practical	Click Here
3		BP102T	Pharmaceutical analysis -I	Click Here
4		BP108P	Pharmaceutical analysis -I – Practical	Click Here
5		BP103T	Pharmaceutics	Click Here
6		BP109P	Pharmaceutics Practical I	Click Here
7		BP104T	Pharmaceutical Inorganic Chemistry	Click Here
8		BP110P	Pharmaceutical Inorganic Chemistry – Practical	Click Here
9		BP105T	Communication skills	Click Here
10		BP111P	Communication skills – Practical	Click Here
11		BP106RBT	Remedial Biology	Click Here
12		BP112RBP	Remedial Biology – Practical	Click Here
13		BP106RM T	Remedial mathematics	Click Here
14	B.Pharm - II Sem	BP201T	Human Anatomy and Physiology	Click Here
15		BP207P	Human Anatomy and Physiology – Practical	Click Here
16		BP202T	Pharmaceutical Organic Chemistry I	Click Here
17		BP208P	Pharmaceutical Organic Chemistry I – Practical	Click Here
18		BP203T	Biochemistry	Click Here
19		BP209P	Biochemistry – Practical	Click Here
20		BP204T	Pathophysiology	Click Here
21		BP205T	Computer Application in Pharmacy	Click Here
22		BP210P	Computer Application in Pharmacy – Practical	Click Here
23		BP206T	Environmental Sciences	Click Here
24	B.Pharm - III Sem	BP301T	Pharmaceutical Organic Chemistry II – Theory	Click Here
25		BP305P	Pharmaceutical Organic Chemistry II – Practical	Click Here
26		BP302T	Physical Pharmaceutics I – Theory	Click Here
27		BP306P	Physical Pharmaceutics I – Practical	Click Here
28		BP303T –	Pharmaceutical Microbiology Theory	Click Here
29		BP307P	Pharmaceutical Microbiology – Practical	Click Here
30		BP304T	Pharmaceutical Engineering – Theory	Click Here
31		BP 308P	Pharmaceutical Engineering –Practical	Click Here
32	B.Pharm - IV Sem	BP401T	Pharmaceutical Organic Chemistry III– Theory	Click Here
33		BP402T	Medicinal Chemistry I – Theory	Click Here



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34		BP406P	Medicinal Chemistry I – Practical	Click Here
35		BP403T	Physical Pharmaceutics II – Theory	Click Here
36		BP407P	Physical Pharmaceutics II – Practical	Click Here
37		BP404T	Pharmacology I – Theory	Click Here
38		BP408P	Pharmacology I – Practical	Click Here
39		BP405T	Pharmacognosy and Phytochemistry I– Theory	Click Here
40		BP409P	Pharmacognosy and Phytochemistry I – Practical	Click Here
41	B.Pharm - V Sem	BP501T	Medicinal Chemistry II – Theory	Click Here
42		BP502T	Formulative Pharmacy– Theory	Click Here
43		BP506P	Formulative Pharmacy – Practical	Click Here
44		BP503T	Pharmacology II – Theory	Click Here
45		BP507P	Pharmacology II – Practical	Click Here
46		BP504T	Pharmacognosy and Phytochemistry II– Theory	Click Here
47		BP508P	Pharmacognosy and Phytochemistry II – 4 - 2 Practical	Click Here
48		BP505T	Pharmaceutical Jurisprudence – Theory	Click Here
49	B.Pharm - VI Sem	BP601T	Medicinal Chemistry III – Theory	Click Here
50		BP607P	Medicinal chemistry III – Practical	Click Here
51		BP602T	Pharmacology III – Theory	Click Here
52		BP608P	Pharmacology III – Practical	Click Here
53		BP603T	Herbal Drug Technology – Theory	Click Here
54		BP609P	Herbal Drug Technology – Practical	Click Here
55		BP604T	Biopharmaceutics and Pharmacokinetics – 3 1 4 Theory	Click Here
56		BP605T	Pharmaceutical Biotechnology – Theory	Click Here
57		BP606T	Quality Assurance –Theory	Click Here
58	B.Pharm - VII Sem	BP701T	Instrumental Methods of Analysis – Theory	Click Here
59		BP705P	Instrumental Methods of Analysis – Practical	Click Here
60		BP702T	Industrial Pharmacy – Theory	Click Here
61		BP703T	Pharmacy Practice – Theory	Click Here
62		BP704T	Novel Drug Delivery System – Theory	Click Here
63		BP706PS	Practice School	Click Here
64	B.Pharm - VIII Sem	BP801T	Biostatistics and Research Methodology	Click Here
65		BP802T	Social and Preventive Pharmacy	Click Here
66		BP803ET	Pharmaceutical Marketing	Click Here
67		BP805ET	Pharmacovigilance	Click Here
68		BP806ET	Quality Control and Standardizations of Herbals	Click Here
69		BP807ET	Computer Aided Drug Design	Click Here
70		BP810ET	Experimental Pharmacology	Click Here
71		BP812PW	Project Work	Click Here



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M. PHARM - Pharmaceutics (MPH)				
72	M.Pharm - I SEM	MPA101T	Modern Pharmaceutical Analytical Techniques	Click Here
73		MPH101T	Modified Release Drug Delivery System	Click Here
74		MPH102T	Modern Pharmaceutics	Click Here
75		MPH103T	Pharmaceutical Regulatory Affair	Click Here
76		MPH104P	Pharmaceutics Practical I	Click Here
77	M.Pharm - II SEM	MPH201T	Molecular Pharmaceutics(Nano Tech and Targeted DDS)	Click Here
78		MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	Click Here
79		MPH203T	Computer Aided Drug Development System	Click Here
80		MPH204T	Cosmetic and Cosmeceuticals	Click Here
81		MPH205P	Pharmaceutics Practical I	Click Here
82	M.Pharm - III SEM	MRM101T	Research Methodology and Biostatistics*	Click Here
83	M.Pharm - IV SEM		Research work and Colloquium	Click Here
M. PHARM - Pharmacology(MPL)				
84	M.Pharm - I SEM	MPL101T	Advanced Pharmacology-I	Click Here
85		MPL102T	Pharmacological and Toxicological Screening Methods	Click Here
86		MPL103T	Cellular and Molecular Pharmacology	Click Here
87		MPL104P	Pharmacology Practical I	Click Here
88	M.Pharm - II SEM	MPL201T	Advanced Pharmacology II	Click Here
89		MPL102T	Pharmacological and Toxicological Screening Methods II	Click Here
90		MPL203T	Principles of Drug Discovery	Click Here
91		MPL204T	Clinical research and pharmacovigilance	Click Here
92		MPL205P	Experimental Pharmacology practical- II	Click Here
M. PHARM - Pharmaceutical Quality Assurance (MQA)				
93	M.Pharm - I SEM	MQA101T	Quality Management System	Click Here
94		MQA102T	Quality Control and Quality Assurance	Click Here
95		MQA103T	Product Development and Technology Transfer	Click Here
96		MQA104P	Pharmaceutical Quality Assurance Practical I	Click Here
97	M.Pharm - II SEM	MQA201T	Hazards and Safety Management	Click Here
98		MQA202T	Pharmaceutical Validation	Click Here
99		MQA203T	Audits and Regulatory Compliance	Click Here
100		MQA204T	Pharmaceutical Manufacturing Technology	Click Here
101		MQA205P	Pharmaceutical Quality Assurance Practical II	Click Here
M.PHARM - Pharmaceutical Analysis(MPA)				
102	M.Pharm - I SEM	MPA102T	Advanced Pharmaceutical Analysis	Click Here
103		MPA103T	Pharmaceutical Validation	Click Here
104		MPA104T	Food Analysis	Click Here
105		MPA105P	Pharmaceutical Analysis Practical I	Click Here



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106	M.Pharm - II SEM	MPA201T	Advanced Instrumental Analysis	Click Here
107		MPA202T	Modern Bio-Analytical Techniques	Click Here
108		MPA203T	Quality Control and Quality Assurance	Click Here
109		MPA204T	Cosmetic Analysis and Evaluation	Click Here
110		MPA205P	Analysis Practical II	Click Here
M.PHARM - Pharmaceutical Chemistry(MPC)				
111	M.Pharm - I SEM	MPC101T	Advanced Organic Chemistry -I	Click Here
112		MPC102T	Advanced Medicinal chemistry	Click Here
113		MPC103T	Chemistry of Natural Products	Click Here
114		MPC104P	Pharmaceutical Chemistry Practical I	Click Here
115	M.Pharm - II SEM	MPC201T	Advanced Spectral Analysis	Click Here
116		MPC202T	Advanced Organic Chemistry -II	Click Here
117		MPC203T	Computer Aided Drug Design	Click Here
118		MPC204T	Pharmaceutical Process Chemistry	Click Here
119		MPC205P	Pharmaceutical Chemistry Practical II	Click Here
PHARM D				
120	Pharm D - I YEAR	1.1	Human Anatomy and Physiology	Click Here
121			Human Anatomy and Physiology(Practical)	Click Here
122		1.2	Pharmaceutics	Click Here
123			Pharmaceutics(Practical)	Click Here
124		1.3	Medicinal Biochemistry	Click Here
125			Medicinal Biochemistry(Practical)	Click Here
126		1.4	Pharmaceutical Organic Chemistry	Click Here
127			Pharmaceutical Organic Chemistry Practical	Click Here
128		1.5	Pharmaceutical Inorganic Chemistry	Click Here
129			Pharmaceutical Inorganic Chemistry(Practical	Click Here
130		1.6	Remedial Mathematics	Click Here
131			Remedial Biology	Click Here
132		1.6	Biology practical	Click Here
133	Pharm D - II YEAR	2.1	Pathophysiology	Click Here
134		2.2	Pharmaceutical Microbiology	Click Here
135			Pharmaceutical Microbiology practical	Click Here
136		2.3	Pharmacognosy & Phytopharmaceuticals	Click Here
137			Pharmacognosy & Phytopharmaceuticals Practicals	Click Here
138		2.4	Pharmacology-I	Click Here
139		2.5	Community Pharmacy	Click Here
140		2.6	Pharmacotherapeutics-I	Click Here
141			Pharmacotherapeutics-I(practical)	Click Here
142	Pharm D - III YEAR	3.1	Pharmacology-II	Click Here
143			Pharmacology-II practical	Click Here
144		3.2	Pharmaceutical Analysis	Click Here



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145			Pharmaceutical Analysis practical	Click Here
146		3.3	Pharmacotherapeutics-II	Click Here
147			Pharmacotherapeutics-II practical	Click Here
148		3.4	Pharmaceutical Jurisprudence	Click Here
149		3.5	Medicinal Chemistry	Click Here
150			Medicinal Chemistry practical	Click Here
151		3.6	Pharmaceutical Formulations	Click Here
152			Pharmaceutical Formulations practical	Click Here
153		4.1	Pharmacotherapeutics-III	Click Here
154			Pharmacotherapeutics-III practical	Click Here
155		4.2	Hospital Pharmacy	Click Here
156			Hospital Pharmacy practical	Click Here
157	Pharm D - IV YEAR	4.3	Clinical Pharmacy	Click Here
158			Clinical Pharmacy practical	Click Here
159		4.4	Biostatistics & Research Methodology	Click Here
160		4.5	Biopharmaceutics & Pharmacokinetics	Click Here
161			Biopharmaceutics & Pharmacokinetics practical	Click Here
162		4.6	Clinical Toxicology	Click Here
163	Pharm D - V YEAR	5.1	Clinical Research	Click Here
164		5.2	Pharmacoepidemiology and Pharmacoeconomics	Click Here
165		5.3	Clinical Pharmacokinetics & Pharmacotherapeutic Drug Monitoring	Click Here
166		5.4	Project	Click Here
167	Pharm D - VI YEAR	5.5	Internship	Click Here
PHARM D -(Post Baccalaureate)				
168	Pharm D (Post Baccalaureate) - I YEAR	1.1	Pharmacotherapeutic I & II Theory	Click Here
169			Pharmacotherapeutic I & II(practical)	Click Here
170		1.2	Hospital and Community pharmacy Theory	Click Here
171			Hospital and Community pharmacy practical	Click Here



ರಾಜೀವ್ ಗಾಂಧಿ ಆರೋಗ್ಯ ವಿಜ್ಞಾನಗಳ ವಿಶ್ವವಿದ್ಯಾಲಯ, ಕರ್ನಾಟಕ, ಬೆಂಗಳೂರು

RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru - 560 041

RGU/AUTH/BPHARM/146/2017-18

10.05.2017

NOTIFICATION

Sub: Revised ordinance relating to Bachelor of Pharmacy (B.Pharm) Degree course (Semester System)

Ref: (1) PCI Notification ref.No.14-136-2016-PCI,14-154/2015-PCI (53095-55431) dated 21.12.2016
(2) Proceedings of meeting of BOS in Pharmacy (UG) held on 03.12.2016
(3) Proceedings of meeting of Faculty of Pharmacy held on 05.12.2016
(4) Proceedings of meeting of Academic Council held on 22.12.2016
(5) Approval of Syndicate in its 125th meeting held on 06.01.2017.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994, Syndicate is pleased to notify the revised ordinance relating to Bachelor of Pharmacy (B.Pharm) Degree course (Semester System) as shown in annexure appended herewith.

This revised ordinance shall come into force from the academic year 2017-18 and onwards. However, for the students taking admission directly to 2nd year of B.Pharm Degree course through lateral entry, the said ordinance shall come into force from the academic year 2018-19 and onwards.

By Order


REGISTRAR

To

1. All the Principals of Pharmacy Colleges affiliated to RGUHS
2. The Registrar (Evaluation), RGUHS
3. The Director, Dept. of Curriculum Development, RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore-560 001.
2. The Secretary to Government, Health & Family Welfare Department (Medical Education), Vikasa Scudha, Bangalore-560 001.
3. The PA to Vice-Chancellor/Registrar/Registrar (Evaluation), RGUHS, Bangalore
4. The System Analyst, RGUHS to host the notification on RGUHS website.
5. Guard File/Office Copy




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BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the various experiments related to special senses and nervous system.
5. Appreciate coordinated working pattern of different organs of each system

Course Content:

Unit I

10 hours

☐ **Introduction to human body**

Definition and scope of anatomy and physiology, levels of structural organization and body systems, basic life processes, homeostasis, basic anatomical terminology.

☐ **Cellular level of organization**

Structure and functions of cell, transport across cell membrane, cell division, cell junctions. General principles of cell communication, intracellular signaling pathway activation by extracellular signal molecule, Forms of intracellular signaling: a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine

☐ **Tissue level of organization**

Classification of tissues, structure, location and functions of epithelial, muscular and nervous and connective tissues.

Unit II

10 hours

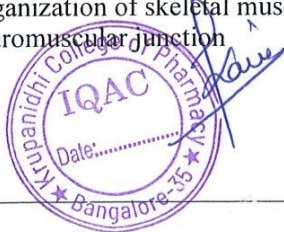
☐ **Integumentary system**

Structure and functions of skin

☐ **Skeletal system**

Divisions of skeletal system, types of bone, salient features and functions of bones of axial and appendicular skeletal system

Organization of skeletal muscle, physiology of muscle contraction, neuromuscular junction



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☐ **Joints**

Structural and functional classification, types of joints movements and its articulation

Unit III

10 hours

☐ **Nervous system**

Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters.

Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)

Unit IV

08 hours

Peripheral nervous system:

Classification of peripheral nervous system: Structure and functions of sympathetic and parasympathetic nervous system.

Origin and functions of spinal and cranial nerves.

☐ **Special senses**

Structure and functions of eye, ear, nose and tongue and their disorders.

Unit V

07 hours

☐ **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.




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BP107P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

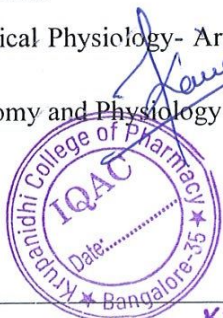
4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. To study the integumentary and special senses using specimen, models, etc.,
7. To study the nervous system using specimen, models, etc.,
8. To study the endocrine system using specimen, models, etc
9. To demonstrate the general neurological examination
 10. To demonstrate the function of olfactory nerve
 11. To examine the different types of taste.
 12. To demonstrate the visual acuity
 13. To demonstrate the reflex activity
 14. Recording of body temperature
 15. To demonstrate positive and negative feedback mechanism.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C. Guyton and John E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.



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6. Textbook of Human Histology by Inderbir Singh, Jaypee brother's medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brother's medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books (Latest Editions)

1. Physiological basis of Medical Practice-Best and Taylor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterje ,Academic Publishers Kolkata




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BP102T. PHARMACEUTICAL ANALYSIS (Theory)

45 Hours

Scope: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs

Objectives: Upon completion of the course student shall be able to

- ☐ understand the principles of volumetric and electro chemical analysis
- ☐ carryout various volumetric and electrochemical titrations
- ☐ develop analytical skills

Course Content:

UNIT-I

10 Hours

(a) **Pharmaceutical analysis-** Definition and scope

- i) Different techniques of analysis
- ii) Methods of expressing concentration
- iii) Primary and secondary standards.
- iv) Preparation and standardization of various molar and normal solutions- Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate

(b) **Errors:** Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

UNIT-II

10 Hours

- ☐ **Acid base titration:** Theories of acid base indicators, classification of acid base titrations and theory involved in titrations of strong, weak, and very weak acids and bases, neutralization curves
- ☐ **Non aqueous titration:** Solvents, acidimetry and alkalimetry titration and estimation of Sodium benzoate and Ephedrine HCl

UNIT-III

10 Hours

- ☐ **Precipitation titrations:** Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.
- ☐ **Complexometric titration:** Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.
- ☐ **Gravimetry:** Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.



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UNIT-IV

08 Hours

Redox titrations

- (a) Concepts of oxidation and reduction
- (b) Types of redox titrations (Principles and applications)

Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

UNIT-V

07 Hours

□ Electrochemical methods of analysis

- **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
- **Potentiometry** - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.
- **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications



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BP108P. PHARMACEUTICAL ANALYSIS (Practical)

4 Hours / Week

I Preparation and standardization of

- (1) Sodium hydroxide
- (2) Sulphuric acid
- (3) Sodium thiosulfate
- (4) Potassium permanganate
- (5) Ceric ammonium sulphate

II Assay of the following compounds along with Standardization of Titrant

- (1) Ammonium chloride by acid base titration
- (2) Ferrous sulphate by Cerimetry
- (3) Copper sulphate by Iodometry
- (4) Calcium gluconate by complexometry
- (5) Hydrogen peroxide by Permanganometry
- (6) Sodium benzoate by non-aqueous titration
- (7) Sodium Chloride by precipitation titration

III Determination of Normality by electro-analytical methods

- (1) Conductometric titration of strong acid against strong base
- (2) Conductometric titration of strong acid and weak acid against strong base
- (3) Potentiometric titration of strong acid against strong base

Recommended Books: (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
4. Bentley and Driver's Textbook of Pharmaceutical Chemistry
5. John H. Kennedy, Analytical chemistry principles
6. Indian Pharmacopoeia.



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BP103T. PHARMACEUTICS- I (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- ☐ Know the history of profession of pharmacy
- ☐ Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- ☐ Understand the professional way of handling the prescription
- ☐ Preparation of various conventional dosage forms

Course Content:

UNIT – I

10 Hours

- ☐ **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- ☐ **Dosage forms:** Introduction to dosage forms, classification and definitions
- ☐ **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- ☐ **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II

10 Hours

- ☐ **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- ☐ **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- ☐ **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques




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UNIT – III

08 Hours

- ☐ **Monophasic liquids:** Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments and Lotions.
- ☐ **Biphasic liquids:**
- ☐ **Suspensions:** Definition, advantages and disadvantages, classifications, Preparation of suspensions; Flocculated and Deflocculated suspension & stability problems and methods to overcome.
- ☐ **Emulsions:** Definition, classification, emulsifying agent, test for the identification of type of Emulsion, Methods of preparation & stability problems and methods to overcome.

UNIT – IV

08 Hours

- ☐ **Suppositories:** Definition, types, advantages and disadvantages, types of bases, methods of preparations. Displacement value & its calculations, evaluation of suppositories.
- ☐ **Pharmaceutical incompatibilities:** Definition, classification, physical, chemical and therapeutic incompatibilities with examples.

UNIT – V

07 Hours

- ☐ **Semisolid dosage forms:** Definitions, classification, mechanisms and factors influencing dermal penetration of drugs. Preparation of ointments, pastes, creams and gels. Excipients used in semi solid dosage forms. Evaluation of semi solid dosages forms




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BP109P. PHARMACEUTICS I (Practical)

3 Hours / week

- 1. Syrups**
 - a) Syrup IP
 - b) Paracetamol pediatric syrup
- 2. Elixirs**
 - a) Piperazine citrate elixir
 - b) Paracetamol pediatric elixir
- 3. Linctus**
 - a) Simple Linctus BPC
- 4. Solutions**
 - a) Strong solution of ammonium acetate
 - b) Cresol with soap solution
- 5. Suspensions**
 - a) Calamine lotion
 - b) Magnesium Hydroxide mixture
- 5. Emulsions**
 - a) Turpentine Liniment
 - b) Liquid paraffin emulsion
- 6. Powders and Granules**
 - a) ORS powder (WHO)
 - b) Effervescent granules
 - c) Dusting powder
- 7. Suppositories**
 - a) Glycero gelatin suppository
 - b) Soap glycerin suppository
- 8. Semisolids**
 - a) Sulphur ointment
 - b) Non staining iodine ointment with methyl salicylate
 - c) Bentonite gel
- 9. Gargles and Mouthwashes**
 - a) Potassium chlorate gargle
 - b) Chlorhexidine mouthwash

Recommended Books: (Latest Editions)




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1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie: Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh: Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres: Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.




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BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

45 Hours

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- ☐ know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- ☐ understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content:

UNIT I

10 Hours

- ☐ **Impurities in pharmaceutical substances:** History of Pharmacopoeia, Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate

General methods of preparation, assay for the compounds superscripted with asterisk (*), properties and medicinal uses of inorganic compounds belonging to the following classes

UNIT II

10 Hours

- ☐ **Acids, Bases and Buffers:** Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity.
- ☐ **Major extra and intracellular electrolytes:** Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance.
- ☐ **Dental products:** Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement.

UNIT III

10 Hours

- ☐ **Gastrointestinal agents**

Acidifiers: Ammonium chloride* and Dil. HCl

Antacid: Ideal properties of antacids, combinations of antacids, Sodium



Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture

Cathartics: Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite

Antimicrobials: Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations

UNIT IV

08 Hours

☐ **Miscellaneous compounds**

Expectorants: Potassium iodide, Ammonium chloride*.

Emetics: Copper sulphate*, Sodium potassium tartarate

Haematinics: Ferrous sulphate*, Ferrous gluconate

Poison and Antidote: Sodium thiosulphate*, Activated charcoal, Sodium nitrite³³³

Astringents: Zinc Sulphate, Potash Alum

UNIT V

07 Hours

- ☐ **Radiopharmaceuticals:** Radio activity, Measurement of radioactivity, Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I^{131} , Storage conditions, precautions & pharmaceutical application of radioactive substances.




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BP110P. PHARMACEUTICAL INORGANIC CHEMISTRY (Practical)

4 Hours / Week

I Limit tests for following ions

Limit test for Chlorides and Sulphates
Modified limit test for Chlorides and Sulphates
Limit test for Iron
Limit test for Heavy metals
Limit test for Lead
Limit test for Arsenic

II Identification test

Magnesium hydroxide
Ferrous sulphate
Sodium bicarbonate
Calcium gluconate
Copper sulphate

III Test for purity

Swelling power of Bentonite
Neutralizing capacity of aluminum hydroxide gel
Determination of potassium iodate and iodine in potassium Iodide

IV Preparation of inorganic pharmaceuticals

Boric acid
Potash alum
Ferrous sulphate

Recommended Books (Latest Editions)

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia



BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I

07 Hours

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II

07 Hours

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style



UNIT – III

07 Hours

- ☐ **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- ☐ **Effective Written Communication:** Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- ☐ **Writing Effectively:** Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message

UNIT – IV

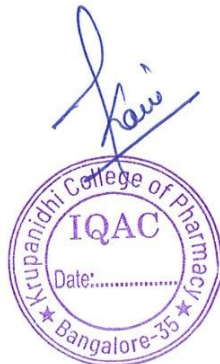
05 Hours

- ☐ **Interview Skills:** Purpose of an interview, Do's and Dont's of an interview
- ☐ **Giving Presentations:** Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

UNIT – V

04 Hours

- ☐ **Group Discussion:** Introduction, Communication skills in group discussion, Do's and Dont's of group discussion



BP111P.COMMUNICATION SKILLS (Practical)

2 Hours / week

The following learning modules are to be conducted using wordsworth[®] English language lab software

Basic communication covering the following topics

Meeting People

Asking Questions

Making Friends

What did you do?

Do's and Dont's

Pronunciations covering the following topics

Pronunciation (Consonant Sounds)

Pronunciation and Nouns

Pronunciation (Vowel Sounds)

Advanced Learning

Listening Comprehension / Direct and Indirect Speech

Figures of Speech

Effective Communication

Writing Skills

Effective Writing

Interview Handling Skills

E-Mail etiquette

Presentation Skills



Recommended Books: (Latest Edition)

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2nd Edition, New arrivals – PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999




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BP 106RBT.REMEDIAL BIOLOGY (Theory)

30 Hours

Scope: To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

Objectives: Upon completion of the course, the student shall be able to

- ☐ know the classification and salient features of five kingdoms of life
- ☐ understand the basic components of anatomy & physiology of plant
- ☐ know understand the basic components of anatomy & physiology animal with special reference to human

UNIT I

07 Hours

Living world:

- ☐ Definition and characters of living organisms
- ☐ Diversity in the living world
- ☐ Binomial nomenclature
- ☐ Five kingdoms of life and basis of classification. Salient features of Monera, Protista, Fungi, Animalia and Plantae, Virus,

Morphology of Flowering plants

- ☐ Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- ☐ General Anatomy of Root, stem, leaf of monocotyledons & Dicotyledones.

UNIT II

07 Hours

Body fluids and circulation

- ☐ Composition of blood, blood groups, coagulation of blood
- ☐ Composition and functions of lymph
- ☐ Human circulatory system
- ☐ Structure of human heart and blood vessels
- ☐ Cardiac cycle, cardiac output and ECG

Digestion and Absorption

- ☐ Human alimentary canal and digestive glands
- ☐ Role of digestive enzymes
- ☐ Digestion, absorption and assimilation of digested food

Breathing and respiration

- ☐ Human respiratory system
- ☐ Mechanism of breathing and its regulation
- ☐ Exchange of gases, transport of gases and regulation of respiration
- ☐ Respiratory volumes



UNIT III

07 Hours

Excretory products and their elimination

- ☐ Modes of excretion
- ☐ Human excretory system- structure and function
- ☐ Urine formation
- ☐ Rennin angiotensin system

Neural control and coordination

- ☐ Definition and classification of nervous system
- ☐ Structure of a neuron
- ☐ Generation and conduction of nerve impulse
- ☐ Structure of brain and spinal cord
- ☐ Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- ☐ Endocrine glands and their secretions
- ☐ Functions of hormones secreted by endocrine glands

Human reproduction

- ☐ Parts of female reproductive system
- ☐ Parts of male reproductive system
- ☐ Spermatogenesis and Oogenesis
- ☐ Menstrual cycle

UNIT IV

05 Hours

Plants and mineral nutrition:

- ☐ Essential mineral, macro and micronutrients
- ☐ Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- ☐ Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V

04 Hours

Plant respiration: Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- ☐ Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators

Cell - The unit of life

- ☐ Structure and functions of cell and cell organelles. Cell division

Tissues

- ☐ Definition, types of tissues, location and functions.



Text Books

- a. Text book of Biology by S. B. Gokhale
- b. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

- a. A Text book of Biology by B.V. Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d.Outlines of Zoology by M. Ekambaranatha ayyer and T. N. Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate




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BP112RBP.REMEDIAL BIOLOGY (Practical)

30 Hours

1. Introduction to experiments in biology
 - a) Study of Microscope
 - b) Section cutting techniques
 - c) Mounting and staining
 - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf and its modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi




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BP 106RMT.REMEDIAL MATHEMATICS (Theory)

30 Hours

Scope: This is an introductory course in mathematics. This subject deals with the introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

Objectives: Upon completion of the course the student shall be able to:-

1. Know the theory and their application in Pharmacy
2. Solve the different types of problems by applying theory
3. Appreciate the important application of mathematics in Pharmacy

Course Content:

UNIT – I

06 Hours

□ Partial fraction

Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics

□ Logarithms

Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems.

□ Function:

Real Valued function, Classification of real valued functions,

□ Limits and continuity :

Introduction, Limit of a function, Definition of limit of a function (□ - □

definition), $\lim_{x \rightarrow a} \frac{x^n - a^n}{x - a} = na^{n-1}$, $\lim_{x \rightarrow 0} \frac{\sin x}{x} = 1$,

UNIT –II

06 Hours

□ Matrices and Determinant:

Introduction matrices, Types of matrices, Operation on matrices, Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants, Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix, Singular and non-singular matrices, Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer's rule, Characteristic equation and roots of a square matrix, Cayley-Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations.



UNIT – III

06 Hours

□ Calculus

Differentiation : Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function, Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) – **Without Proof**, Derivative of x^n w.r.t x , where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles (**without Proof**), Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application

UNIT – IV

06 Hours

□ Analytical Geometry

Introduction: Signs of the Coordinates, Distance formula,

Straight Line : Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line

Integration:

Introduction, Definition, Standard formulae, Rules of integration, Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application

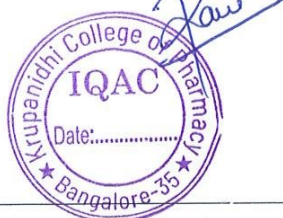
UNIT-V

06 Hours

- **Differential Equations** : Some basic definitions, Order and degree, Equations in separable form, Homogeneous equations, Linear Differential equations, Exact equations, **Application in solving Pharmacokinetic equations**
- **Laplace Transform** : Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations, **Application in solving Chemical kinetics and Pharmacokinetics equations**

Recommended Books (Latest Edition)

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal



BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

Objectives: Upon completion of this course the student should be able to:

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

Course Content:

Unit I

10 hours

☐ **Body fluids and blood**

- ☐ Body fluids, composition and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood, Reticulo endothelial system.

☐ **Lymphatic system**

Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system

Unit II

10 hours

☐ **Cardiovascular system**

Heart – anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heart beat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram and disorders of heart.

Unit III

06 hours

☐ **Digestive system**

Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine



and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

☐ **Respiratory system**

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Unit IV

☐ **Respiratory system**

10 hours

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

☐ **Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit V

09 hours

☐ **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

☐ **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance




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BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)

4 Hours/week

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. Introduction to hemocytometry.
2. Enumeration of white blood cell (WBC) count
3. Enumeration of total red blood corpuscles (RBC) count
4. Determination of bleeding time
5. Determination of clotting time
6. Estimation of hemoglobin content
7. Determination of blood group.
8. Determination of erythrocyte sedimentation rate (ESR).
9. Determination of heart rate and pulse rate.
10. Recording of blood pressure.
11. Determination of tidal volume and vital capacity.
12. Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
13. Recording of basal mass index
14. Study of family planning devices and pregnancy diagnosis test.
15. Demonstration of total blood count by cell analyser
16. Permanent slides of vital organs and gonads.

Recommended Books (Latest Editions)

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA



4. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

Reference Books:

1. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
2. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
3. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterje ,Academic Publishers Kolkata



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BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY –I (Theory)

45 Hours

Scope: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. identify/confirm the identification of organic compound

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT-I

07 Hours

☐ Classification, nomenclature and isomerism

Classification of Organic Compounds

Common and IUPAC systems of nomenclature of organic compounds

(up to 10 Carbons open chain and carbocyclic compounds)

Structural isomerisms in organic compounds

UNIT-II 10 Hours

☐ Alkanes*, Alkenes* and Conjugated dienes*

sp^3 hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, sp^2 hybridization in alkenes

E_1 and E_2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeff's orientation and evidences. E_1 versus E_2 reactions, Factors affecting E_1 and E_2 reactions. Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, Anti Markownikoff's orientation.

Stability of conjugated dienes, Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement

UNIT-III 10 Hours



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☐ **Alkyl halides***

SN₁ and SN₂ reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations.

SN₁ versus SN₂ reactions, Factors affecting SN₁ and SN₂ reactions

Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform.

- ☐ **Alcohols***- Qualitative tests, Structure and uses of Ethyl alcohol, chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol

UNIT-IV 10 Hours

☐ **Carbonyl compounds* (Aldehydes and ketones)**

Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation, Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation, Perkin condensation, qualitative tests, Structure and uses of Formaldehyde, Paraldehyde, Acetone, Chloral hydrate, Hexamine, Benzaldehyde, Vanilin, Cinnamaldehyde.

UNIT-V

08 Hours

☐ **Carboxylic acids***

Acidity of carboxylic acids, effect of substituents on acidity, inductive effect and qualitative tests for carboxylic acids, amide and ester

Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid

- ☐ **Aliphatic amines*** - Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine, Ethylenediamine, Amphetamine




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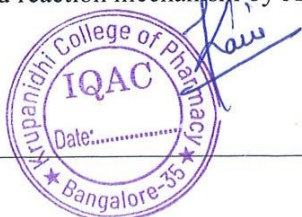
BP208P. PHARMACEUTICAL ORGANIC CHEMISTRY -I (Practical)

4 Hours / week

1. Systematic qualitative analysis of unknown organic compounds like
 1. Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc.
 2. Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test
 3. Solubility test
 4. Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides.
 5. Melting point/Boiling point of organic compounds
 6. Identification of the unknown compound from the literature using melting point/ boiling point.
 7. Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point.
 8. Minimum 5 unknown organic compounds to be analysed systematically.
2. Preparation of suitable solid derivatives from organic compounds
3. Construction of molecular models

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwalia/Chatwal.



BP203 T. BIOCHEMISTRY (Theory)

45 Hours

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shall be able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content:

UNIT I

10 Hours

☐ Carbohydrate metabolism

Glycolysis – Pathway, energetics and significance

Citric acid cycle- Pathway, energetics and significance

HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency

Glycogen metabolism Pathways and glycogen storage diseases (GSD)

Gluconeogenesis- Pathway and its significance

Hormonal regulation of blood glucose level and Diabetes mellitus

☐ Biological oxidation

Electron transport chain (ETC) and its mechanism.

Oxidative phosphorylation & its mechanism and substrate level phosphorylation

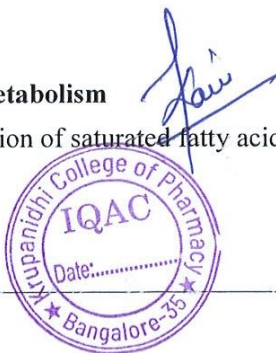
Inhibitors ETC and oxidative phosphorylation/Uncouplers

UNIT II

10 Hours

☐ Lipid metabolism

β -Oxidation of saturated fatty acid (Palmitic acid)



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Formation and utilization of ketone bodies; ketoacidosis

De novo synthesis of fatty acids (Palmitic acid)

Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D

Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

☐ **Amino acid metabolism**

General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders

Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alpeptonuria, tyrosinemia)

Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline

Catabolism of heme; hyperbilirubinemia and jaundice

UNIT III

10 Hours

☐ **Nucleic acid metabolism and genetic information transfer**

Biosynthesis of purine and pyrimidine nucleotides

Catabolism of purine nucleotides and Hyperuricemia and Gout disease Organization of mammalian genome

Structure of DNA and RNA and their functions

DNA replication (semi conservative model)

Transcription or RNA synthesis

Genetic code, Translation or Protein synthesis and inhibitors

UNIT IV

08 Hours

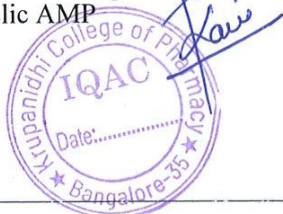
☐ **Biomolecules**

Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

☐ **Bioenergetics**

Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential.

Energy rich compounds; classification; biological significances of ATP and cyclic AMP



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UNIT V

07 Hours

□ Enzymes

Introduction, properties, nomenclature and IUB classification of enzymes

Enzyme kinetics (Michaelis plot, Line Weaver Burke plot)

Enzyme inhibitors with examples

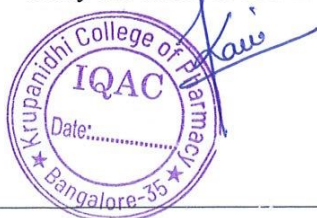
Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation

Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes –Structure and biochemical functions

BP 209 P. BIOCHEMISTRY (Practical)

4 Hours / Week

1. Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch)
2. Identification tests for Proteins (albumin and Casein)
3. Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method)
4. Qualitative analysis of urine for abnormal constituents
5. Determination of blood creatinine
6. Determination of blood sugar
7. Determination of serum total cholesterol
8. Preparation of buffer solution and measurement of pH
9. Study of enzymatic hydrolysis of starch
10. Determination of Salivary amylase activity
11. Study the effect of Temperature on Salivary amylase activity.
12. Study the effect of substrate concentration on salivary amylase activity.




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Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.

Objectives: Upon completion of the subject student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I

10Hours

□ Basic principles of Cell injury and Adaptation:

Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance



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☐ **Basic mechanism involved in the process of inflammation and repair:**

Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of

WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit II

10Hours

☐ **Cardiovascular System:**

Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

☐ **Respiratory system:** Asthma, Chronic obstructive airways diseases.

☐ **Renal system:** Acute and chronic renal failure .

Unit II

10Hours

☐ **Haematological Diseases:**

Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

☐ **Endocrine system:** Diabetes, thyroid diseases, disorders of sex hormones

☐ **Nervous system:** Epilepsy, Parkinson's disease, stroke, psychiatric disorders: depression, schizophrenia and Alzheimer's disease.

☐ **Gastrointestinal system:** Peptic Ulcer

☐

Unit IV

8 Hours

☐ Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.

☐ **Disease of bones and joints:** Rheumatoid arthritis, osteoporosis and gout

☐ **Principles of cancer:** classification, etiology and pathogenesis of cancer

☐ **Diseases of bones and joints:** Rheumatoid Arthritis, Osteoporosis, Gout

☐ **Principles of Cancer:** Classification, etiology and pathogenesis of Cancer

Unit V

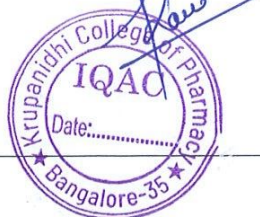
7 Hours

☐ **Infectious diseases:** Meningitis, Typhoid, Leprosy, Tuberculosis

Urinary tract infections

☐ **Sexually transmitted diseases:** AIDS, Syphilis, Gonorrhea

Recommended Books (Latest Editions)




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1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy: A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

Recommended Journals

1. The Journal of Pathology. ISSN: 1096-9896 (Online)
2. The American Journal of Pathology. ISSN: 0002-9440
3. Pathology. 1465-3931 (Online)
4. International Journal of Physiology, Pathophysiology and Pharmacology. ISSN: 1944-8171 (Online)
5. Indian Journal of Pathology and Microbiology. ISSN-0377-4929.




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BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I

06 hours

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT – II

06 hours

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products

Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System




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UNIT – IV

06 hours

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

UNIT-V

06 hours

Computers as data analysis in Preclinical development: Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMMS)



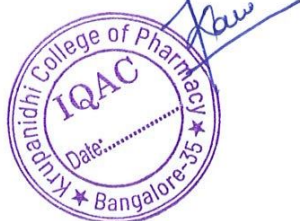

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BP210P. COMPUTER APPLICATIONS IN PHARMACY (Practical)

1. Design a questionnaire using a word processing package to gather information about a particular disease.
2. Create a HTML web page to show personal information.
3. Retrieve the information of a drug and its adverse effects using online tools
4. Creating mailing labels Using Label Wizard , generating label in MS WORD
5. Create a database in MS Access to store the patient information with the required fields Using access
6. Design a form in MS Access to view, add, delete and modify the patient record in the database
7. Generating report and printing the report from patient database
8. Creating invoice table using – MS Access
9. Drug information storage and retrieval using MS Access
10. Creating and working with queries in MS Access
11. Exporting Tables, Queries, Forms and Reports to web pages
12. Exporting Tables, Queries, Forms and Reports to XML pages

Recommended books (Latest edition):

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002




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BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

Course content:

Unit-I

10hours

The Multidisciplinary nature of environmental studies

Natural Resources

Renewable and non-renewable resources:

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Unit-II

10hours

Ecosystems

- ☐ Concept of an ecosystem.
- ☐ Structure and function of an ecosystem.

☐ Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Unit- III

10hours

Environmental Pollution: Air pollution; Water pollution; Soil pollution



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Recommended Books (Latest edition):

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clanderson Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment



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BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY –II (Theory)

45 Hours

Scope: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

Objectives: Upon completion of the course the student shall be able to

1. write the structure, name and the type of isomerism of the organic compound
2. write the reaction, name the reaction and orientation of reactions
3. account for reactivity/stability of compounds,
4. prepare organic compounds

Course Content:

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained

To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

UNIT I

10 Hours

☐ Benzene and its derivatives

- A. Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule
- B. Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation.
- C. Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction
- D. Structure and uses of DDT, Saccharin, BHC and Chloramine

UNIT II

10 Hours

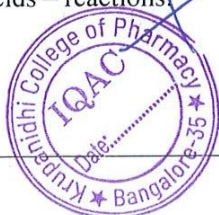
- ☐ **Phenols*** - Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols
- ☐ **Aromatic Amines*** - Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts

UNIT III

10 Hours

☐ Fats and Oils

- a. Fatty acids – reactions



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- b. Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.
- c. Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

UNIT IV

08 Hours

☐ Polynuclear hydrocarbons:

- a. Synthesis, reactions
- b. Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

UNIT V

07 Hours

☐ Cyclo alkanes*

Stabilities – Baeyer's strain theory, limitation of Baeyer's strain theory, Coulson and Moffitt's modification, Sachse Mohr's theory (Theory of strainless rings), reactions of cyclopropane and cyclobutane only



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BP305P. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Practical)

4 Hrs/week

I Experiments involving laboratory techniques

- ☐ Recrystallization
- ☐ Steam distillation

II Determination of following oil values (including standardization of reagents)

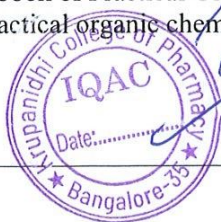
- ☐ Acid value
- ☐ Saponification value
- ☐ Iodine value

III Preparation of compounds

- ☐ Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction.
- ☐ 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline/
- ☐ Acetanilide by halogenation (Bromination) reaction.
- ☐ 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction.
- ☐ Benzoic acid from Benzyl chloride by oxidation reaction.
- ☐ Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction.
- ☐ 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions.
- ☐ Benzil from Benzoin by oxidation reaction.
- ☐ Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction
- ☐ Cinnamic acid from Benzaldehyde by Perkin reaction
- ☐ *P*-Iodo benzoic acid from *P*-amino benzoic acid

Recommended Books (Latest Editions)

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.



8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and development

Course Content:

UNIT-I

10 Hours

Solubility of drugs: Solubility expressions, mechanisms of solute solvent interactions, ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, Dissolution & drug release, diffusion principles in biological systems. Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) Raoult's law, real solutions, azeotropic mixtures, fractional distillation. Partially miscible liquids, Critical solution temperature and applications. Distribution law, its limitations and applications

UNIT-II

10Hours

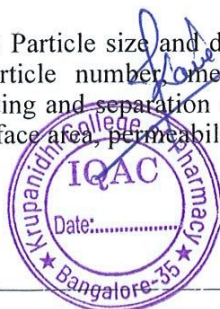
States of Matter and properties of matter: State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point, eutectic mixtures, gases, aerosols – inhalers, relative humidity, liquid complexes, liquid crystals, glassy states, solid-crystalline, amorphous & polymorphism.

Physicochemical properties of drug molecules: Refractive index, optical rotation, dielectric constant, dipole moment, dissociation constant, determinations and applications

UNIT-III

10Hours

Micromeritics: Particle size and distribution. average particle size, number and weight distribution, particle number methods for determining particle size by (different methods), counting and separation method, particle shape, specific surface, methods for determining surface area, permeability, adsorption, derived properties of powders,



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porosity, packing arrangement, densities, bulkiness & flow properties.

UNIT-IV

08Hours

Complexation and protein binding: Introduction, Classification of Complexation, Applications, methods of analysis, protein binding, Complexation and drug action, crystalline structures of complexes and thermodynamic treatment of stability constants.

UNIT-V

07 Hours

pH, buffers and Isotonic solutions: Sorensen's pH scale, pH determination (electrometric and calorimetric), applications of buffers, buffer equation, buffer capacity, buffers in pharmaceutical and biological systems, buffered isotonic solutions.




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BP306P. PHYSICAL PHARMACEUTICS – I (Practical)

4 Hrs/week

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hassel Balch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl₄ and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of particle size, particle size distribution using sieving method
7. Determination of particle size, particle size distribution using Microscopic method
8. Determination of bulk density, true density and porosity
9. Determine the angle of repose and influence of lubricant on angle of repose
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubility method
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Recommended Books: (Latest Editions)

1. Physical pharmacy by Alfred Martin
2. Experimental pharmaceuticals by Eugene, Paroff.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical pharmaceuticals by Ramasamy C and ManavalanR.
8. Laboratory manual of physical pharmaceuticals, C.V.S. Subramanyam, J. Thimma settee




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BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

45Hours

Scope:

- ☐ In the broadest sense, scope of microbiology is the study of all organisms that are invisible to the naked eye- that is the study of microorganisms.
- ☐ Microorganisms are necessary for the production of bread, cheese, beer, antibiotics, vaccines, vitamins, enzymes etc.
- ☐ Microbiology has an impact on medicine, agriculture, food science, ecology, genetics, biochemistry, immunology etc.

Objectives: Upon completion of the subject student shall be able to;

1. Understand methods of identification, cultivation and preservation of various microorganisms
2. Importance of sterilization in microbiology. and pharmaceutical industry
3. Learn sterility testing of pharmaceutical products.
4. Microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course content:

Unit I

10 Hours

Introduction, history of microbiology, its branches, scope and its importance.

Introduction to Prokaryotes and Eukaryotes

Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

Unit II

10 Hours

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Study of principle, procedure, merits, demerits and applications of Physical, chemical and mechanical method of sterilization.

Evaluation of the efficiency of sterilization methods.



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Equipments employed in large scale sterilization.

Sterility indicators.

Unit III

10 Hours

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Virus.

Classification and mode of action of disinfectants

Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions

Evaluation of bactericidal & Bacteriostatic.

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

Unit IV

08 Hours

Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.

Assessment of a new antibiotic and testing of antimicrobial activity of a new substance.

General aspects-environmental cleanliness.

Unit V

07Hours

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.

Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures.

Application of cell cultures in pharmaceutical industry and research.




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BP 307P.PHARMACEUTICAL MICROBIOLOGY (Practical)

4 Hrs/week

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test (IMViC reactions)
11. Revision Practical Class

Recommended Books (Latest edition)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probiher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company



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BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope: This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives: Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

Course content:

UNIT-I

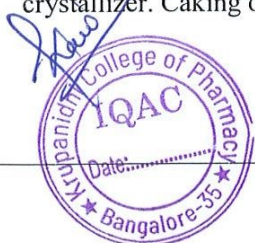
10 Hours

- ☐ **Flow of fluids:** Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotometer.
- ☐ **Size Reduction:** Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & end runner mill.
- ☐ **Size Separation:** Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Air separator, Bag filter & elutriation tank.
- ☐ **Mixing:** Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetary mixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

UNIT-II

10 Hours

- ☐ **Crystallization:** Objectives, applications, & theory of crystallization. Solubility curves, principles, construction, working, uses, merits and demerits of Agitated batch crystallizer, Swenson Walker Crystallizer, Krystal crystallizer, Vacuum crystallizer. Caking of crystals, factors affecting caking & prevention of caking.




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- **Evaporation:** Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator & Economy of multiple effect evaporator.
- **Heat Transfer:** Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

UNIT- III

10 Hours

- **Drying:** Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer.
- **Distillation:** Objectives, applications & types of distillation. principles, construction, working, uses, merits and demerits of (lab scale and industrial scale) Simple distillation, preparation of purified water and water for injection BP by distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

UNIT-IV

08 Hours

- **Filtration:** Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.
- **Centrifugation:** Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

UNIT- V

07 Hours

- **Plant location, industrial hazards and plant safety:** Plant Layout, utilities and services, Mechanical hazards, Chemical hazards, Fire hazards, explosive hazards and their safety.
- **Materials of pharmaceutical plant construction, Corrosion and its prevention:** Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non metals.
- **Material handling systems:** Objectives & applications of Material handling systems, different types of conveyors such as belt, screw and pneumatic conveyors.




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Recommended Books: (Latest Editions)

1. Introduction to chemical engineering – Walter L Badger & Julius Banchemo, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

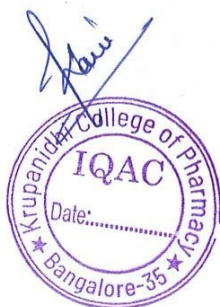



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BP308P - PHARMACEUTICAL ENGINEERING (Practical)

4 Hours/week

- I. Determination of radiation constant of brass, iron, unpainted and painted glass.
- II. Steam distillation – To calculate the efficiency of steam distillation.
- III. To determine the overall heat transfer coefficient by heat exchanger.
- IV. Construction of drying curves (for calcium carbonate and starch).
- V. Determination of moisture content and loss on drying.
- VI. Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method.
- VII. Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
- VIII. Size analysis by sieving – To evaluate size distribution of tablet granulations – Construction of various size frequency curves including arithmetic and logarithmic probability plots.
- IX. Size reduction: To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill.
- X. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment.
- XI. Factors affecting Rate of Filtration and Evaporation (Surface area, Concentration and Thickness/ viscosity
- XII. To study the effect of time on the Rate of Crystallization.
- XIII. To calculate the uniformity Index for given sample by using Double Cone Blender.



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BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

45 Hours

Scope: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important heterocyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

Objectives: At the end of the course, the student shall be able to

1. understand the methods of preparation and properties of organic compounds
2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
3. know the medicinal uses and other applications of organic compounds

Course Content:

Note: To emphasize on definition, types, mechanisms, examples, uses/applications

UNIT-I

10 Hours

Stereo isomerism

Optical isomerism –

Optical activity, enantiomerism, diastereoisomerism, meso compounds

Elements of symmetry, chiral and achiral molecules

DL system of nomenclature of optical isomers, sequence rules, RS system of nomenclature of optical isomers

Reactions of chiral molecules

Racemic modification and resolution of racemic mixture.

Asymmetric synthesis: partial and absolute

UNIT-II

10 Hours

Geometrical isomerism

Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems)

Methods of determination of configuration of geometrical isomers.

Conformational isomerism in Ethane, n-Butane and Cyclohexane.

Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity.

Stereospecific and stereoselective reactions

UNIT-III

10 Hours



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Heterocyclic compounds:

Nomenclature and classification

Synthesis, reactions and medicinal uses of following compounds/derivatives
Pyrrole, Furan, and Thiophene - Relative aromaticity, reactivity and Basicity of pyrrole

UNIT-IV**8 Hours**

Synthesis, reactions and medicinal uses of following compounds/derivatives
Pyrazole, Imidazole, Oxazole and Thiazole.

Pyridine, Quinoline, Isoquinoline, Acridine and Indole. Basicity of pyridine
Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives

UNIT-V**07 Hours****Reactions of synthetic importance**

Metal hydride reduction (NaBH_4 and LiAlH_4), Clemmensen reduction, Birch reduction, Wolff Kishner reduction.

Oppenauer-oxidation and Dakin reaction.

Beckmanns rearrangement and Schmidt rearrangement.

Claisen-Schmidt condensation

Recommended Books (Latest Editions)

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist



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BP402T. MEDICINAL CHEMISTRY – I (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. understand the chemistry of drugs with respect to their pharmacological activity
2. understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. know the Structural Activity Relationship (SAR) of different class of drugs
4. write the chemical synthesis of some drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

10 Hours

Introduction to Medicinal Chemistry

History and development of medicinal chemistry

Physicochemical properties in relation to biological action

Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Protein binding, Chelation, Bioisosterism, Optical and Geometrical isomerism.

Drug metabolism

Drug metabolism principles- Phase I and Phase II.

Factors affecting drug metabolism including stereo chemical aspects.

UNIT- II

10 Hours

Drugs acting on Autonomic Nervous System

Adrenergic Neurotransmitters:

Biosynthesis and catabolism of catecholamine.

Adrenergic receptors (Alpha & Beta) and their distribution.

Sympathomimetic agents: SAR of Sympathomimetic agents

Direct acting: Nor-epinephrine, Epinephrine, Phenylephrine*, Dopamine,



Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline.

- ☐ Indirect acting agents: Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine.
- ☐ Agents with mixed mechanism: Ephedrine, Metaraminol.

Adrenergic Antagonists:

Alpha adrenergic blockers: Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide.

Beta adrenergic blockers: SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol.

UNIT-III

10 Hours

Cholinergic neurotransmitters:

Biosynthesis and catabolism of acetylcholine.

Cholinergic receptors (Muscarinic & Nicotinic) and their distribution.

Parasympathomimetic agents: SAR of Parasympathomimetic agents

Direct acting agents: Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine.

Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible):

Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathion, Malathion.

Cholinesterase reactivator: Pralidoxime chloride.

Cholinergic Blocking agents: SAR of cholinolytic agents

Solanaceous alkaloids and analogues: Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide*.

Synthetic cholinergic blocking agents: Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

UNIT- IV

08 Hours

Drugs acting on Central Nervous System



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A. Sedatives and Hypnotics:

Benzodiazepines: SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem

Barbiturates: SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital

Miscellaneous:

Amides & imides: Glutethimide.

Alcohol & their carbamate derivatives: Meprobamate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazines: SAR of Phenothiazines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Ring Analogues of Phenothiazines: Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluoro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

C. Anticonvulsants: SAR of Anticonvulsants, mechanism of anticonvulsant action

Barbiturates: Phenobarbitone, Methobarbital.

Hydantoins: Phenytoin*, Mephentyoin, Ethoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

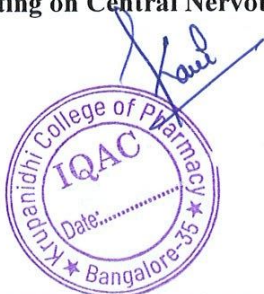
Benzodiazepines: Clonazepam

Miscellaneous: Primidone, Valproic acid, Gabapentin, Felbamate

UNIT – V

07 Hours

Drugs acting on Central Nervous System




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General anesthetics:

Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.

Ultra short acting barbiturates: Methohexital sodium*, Thiamylal sodium, Thiopental sodium.

Dissociative anesthetics: Ketamine hydrochloride.*

Narcotic and non-narcotic analgesics

Morphine and related drugs: SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anileridine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate.

Narcotic antagonists: Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride.

Anti-inflammatory agents: Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.




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BP406P. MEDICINAL CHEMISTRY – I (Practical)

4 Hours/Week

I Preparation of drugs/ intermediates

- 1 1,3-pyrazole
- 2 1,3-oxazole
- 3 Benzimidazole
- 4 Benztriazole
- 5 2,3- diphenyl quinoxaline
- 6 Benzocaine

7 Phenytoin

8 Phenothiazine

9 Barbiturate

II Assay of drugs

- 1 Chlorpromazine
- 2 Phenobarbitone
- 3 Atropine
- 4 Ibuprofen
- 5 Aspirin
- 6 Furosemide

III Determination of Partition coefficient for any two drugs

Recommended Books (Latest Editions)

1. Wilson and Giswood's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.



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7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.



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BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

45Hours

Scope: The course deals with the various physical, physicochemical properties and principle involved in dosage forms, formulations. Theory and practical components of the subject help the student to get a better insight in to various areas of formulation research and development and stability studies of pharmaceuticals.

Objectives: Upon the completion of the course student shall be able to

1. Understand various physicochemical properties of drug molecules in the designing the dosage form
2. Know the principles of chemical kinetics & to use them in assigning expiry date for Formulation
3. Demonstrate use of physicochemical properties in evaluation of dosage forms.
4. Appreciate physicochemical properties of drug molecules in formulation research and Development

Course Content:

UNIT-I

10 Hours

Drug stability: Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order. Physical and chemical factors influencing the chemical degradation of pharmaceutical product: temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems. Stabilization of medicinal agents against common reactions like hydrolysis & oxidation. Accelerated stability testing in expiration dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

UNIT-II

10 Hours

Rheology: Newtonian systems, law of flow, kinematic viscosity, effect of temperature, non-Newtonian systems, pseudoplastic, dilatants, plastic, thixotropy, thixotropy in formulation, determination of viscosity, capillary, falling Sphere, rotational viscometers

Deformation of solids: Plastic and elastic deformation, Heckel equation, Stress, Strain, Elastic Modulus

UNIT-III

10 Hours

Coarse dispersion: Suspension, interfacial properties of suspended particles, settling in suspensions, formulation of suspensions. Emulsions and theories of emulsification, microemulsion and multiple emulsions; Physical stability of emulsions, preservation of emulsions, rheological properties of emulsions, phase equilibria and emulsion formulation.

UNIT-IV

08 Hours

Surface and interfacial phenomenon: Liquid interface, surface & interfacial tensions,



surface free energy, measurement of surface & interfacial tensions, spreading coefficient, adsorption at liquid interfaces, surface active agents, HLB Scale, solubilisation, detergency, adsorption at solid interface.

UNIT-V

07 Hours

Colloidal dispersions: Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles, classification of colloids & comparative account of their general properties. Optical, kinetic & electrical properties. Effect of electrolytes, coacervation, peptization & protective action.



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BP 407P. PHYSICAL PHARMACEUTICS- II (Practical)

3 Hrs/week

1. Determination of surface tension of given liquids by drop count and drop weight method
2. Determination of HLB number of a surfactant by saponification method
3. Determination of Freundlich and Langmuir constants using activated char coal
4. Determination of critical micellar concentration of surfactants
5. Determination of viscosity of liquid using Ostwald's viscometer
6. Determination sedimentation volume with effect of different suspending agent
7. Determination sedimentation volume with effect of different concentration of single suspending agent
8. Determination of viscosity of semisolid by using Brookfield viscometer
9. Determination of reaction rate constant first order.
10. Determination of reaction rate constant second order
11. Accelerated stability studies

Recommended Books: (Latest Editions)

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.




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BP 404 T. PHARMACOLOGY-I (Theory)

45 Hrs

Scope: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

Objectives: Upon completion of this course the student should be able to

1. Understand the pharmacological actions of different categories of drugs
2. Explain the mechanism of drug action at organ system/sub cellular/ macromolecular levels.
3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
4. Observe the effect of drugs on animals by simulated experiments
5. Appreciate correlation of pharmacology with other bio medical sciences

Course Content:

UNIT-I

08 hours

1. General Pharmacology

- a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.
- b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

UNIT-II

12 Hours

General Pharmacology

- a. Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.
- b. Adverse drug reactions.
- c. Drug interactions (pharmacokinetic and pharmacodynamic)
- d. Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance.



UNIT-III

10 Hours

2. Pharmacology of peripheral nervous system

- a. Organization and function of ANS.
- b. Neurohumoral transmission, co-transmission and classification of neurotransmitters.
- c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.
- d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).
- e. Local anesthetic agents.
- f. Drugs used in myasthenia gravis and glaucoma

UNIT-IV

08 Hours

3. Pharmacology of central nervous system

- a. Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine.
- b. General anesthetics and pre-anesthetics.
- c. Sedatives, hypnotics and centrally acting muscle relaxants.
- d. Anti-epileptics
- e. Alcohols and disulfiram

UNIT-V

07 Hours

3. Pharmacology of central nervous system

- a. Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens.
- b. Drugs used in Parkinsons disease and Alzheimer's disease.
- c. CNS stimulants and nootropics.
- d. Opioid analgesics and antagonists
- e. Drug addiction, drug abuse, tolerance and dependence.




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BP 408 P.PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anesthetics by different methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics. The Clinical use of Drugs, The Point Lippincott Williams & Wilkins
5. Mycek M.J., Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology



6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,



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**BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) 45
Hours**

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

UNIT-II

10 Hours

Cultivation, Collection, Processing and storage of drugs of natural origin:

Cultivation and Collection of drugs of natural origin

Factors influencing cultivation of medicinal plants.

Plant hormones and their applications.

Polyploidy, mutation and hybridization with reference to medicinal plants

Conservation of medicinal plants

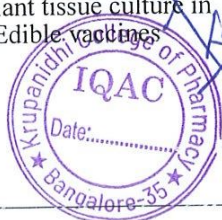
UNIT-III

07 Hours

Plant tissue culture:

Historical development of plant tissue culture, types of cultures, Nutritional requirements, growth and their maintenance.

Applications of plant tissue culture in pharmacognosy. Edible vaccines




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UNIT IV 10 Hours Pharmacognosy in various systems of medicine:

Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine.

Introduction to secondary metabolites:

Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins

UNIT V

08 Hours

Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs

Plant Products:

Fibers - Cotton, Jute, Hemp

Hallucinogens, Teratogens, Natural allergens

Primary metabolites:

General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primary metabolites:

Carbohydrates: Acacia, Agar, Tragacanth, Honey

Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin).

Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax

Marine Drugs:

Novel medicinal agents from marine sources




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BP408 P. PHARMACOGNOSY AND PHYTOCHEMISTRY I (Practical)

4 Hours/Week

1. Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil
2. Determination of stomatal number and index
3. Determination of vein islet number, vein islet termination and palisade ratio.
4. Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer
5. Determination of Fiber length and width
6. Determination of number of starch grains by Lycopodium spore method
7. Determination of Ash value
8. Determination of Extractive values of crude drugs
9. Determination of moisture content of crude drugs
10. Determination of swelling index and foaming

Recommended Books: (Latest Editions)

1. W.C. Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
7. Essentials of Pharmacognosy, Dr. S.H. Ansari, 11th edition, Birla publications, New Delhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhale
9. Anatomy of Crude Drugs by M.A. Iyengar




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BP501T. MEDICINAL CHEMISTRY – II (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

Objectives: Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

UNIT- I

10 Hours

Antihistaminic agents: Histamine, receptors and their distribution in the humanbody

H₁-antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium

H₂-antagonists: Cimetidine*, Famotidine, Ranitidin.

Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole

Anti-neoplastic agents:

Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan,



Chlorambucil, Busulfan, Thiotepea

Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine

Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin

Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate

Miscellaneous: Cisplatin, Mitotane.

UNIT – II

10 Hours

Anti-anginal:

Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.

Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

Diuretics:

Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide.

Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide,

Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid.

Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.

Osmotic Diuretics: Mannitol

Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride.

UNIT- III

10 Hours

Anti-arrhythmic Drugs: Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcanide hydrochloride, Amiodarone, Sotalol.

Anti-hyperlipidemic agents: Clofibrate, Lovastatin, Cholesteramine and Cholestipol

Coagulant & Anticoagulants: Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide,



Bosentan, Tezosentan.



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UNIT- IV

08 Hours

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandrolone, Progestones, Oestriol, Oestradiol, Oestrone, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

Thyroid and antithyroid drugs: L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT – V

07 Hours

Antidiabetic agents:

Insulin and its preparations

Sulfonyl ureas: Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acarbose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives: Cocaine, Hexylcaine, Mepylcaine, Cyclomethycaine, Piperocaine.

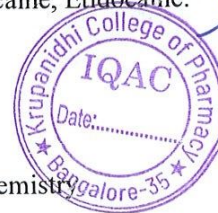
Amino Benzoic acid derivatives: Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate.

Lidocaine/Anilide derivatives: Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

Miscellaneous: Phenacaine, Dipreron, Dibucaine.*

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.
7. Organic Chemistry by I.L. Finar, Vol. II.



8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.



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BP 502 T. FORMULATIVE PHARMACY (Theory)

45 Hours

Scope: Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

Objectives: Upon completion of the course the student shall be able to

1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
2. Know various considerations in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I 07 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs

Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

UNIT-II

10 Hours

Tablets:

- a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.
- b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.
- c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of solutions, suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia.



UNIT-III

08 Hours

Capsules:

- a. **Hard gelatin capsules:** Introduction, Extraction of gelatin and production of hard gelatin capsule shells. size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules. In process and final product quality control tests for capsules.
- b. **Soft gelatin capsules:** Nature of shell and capsule content, size of capsules, importance of base adsorption and minimum/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules

Pellets: Introduction, formulation requirements, pelletization process, equipments for manufacture of pellets

UNIT-IV

10 Hours

Parenteral Products:

- a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity
- b. Production procedure, production facilities and controls.
- c. Formulation of injections, sterile powders, emulsions, suspensions, large volume parenterals and lyophilized products, Sterilization.
- d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests.

Ophthalmic Preparations: Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions; methods of preparation; labeling, containers; evaluation of ophthalmic preparations

UNIT-V

10 Hours

Cosmetics: Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream and vanishing cream, tooth pastes, hair dyes and sunscreens.

Pharmaceutical Aerosols: Definition, propellants, containers, valves, types of aerosol systems; formulation and manufacture of aerosols; Evaluation of aerosols; Quality control and stability studies.

Packaging Materials Science: Materials used for packaging of pharmaceutical products, factors influencing choice of containers, legal and official requirements for containers, stability aspects of packaging materials, quality control tests.



BP 506 P. FORMULATIVE PHARMACY (Practical)

4 Hours/week

1. Preformulation study for prepared granules
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Preparation of Paracetamol Syrup
9. Preparation of Eye drops
10. Preparation of Pellets by extrusion spheronization technique
11. Preparation of Creams (cold / vanishing cream)
12. Evaluation of Glass containers

Recommended Books: (Latest Editions)

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill Livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.



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BP503.T. PHARMACOLOGY-II (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

Objectives: Upon completion of this course the student should be able to

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

UNIT-II

10hours

1. Pharmacology of drugs acting on cardio vascular system

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

2. Pharmacology of drugs acting on urinary system

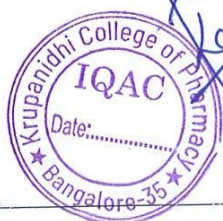
- a. Diuretics
- b. Anti-diuretics.

UNIT-III

10hours

3. Autocoids and related drugs

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leukotrienes.
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs.



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UNIT-IV

08hours

5. Pharmacology of drugs acting on endocrine system

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V

07hours

5. Pharmacology of drugs acting on endocrine system

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

6. Bioassay

- a. Principles and applications of bioassay.
- b. Types of bioassay
- c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT




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BP 507 P. PHARMACOLOGY-II (Practical)

4Hrs/Week

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA_2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD_2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.



BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

45Hours

Scope: The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. to know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents
2. to understand the preparation and development of herbal formulation.
3. to understand the herbal drug interactions
4. to carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

- a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.
- b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

20 Hours

General introduction, composition, chemistry & chemical classes, general methods of extraction & analysis, biosources, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,

Tannins: Catechu, Pterocarpus

Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

Glycosides: Senna, Aloes, Bitter Almond

Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

UNIT-III

10 Hours

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

UNIT IV

8 Hours

Basics of Phytochemistry

Modern methods of extraction, application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs.



BP 508 P. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Practical)
4 Hours/Week

1. Morphology, histology and powder characteristics & extraction & detection of: Cinchona, Cinnamon, Senna, Clove, Ephedra, Fennel and Coriander
2. Exercise involving isolation & detection of active principles
 - a. Caffeine - from tea dust.
 - b. Diosgenin from Dioscorea
 - c. Atropine from Belladonna
 - d. Sennosides from Senna
3. Separation of sugars by Paper chromatography
4. TLC of herbal extract
5. Distillation of volatile oils and detection of phytoconstituents by TLC
6. Analysis of crude drugs by chemical tests: (i) Asafoetida (ii) Benzoin (iii) Colophony (iv) Aloes (v) Myrrh

Recommended Books: (Latest Editions)

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhale (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), 1st Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, 1st edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi.
7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit.
13. Text Book of Biotechnology by R.C. Dubey.




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BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

45 Hours

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India.

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the act and rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA)

Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the act and rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-III

10 Hours

- **Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; its constitution and functions, Registration of Pharmacists, Offences and



Penalties

- ❑ **Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- ❑ **Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT-IV

08 Hours

- ❑ **Study of Salient Features of Drugs and magic remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- ❑ **Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- ❑ **National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)-2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-V

07 Hours

- ❑ **Pharmaceutical Legislations –** A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee
- ❑ **Code of Pharmaceutical ethics** Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- ❑ **Medical Termination of pregnancy act**
- ❑ **Right to information Act**
- ❑ **Introduction to Intellectual Property Rights (IPR)**

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh



2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory)




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BP601T. MEDICINAL CHEMISTRY – III (Theory)

45 Hours

Scope: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

Objectives: Upon completion of the course student shall be able to

1. Understand the importance of drug design and different techniques of drug design.
2. Understand the chemistry of drugs with respect to their biological activity.
3. Know the metabolism, adverse effects and therapeutic value of drugs.
4. Know the importance of SAR of drugs.

Course Content:

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*)

UNIT – I

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.

β-Lactam antibiotics: Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams

Aminoglycosides: Streptomycin, Neomycin, Kanamycin

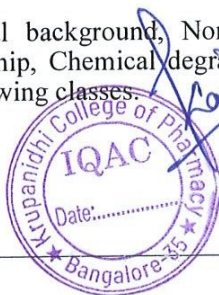
Tetracyclines: Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

10 Hours

Antibiotics

Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes.



Macrolide: Erythromycin Clarithromycin, Azithromycin.

Miscellaneous: Chloramphenicol*, Clindamycin.

Prodrugs: Basic concepts and application of prodrugs design.

Antimalarials: Etiology of malaria.

Quinolines: SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine.

Biguanides and dihydro triazines: Cycloguanil pamoate, Proguanil.

Miscellaneous: Pyrimethamine, Artesunate, Artemether, Atovaquone.

UNIT – III

10 Hours

Anti-tubercular Agents

Synthetic anti tubercular agents: Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*

Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine, Streptomycin, Capreomycin sulphate.

Urinary tract anti-infective agents

Quinolones: SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin

Miscellaneous: Furazolidine, Nitrofurantoin*, Methanamine.

Antiviral agents:

Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirdine, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV

08 Hours

Antifungal agents:

Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.

Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole, Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate*.

Anti-protozoal Agents: Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine.

Anthelmintics: Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin.



Sulphonamides and Sulfones

Historical development, chemistry, classification and SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.

Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.

Sulfones: Dapsone*.

UNIT – V

07 Hours

Introduction to Drug Design

Various approaches used in drug design.

Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis.

Pharmacophore modeling and docking techniques.

Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.



BP607P. MEDICINAL CHEMISTRY- III (Practical)

4 Hours / week

I Preparation of drugs and intermediates

- 1 Sulphanilamide
- 2 7-Hydroxy, 4-methyl coumarin
- 3 Chlorobutanol
- 4 Triphenyl imidazole
- 5 Tolbutamide
- 6 Hexamine

II Assay of drugs

- 1 Isonicotinic acid hydrazide
- 2 Chloroquine
- 3 Metronidazole
- 4 Dapsone
- 5 Chlorpheniramine maleate
- 6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates by Microwave irradiation technique

IV Drawing structures and reactions using chem draw®

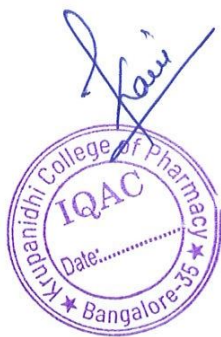
V Determination of physicochemical properties such as logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5)

Recommended Books (Latest Editions)

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Burger's Medicinal Chemistry, Vol I to IV.
4. Introduction to principles of drug design- Smith and Williams.
5. Remington's Pharmaceutical Sciences.
6. Martindale's extra pharmacopoeia.



7. Organic Chemistry by I.L. Finar, Vol. II.
8. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
9. Indian Pharmacopoeia.
10. Text book of practical organic chemistry- A.I.Vogel.




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BP602 T. PHARMACOLOGY-III (Theory)

45 Hours

Scope: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

Objectives: Upon completion of this course the student should be able to:

1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
2. comprehend the principles of toxicology and treatment of various poisonings and
3. appreciate correlation of pharmacology with related medical sciences.

Course Content:

UNIT-I

10hours

1. Pharmacology of drugs acting on Respiratory system

- a. Anti -asthmatic drugs
- b. Drugs used in the management of COPD
- c. Expectorants and antitussives
- d. Nasal decongestants
- e. Respiratory stimulants

2. Pharmacology of drugs acting on the Gastrointestinal Tract

- a. Antiulcer agents.
- b. Drugs for constipation and diarrhoea.
- c. Appetite stimulants and suppressants.
- d. Digestants and carminatives.
- e. Emetics and anti-emetics.

UNIT-II

10hours

3. Chemotherapy

- a. General principles of chemotherapy.
- b. Sulfonamides and cotrimoxazole.
- c. Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolones, tetracycline and aminoglycosides

UNIT-III

10hours

3. Chemotherapy

- a. Antitubercular agents
- b. Antileprotic agents



- c. Antifungal agents
- d. Antiviral drugs
- e. Anthelmintics
- f. Antimalarial drugs
- g. Antiamoebic agents

UNIT-IV

08hours

3. Chemotherapy

- l. Urinary tract infections and sexually transmitted diseases.
- m. Chemotherapy of malignancy.

4. Immunopharmacology

- a. Immunostimulants
 - b. Immunosuppressant
- Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

07hours

5. Principles of toxicology

- a. Definition and basic knowledge of acute, subacute and chronic toxicity.
- b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity
- c. General principles of treatment of poisoning
- d. Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning.

6. Chronopharmacology

- a. Definition of rhythm and cycles.
- b. Biological clock and their significance leading to chronotherapy.



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BP 608 P. PHARMACOLOGY-III (Practical)

4Hrs/Week

1. Dose calculation in pharmacological experiments
2. Antiallergic activity by mast cell stabilization assay
3. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model.
4. Study of effect of drugs on gastrointestinal motility
5. Effect of agonist and antagonists on guinea pig ileum
6. Estimation of serum biochemical parameters by using semi- autoanalyser
7. Effect of saline purgative on frog intestine
8. Insulin hypoglycemic effect in rabbit
9. Test for pyrogens (rabbit method)
10. Determination of acute oral toxicity (LD50) of a drug from a given data
11. Determination of acute skin irritation / corrosion of a test substance
12. Determination of acute eye irritation / corrosion of a test substance
13. Calculation of pharmacokinetic parameters from a given data
14. Biostatistics methods in experimental pharmacology(student's t test, ANOVA)
15. Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test)

**Experiments are demonstrated by simulated experiments/videos*

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.



BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

45 hours

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I

6 Hours

Herbs as raw materials

Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation
Source of Herbs

Selection, identification and authentication of herbal materials
Processing of herbal raw material

Biodynamic Agriculture

Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides.

UNIT-II

05 Hours

- a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
- b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma.

UNIT-III 7 Hours Nutraceuticals

General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases.

Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina

Herbal-Drug and Herb-Food Interactions: General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkoboba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-IV

Herbal Cosmetics

10 Hours



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Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- V

10 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

UNIT-VI

07 Hours

General Introduction to Herbal Industry

Herbal drugs industry: Present scope and future prospects.

A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

Components of GMP (Schedule – T) and its objectives

Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.



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BP 609 P. HERBAL DRUG TECHNOLOGY (Practical)

4 hours/ week

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of Ash value
3. Determination of moisture content of crude drugs
4. Determination of Extractive values of crude drugs
5. Determination of the alcohol content of Asava and Arista
6. Preparation of herbal cosmetics
7. Preparation and standardization of herbal formulation
8. Determination of swelling index and foaming index
9. Monograph analysis of herbal drugs from recent Pharmacopoeias
10. Analysis of fixed oils

Recommended Books: (Latest Editions)

1. Textbook of Pharmacognosy by Trease & Evans.
2. Textbook of Pharmacognosy by Tyler, Brady & Robber.
3. Pharmacognosy by Kokate, Purohit and Gokhale
4. Essential of Pharmacognosy by Dr.S.H.Ansari
5. Pharmacognosy & Phytochemistry by V.D.Rangari
6. Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)
7. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.



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BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

45 Hours

Scope: This subject is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of Biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives: Upon completion of the course student shall be able to:

1. Understand the basic concepts in biopharmaceutics and pharmacokinetics.
2. Use plasma data and derive the pharmacokinetic parameters to describe the process of drug absorption, distribution, metabolism and elimination.
3. Critically evaluate biopharmaceutic studies involving drug product equivalency
4. Design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
5. detect potential clinical pharmacokinetic problems and apply basic pharmacokinetic principles to solve them

Course Content:

UNIT-I

10 Hours

Introduction to Biopharmaceutics

Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes, Distribution of drugs Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs

UNIT- II

10 Hours

Drug Elimination renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

Bioavailability and Bioequivalence: Objectives of bioavailability studies, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro, in-vivo correlations, bioequivalence studies, methods to enhance the bioavailability.

UNIT- III 10 Hours Pharmacokinetics: Introduction to Pharmacokinetics models, Compartment models, Non compartment models, physiological models, One compartment open model. a. Intravenous Injection (Bolus) b. Intravenous infusion, extra vascular administrations, calculations of K_a , K_E . From plasma and urinary excretion data

UNIT- IV

08 Hours



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Multicompartment models: Two compartment open model. IV bolus

Multiple – Dosage Regimens:

- a). Repetitive Intravenous injections – One Compartment Open Model
- b). Repetitive Extravascular dosing – One Compartment Open model

UNIT- V 07 Hours Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

c. Michaelis-menton method of estimating parameters, Biotransformation of drugs

Recommended Books: (Latest Editions)

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition. USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi Donald, R. Marcel Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and
9. Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
10. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
11. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
12. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania



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BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

45 Hours

Scope:

- ☐ Biotechnology has a long promise to revolutionize the biological sciences and technology.
- ☐ Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting.
- ☐ Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs.
- ☐ Biotechnology has already produced transgenic crops and animals and the future promises lot more.
- ☐ It is basically a research-based subject.

Objectives: Upon completion of the subject student shall be able to;

1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
2. Genetic engineering applications in relation to production of pharmaceuticals
3. Importance of Monoclonal antibodies in Industries
4. Appreciate the use of microorganisms in fermentation technology

Unit I

10 Hours

- a) Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.
- b) Enzyme Biotechnology- Methods of enzyme immobilization and applications.
- c) Biosensors- Working and applications of biosensors in Pharmaceutical Industries.
- d) Brief introduction to Protein Engineering.
- e) Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.
- f) Basic principles of genetic engineering.

Unit II

10 Hours

- a) Study of cloning vectors, restriction endonucleases and DNA ligase.
- b) Recombinant DNA technology. Application of genetic engineering in medicine.
- c) Application of r DNA technology and genetic engineering in the products:
- d) Interferon b) Vaccines- hepatitis- B c) Hormones- Insulin.
- e) Brief introduction to PCR

Types of immunity- humoral immunity, cellular immunity

Unit III

10 Hours



- a) Structure of Immunoglobulins
- b) Structure and Function of MHC
- c) Hypersensitivity reactions, Immune stimulation and Immune suppressions.
- d) General method of the preparation of bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity.
- e) Storage conditions and stability of official vaccines
- f) Hybridoma technology- Production, Purification and Applications

Unit IV

08Hours

- a) Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
- b) Genetic organization of Eukaryotes and Prokaryotes
- c) Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
- d) Introduction to Microbial biotransformation and applications.
- e) Mutation.

Unit V

07 Hours

- a. Types of mutation/mutants
- b) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
- c) Large scale production fermenter design and its various controls.
- d) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,

Recommended Books (Latest edition):

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of Recombinant DNA: ASM Press Washington D.C.
2. RA Goldsby et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degrandland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd, New Delhi



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BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

45 Hours

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives: Upon completion of the course student shall be able to:

- ☐ understand the cGMP aspects in a pharmaceutical industry
- ☐ appreciate the importance of documentation
- ☐ understand the scope of quality certifications applicable to pharmaceutical industries
- ☐ understand the responsibilities of QA & QC departments

Course content:

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Quality by design (QbD): Definition, overview, elements of QbD program, tools

ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration

NABL accreditation : Principles and procedure

UNIT - II 10 Hours Organization and personnel: Personnel responsibilities, training, hygiene and personal records. **Premises:** Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and raw materials: Equipments selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

UNIT – III 10 Hours Quality Control: Quality control test for containers, rubber closures and secondary packing



materials.

Good Laboratory Practices: General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities

UNIT – IV 08 Hours Complaints: Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document maintenance in pharmaceutical industry: Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

UNIT – V 07 Hours Calibration and Validation: Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan. Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing: Good warehousing practice, materials management

Recommended Books: (Latest Edition)

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's – P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Dekker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines



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BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Scope: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

Objectives: Upon completion of the course the student shall be able to

1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
2. Understand the chromatographic separation and analysis of drugs.
3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

Course Content:

UNIT –I

10 Hours

UV Visible spectroscopy

Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications - Spectrophotometric titrations, Single component and multi component analysis

Fluorimetry

Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications

UNIT –II

10 Hours

IR spectroscopy

Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations

Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermistor, Pyroelectric detector and applications

Flame Photometry-Principle, Interferences, instrumentation and applications



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Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

UNIT –III

10 Hours

Introduction to chromatography

Adsorption and partition column chromatography-Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography-Introduction, methodology, development techniques, advantages, disadvantages and applications

Electrophoresis- Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT –IV

08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications

High performance liquid chromatography (HPLC)-Introduction, theory, instrumentation, advantages and applications.

UNIT –V

07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications



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BP705P. INSTRUMENTAL METHODS OF ANALYSIS (Practical)

4 Hours/Week

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy
- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by nephelo turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography

Recommended Books (Latest Editions)

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein




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BP 702 T. INDUSTRIAL PHARMACY (Theory)

45 Hours

Scope: This course is designed to impart fundamental knowledge on pharmaceutical product commercialization from laboratory to market

Objectives: Upon completion of the course, the student shall be able to:

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different laws and acts that regulate pharmaceutical industry in India and US
4. Understand the approval process and regulatory requirements for drug products

Course Content:

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to Platform technology

UNIT-II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer: Terminologies, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packing materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TOT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; Technology of Transfer (TOT) related documentation - confidentiality agreements, licensing, MoUs, legal issues

UNIT-III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.



UNIT-IV

08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

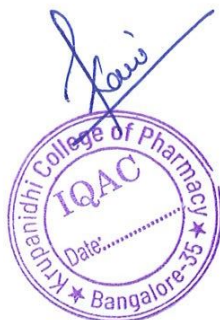
UNIT-V

07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Common Technical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.




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BP 703T. PHARMACY PRACTICE (Theory)

45 Hours

Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

Objectives: Upon completion of the course, the student shall be able to

1. know various drug distribution methods in a hospital
2. appreciate the pharmacy stores management and inventory control
3. monitor drug therapy of patient through medication chart review and clinical review
4. obtain medication history interview and counsel the patients
5. identify drug related problems
6. detect and assess adverse drug reactions
7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
8. know pharmaceutical care services
9. do patient counseling in community pharmacy;
10. appreciate the concept of Rational drug therapy.

Unit I:

10 Hours

a) Hospital and it's organization

Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.

b) Hospital pharmacy and its organization

Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction

Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting



drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) Community Pharmacy

Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Unit II:

10 Hours

a) Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

b) Hospital formulary

Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

c) Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence

Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview

Need for the patient medication history interview, medication interview forms.

f) Community pharmacy management

Financial, materials, staff, and infrastructure requirements.

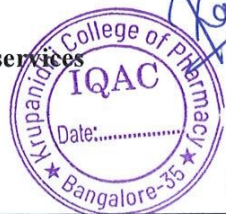
Unit III:

10 Hours

a) Pharmacy and therapeutic committee

Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

b) Drug information services



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Drug and Poison information centre, Sources of drug information, Computerised services, and storage and retrieval of information.

c) Patient counseling

Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist

d) Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

e) Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills- communication with prescribers and patients.

Unit IV

8 Hours

a)

Budget

preparation and implementation

Budget preparation and implementation

b) Clinical Pharmacy

Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care.

c) Over the counter (OTC) sales

Introduction and sale of over the counter, and Rational use of common over the counter medications.

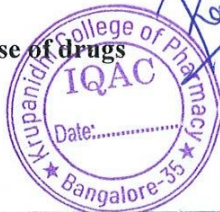
Unit V

7 Hours

a) Drug store management and inventory control

Organisation of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure

b) Investigational use of drugs



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Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests

Blood chemistry, hematology, and urinalysis

Recommended Books (Latest Edition):

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed. Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger; 1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)



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BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

45 Hours

Scope: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Objectives: Upon completion of the course student shall be able

1. To understand various approaches for development of novel drug delivery systems.
2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

Course content:

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations

Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump

Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches

Gastroretentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications

Nasopulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

Unit-IV

08 Hours



Nanotechnology and its Concepts: Concepts and approaches for targeted drug delivery systems, advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome –Preliminary study, ocular formulations and ocuserts

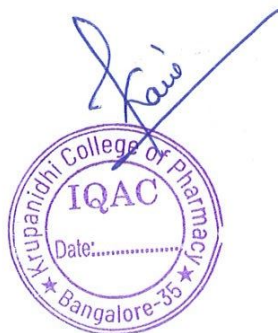
Intrauterine Drug Delivery Systems: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of Controlled Delivery. Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York. Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P. Vyas and R.K. Khar, Controlled Drug Delivery -concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)



BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Scope: To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

Objectives: Upon completion of the course the student shall be able to

- Know the operation of M.S. Excel, SPSS, R and MINITAB[®], DoE (Design of Experiment)
- Know the various statistical techniques to solve statistical problems
- Appreciate statistical techniques in solving the problems.

Course content:

Unit-I

10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems

Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceutical examples

Unit-II 10 Hours Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression- Pharmaceutical Examples **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples

Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference

Unit-III

10 Hours

Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test



Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

8 Hours

Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems:

Statistical Analysis Using Excel, SPSS, MINITAB[®], DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Unit-V

7Hours

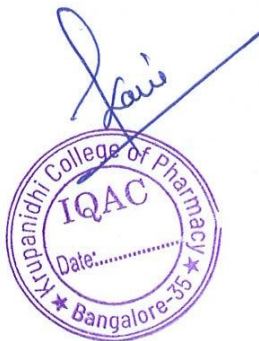
Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantage of factorial design

Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Recommended Books (Latest edition):

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. New York.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery




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BP 802T SOCIAL AND PREVENTIVE PHARMACY

Hours: 45

Scope:

The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Objectives:

After the successful completion of this course, the student shall be able to:

- ☐ Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- ☐ Have a critical way of thinking based on current healthcare development.
- ☐ Evaluate alternative ways of solving problems related to health and pharmaceutical issues

Course content:

Unit I:

10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health

Hygiene and health: personal hygiene and health care; avoidable habits

Unit II: 10 Hours Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse

Unit III: 10 Hours National health programs, its objectives, functioning and outcome of the following:

HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National



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programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit IV:

08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program

Unit V:

07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara GN, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications
3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine—A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, BANARSIDAS BHANOT PUBLISHERS.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

Recommended Journals:

1. Research in Social and Administrative Pharmacy, Elsevier, Ireland



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BP803ET. PHARMACEUTICAL MARKETING (Theory)

45 Hours

Scope:

The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management. The career in product management starts from having hands on experience in sales and marketing only.

Course Objective: The course aim is to provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

Unit I 10 Hours Marketing:

Definition, general concepts, and scope of marketing; Distinction between marketing & selling; Marketing environment; Industry and competitive analysis; Analyzing consumer buying behavior; industrial buying behavior.

Pharmaceutical market:

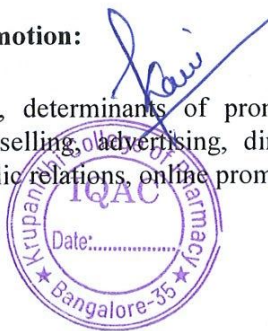
Quantitative and qualitative aspects; size and composition of the market; demographic descriptions and socio-psychological characteristics of the consumer; market segmentation & targeting. Consumer profile; Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist. Analyzing the Market; Role of market research.

Unit II 10 Hours Product decision:

Meaning, Classification, product line and product mix decisions, product life cycle, product portfolio analysis; product positioning; New product decisions; Product branding, packaging and labeling decisions, Product management in pharmaceutical industry.

Unit III 10 Hours Promotion:

Meaning and methods, determinants of promotional mix, promotional budget; An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products.



Unit IV 10 Hours Pharmaceutical marketing channels:

Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: Strategic importance, tasks in physical distribution management.

Professional sales representative (PSR):

Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

Unit V 10 Hours Pricing:

Meaning, importance, objectives, determinants of price; pricing methods and strategies, issues in price management in pharmaceutical industry. An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority).

Emerging concepts in marketing:

Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC GrawHill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.



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BP 805T: PHARMACOVIGILANCE (Theory)

45 hours

Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Objectives:

At completion of this paper it is expected that students will be able to (know, do, and appreciate):

1. Why drug safety monitoring is important?
2. History and development of pharmacovigilance
3. National and international scenario of pharmacovigilance
4. Dictionaries, coding and terminologies used in pharmacovigilance
5. Detection of new adverse drug reactions and their assessment
6. International standards for classification of diseases and drugs
7. Adverse drug reaction reporting systems and communication in pharmacovigilance
8. Methods to generate safety data during pre clinical, clinical and post approval phases of drugs' life cycle
9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
10. Pharmacovigilance Program of India (PvPI)
11. ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
12. CIOMS requirements for ADR reporting
13. Writing case narratives of adverse events and their quality.

Course Content

Unit I

10 Hours

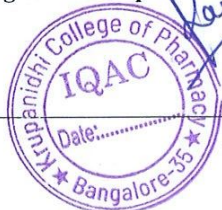
Introduction to Pharmacovigilance

- ☐ History and development of Pharmacovigilance
- ☐ Importance of safety monitoring of Medicine
- ☐ WHO international drug monitoring programme
- ☐ Pharmacovigilance Program of India(PvPI)

Introduction to adverse drug reactions

- ☐ Definitions and classification of ADRs
- ☐ Detection and reporting
- ☐ Methods in Causality assessment
- ☐ Severity and seriousness assessment
- ☐ Predictability and preventability assessment
- ☐ Management of adverse drug reactions

Basic terminologies used in pharmacovigilance



- ☐ Terminologies of adverse medication related events
- ☐ Regulatory terminologies

Unit II

10 hours

Drug and disease classification

- ☐ Anatomical, therapeutic and chemical classification of drugs
- ☐ International classification of diseases
- ☐ Daily defined doses
- ☐ International Non proprietary Names for drugs

Drug dictionaries and coding in pharmacovigilance

- ☐ WHO adverse reaction terminologies
- ☐ MedDRA and Standardised MedDRA queries
- ☐ WHO drug dictionary
- ☐ Eudravigilance medicinal product dictionary

Information resources in pharmacovigilance

- ☐ Basic drug information resources
- ☐ Specialised resources for ADRs

Establishing pharmacovigilance programme

- ☐ Establishing in a hospital
- ☐ Establishment & operation of drug safety department in industry
- ☐ Contract Research Organisations (CROs)
- ☐ Establishing a national programme

Unit III

10 Hours

Vaccine safety surveillance

- ☐ Vaccine Pharmacovigilance
- ☐ Vaccination failure
- ☐ Adverse events following immunization

Pharmacovigilance methods

- ☐ Passive surveillance – Spontaneous reports and case series
- ☐ Stimulated reporting
- ☐ Active surveillance – Sentinel sites, drug event monitoring and registries
- ☐ Comparative observational studies – Cross sectional study, case control study and cohort study
- ☐ Targeted clinical investigations

Communication in pharmacovigilance

- ☐ Effective communication in Pharmacovigilance
- ☐ Communication in Drug Safety Crisis management
- ☐ Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Unit IV

8 Hours

Statistical methods for evaluating medication safety data



Safety data generation

- ☐ Pre clinical phase
- ☐ Clinical phase
- ☐ Post approval phase

ICH Guidelines for Pharmacovigilance

- ☐ Organization and objectives of ICH
- ☐ Expedited reporting
- ☐ Individual case safety reports
- ☐ Periodic safety update reports
- ☐ Post approval expedited reporting
- ☐ Pharmacovigilance planning
- ☐ Good clinical practice in pharmacovigilance studies

Unit V**7 hours****Pharmacogenomics of adverse drug reactions****Drug safety evaluation in special population**

- ☐ Paediatrics
- ☐ Pregnancy and lactation
- ☐ Geriatrics

CIOMS

- ☐ CIOMS Working Groups
- ☐ CIOMS Form

CDSCO (India) and Pharmacovigilance

- ☐ D&C Act and Schedule Y
- ☐ Differences in Indian and global pharmacovigilance requirements

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna



12. <http://www.who.unc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html



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BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Theory)

Scope: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Objectives: Upon completion of the subject student shall be able to;

1. know WHO guidelines for quality control of herbal drugs
2. know Quality assurance in herbal drug industry
3. know the regulatory approval process and their registration in Indian and international markets
4. appreciate EU and ICH guidelines for quality control of herbal drugs

Unit I

10 hours

Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage forms

WHO guidelines for quality control of herbal drugs.
Evaluation of commercial crude drugs intended for use

Unit II

10 hours

Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.

WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

Unit II I

10 hours

EU and ICH guidelines for quality control of herbal drugs.
Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines

Unit IV

08 hours

Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products.

Preparation of documents for new drug application and export registration GMP requirements and Drugs & Cosmetics Act provisions.



Unit V

07 hours

Regulatory requirements for herbal medicines.

WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems Comparison of various Herbal Pharmacopoeias.

Role of chemical and biological markers in standardization of herbal products

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.



Hours Scope: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

Objectives: Upon completion of the course, the student shall be able to understand

- ☐ Design and discovery of lead molecules
- ☐ The role of drug design in drug discovery process
- ☐ The concept of QSAR and docking
- ☐ Various strategies to develop new drug like molecules.
- ☐ The design of new drug molecules using molecular modeling software

Course Content:

UNIT-I 10 Hours Introduction to Drug Discovery and Development

Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

Rational approaches to lead discovery based on traditional medicine, Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.

Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

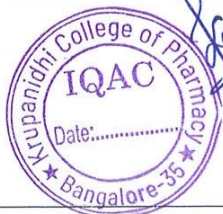
UNIT-II 10 Hours Quantitative Structure Activity Relationship (QSAR)

SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA.

UNIT-III 10 Hours Molecular Modeling and virtual screening techniques

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,

Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.



UNIT-IV 08 Hours Informatics & Methods in drug design

Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

UNIT-V

07 Hours

Molecular Modeling: Introduction to molecular mechanics and quantum mechanics. Energy Minimization methods and Conformational Analysis, global conformational minima determination.

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
5. Koro I kovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.



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BP810 ET.EXPERIMENTAL PHARMACOLOGY

Suggested title:PHARMACOLOGICAL SCREENING METHODS

45 Hours

Scope:This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

Objectives

Upon completion of the course the student shall be able to,

- ☐ Appreciate the applications of various commonly used laboratory animals.
- ☐ Appreciate and demonstrate the various screening methods used in preclinical research
- ☐ Appreciate and demonstrate the importance of biostatistics and research methodology
- ☐ Design and execute a research hypothesis independently

Unit –I	08 Hours
Laboratory Animals: Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.	
Unit –II	10 Hours
Preclinical screening models a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study. b. Study of screening animal models for Diuretics, nootropics, anti-Parkinson's, antiasthmatics, Preclinical screening models: for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease	

Unit –III Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaesthetics	
Unit –IV Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.	
Research methodology and Bio-statistics Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students ‘t’ test and One-way ANOVA. Graphical representation of data	05 Hours

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard




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RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA, BENGALURU
4th T Block, Jayanagar, Bengaluru - 560 041

RGU/AUTH/MPHARM/147/2017-18

10.05.2017

NOTIFICATION

- Sub:** Revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System)
- Ref:** (1) PCI Notification ref.No.14-136-2016-PCI,14-154/2015-PCI (53095-55431) dated 21.12.2016
(2) Proceedings of meeting of BOS in Pharmacy (PG) held on 05.12.2016
(3) Proceedings of meeting of Faculty of Pharmacy held on 05.12.2016
(4) Proceedings of meeting of Academic Council held on 22.12.2016
(5) Approval of Syndicate in its 125th meeting held on 06.01.2017.

In exercise of the powers conferred under section 35 of RGUHS Act, 1994, Syndicate is pleased to notify the revised ordinance relating to Master of Pharmacy (M.Pharm) course (Semester System) as shown in annexure appended herewith.

The revised ordinance shall come into force from the academic year 2017-18 and onwards.

By Order

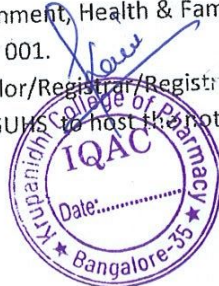
REGISTRAR

To

1. All the Principals of Pharmacy Colleges affiliated to RGUHS
2. The Registrar (Evaluation), RGUHS
3. The Director, Dept. of Curriculum Development, RGUHS

Copy to:

1. The Secretary to Governor, Governor's Secretariat, Raj Bhavan, Bangalore-560 001.
2. The Secretary to Government, Health & Family Welfare Department (Medical Education).Vikasa Soudha, Bangalore-560 001.
3. The PA to Vice-Chancellor/Registrar(Evaluation), RGUHS, Bangalore
4. The System Analyst, RGUHS to host the notification on RGUHS website.
5. Guard File/Office Copy



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MODERN PHARMACEUTICAL ANALYSIS (MPA101T)

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY

60 HOURS

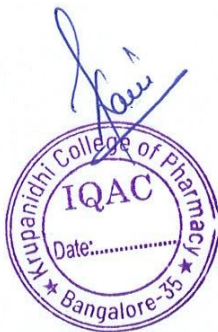
1. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation **11 Hrs**
associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.
IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy
Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.
2. **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ^{13}C NMR. Applications of NMR spectroscopy. **11 Hrs**
3. **Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy **11 Hrs**



- 4 **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following: 11 Hrs
a) Paper chromatography b) Thin Layer chromatography
c) Ion exchange chromatography d) Column chromatography
e) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography
- 5 **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: 11 Hrs
a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.
- 6 **Immunological assays :** RIA (Radio immuno assay), ELISA, 5 Hrs
Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series




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DRUG DELIVERY SYSTEM (MPH101T)

SCOPE

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

OBJECTIVES

Upon completion of the course, student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of
- The formulation and evaluation of Novel drug delivery systems..

THEORY

60 Hrs

10 Hrs

1. **SR/CR formulation:** Introduction & basic concepts, advantages/ disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers :introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems,Bioelectronic Medicines,3D printing of pharmaceuticals, Telepharmacy.

10 Hrs

2. **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems;Mechanically activated, PH activated , Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals

3. **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation,Methods of formulation and its evaluations.

10 Hrs

4. **Ocular Drug Delivery Systems:** Barriers of drug permeation, Methods to overcome barriers.

6 Hrs

5. **Trans Dermal Drug Delivery Systems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation

10 Hrs

6. **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.



8 Hrs

7. **Vaccine delivery systems:** Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

6 Hrs

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable




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MODERN PHARMACEUTICS (MPH102T)

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

Upon completion of the course, student shall be able to understand

- To understand the elements of preformulation studies.
- To understand the Active Pharmaceutical Ingredients and Generic drug Product development
- To learn Industrial Management and GMP Considerations.
- To understand Optimization Techniques & Pilot Plant Scale Up Techniques
- To study Stability Testing, sterilization process & packaging of dosage forms.

THEORY

60 HRS

10 hrs

1. **Preformation Concepts** – Drug Excipient interactions - different methods, kinetics of stability, Stability testing.
Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability
Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation

10 Hrs

2. **Optimization techniques in Pharmaceutical Formulation:** Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

10 Hrs

3. **Validation :** Introduction to Pharmaceutical Validation, Scope & merits of Validation, , Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities

10 Hrs

4. **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials



management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management

10 Hrs

- 5. Compression and compaction:** Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility enhancement techniques.

10 Hrs

- 6. Study of consolidation parameters;** Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckal plats, Similarity factors – f_2 and f_1 , Higuchi and peppas plot, Linearity Concept of significance, Standard deviation , chi square test , student T-test , Anova test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – Rawbins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P.Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.



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REGULATORY AFFAIRS (MPH103T)

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

Objectives:

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

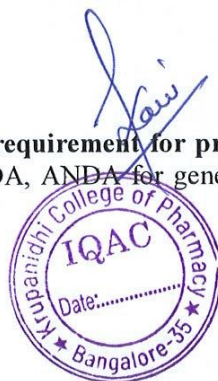
60 Hr

1. **Documentation in pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch- Waxman act and amendments , CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in-vitro ,ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO
2. **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

1

2 hrs

12 hrs



3. CMC, post approval regulatory affairs.Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison.
ICH - Guidelines of ICH-Q,S E,M.
Regulatory requirements of EU, MHRA, TGA and ROW countries.

12

hrs

4. **Non clinical drug development:** Global submission of IND,NDA,ANDA.Investigation medicinal products dossier, dossier (IMPD) and investigator brochure (IB)

12 hrs

5. **Clinical trials:** Developing clinical trial protocols. Institutional review board/independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.

12 hrs

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer,Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>



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PRACTICALS (MPH104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform *In-vitro* dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.



MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS)(MPH201T)

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY

60 Hrs

12 hrs

1. **Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

12hrs

2. **Targeting Methods:** introduction preparation and evaluation. Nano Particles & Liposomes: Types, preparation and evaluation

12hrs

3. **Micro Capsules / Micro Spheres:** Types, preparation and evaluation , Monoclonal Antibodies ; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

12hrs

4. **Pulmonary Drug Delivery Systems :** Aerosols, propellents, ContainersTypes, preparation and evaluation. Intra Nasal Route Delivery systems; Types, preparation and evaluation

12hrs

5. **Veterinary Drug Delivery Systems:** Tablets and bolus, Feed additives, Drinking water medication, Oral paste and gels, Drenchers and Tubing product

REFERENCES:

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel

- Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
 3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, NewDelhi, First edition 1997 (reprint in 2001).

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH202T)

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

At completion of this course it is expected that students will be able understand –

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and apply basic pharmacokinetic
- The principles to solve them

THEORY

1. **Drug Absorption From The Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting passive drug absorption, pH-partition theory of drug absorption. Factors affecting drug absorption: physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transport model:

Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment, Tight-Junction Complex, Structure of Octanol, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

12Hrs

- 2. Biopharmaceutic Considerations in Drug Product Design and In Vitro Drug Product Performance:** Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, Drug Product Performance, *In Vitro*: Dissolution and Drug Release Testing, Compendial Methods of Dissolution, Alternative Methods of Dissolution Testing, Meeting Dissolution Requirements, Problems of Variable Control in Dissolution Testing Performance of Drug Products. *In Vitro-In Vivo* Correlation, Dissolution Profile Comparisons, Drug Product Stability, Considerations in the Design of a Drug Product, Drug Product Considerations.

12Hrs

- 3. Pharmacokinetics:** Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model- IV bolus, IV infusion, Extravascular. Multi Compartment model: Two compartment - model in brief, Non-Linear Pharmacokinetics: Cause of non-linearity, Michaelis – Menten equation, Estimation K_{max} and V_{max} . Drug interactions: Introduction, The effect of protein-binding interactions, The effect of tissue-binding interactions, Cytochrome P450-based drug interactions, Drug interactions linked to transporters.

12Hrs

- 4. Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** Drug Product Performance, Purpose of Bioavailability Studies, Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Evaluation of the Data, Bioequivalence Example, Study Submission and Drug Review Process. Biopharmaceutics Classification System, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and Bioequivalence Studies, Generic Substitution.

12Hrs

- 5. Application of Pharmacokinetics:** Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. pharmacokinetic and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, Oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmarkar and Sunil B.J aishwal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.



COMPUTER AIDED DRUG DEVELOPMENT (MPH203T)

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students' to clarify the concepts.

Objectives

At completion of this course it is expected that students will be able to understand-

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY

60Hrs

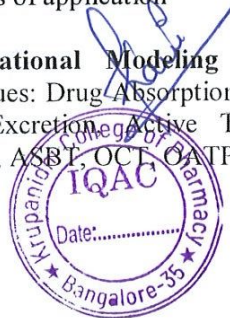
1. **Computers in Pharmaceutical Research and Development:** A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameter Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application

12Hrs

2. **Computational Modeling Of Drug Disposition:** Introduction ,Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution ,Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

12Hrs



3. **Computer-aided formulation development:** Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, microemulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

12Hrs

4. **Computer-aided biopharmaceutical characterization:** Gastrointestinal absorption simulation
Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and *in vitro-in vivo* correlation, Biowaiver considerations

Computer Simulations in Pharmacokinetics and Pharmacodynamics:
Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

12Hrs

5. **Artificial Intelligence (AI), Robotics and Computational fluid dynamics:**
General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

12Hrs

REFERENCES:

1. Computer Applications in Pharmaceutical Research and Development, Sean Ekins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, Jelena Djuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.



COSMETICS AND COSMECEUTICALS (MPH204T)

Scope

This course is designed to impart knowledge and skills necessary for the fundamental need for cosmetic and cosmeceutical products.

Objectives: Upon completion of the course, the students will be able to understand

- The key ingredients used in cosmetics and cosmeceuticals.
- The key building blocks for various formulations.
- The current technologies in the market
- The various key ingredients and basic science to develop cosmetics and cosmeceuticals
- The scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, sensory, stability, and efficacy.

THEORY

60Hrs

12Hrs

1. Formulations approaches and Requirements

Definition of cosmetic products as per EU guidelines .Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arms. Formulation requirements for ethnic needs.

12Hrs

2. Plant Lay out, factory requirements and commonly used cosmetics raw materials

Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants- Classification and application. Emollients rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a cream, shampoo and toothpaste.

Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation.

Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

12Hrs

3. Design of special purpose cosmeceutical products

Sun protection, sunscreens classification and regulatory aspects. addressing dry skin, acne,



sun-protection, pigmentation, prickly heat, wrinkles, body odor. Dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth.

12Hrs

3. Herbal Cosmetics

Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

12Hrs

4. Formulation of Lip care products and Cosmetic Safety .

Chemistry and formulation of paraphylene diamine based hair colorants. Soaps and syndet bars Labelling requirements for cosmetics Study of salient features of cosmetic safety data base developed by private body, and International Nomenclature of Cosmetic Ingredients (INCI). Review of the list of ingredients on the labels of cosmetics, cosmeceuticals, baby care and men's range of the products in the market and conduct comparative study of the formulations.

RECOMMENDED BOOKS:

1. Harry's Cosmeticology. 8th edition
2. Poucher's perfume cosmetics and Soaps, 10th edition
3. Cosmetics - Formulation, manufacture and quality control PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I.Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers catalogue.
6. CTFA directory.




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PRACTICAL (MPH205P)

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes
5. Formulation and evaluation of niosomes
6. Formulation and evaluation of spheruls
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Comparison of dissolution of two different marketed products /brands
9. Protein binding studies of a highly protein bound drug & poorly protein bound drug
10. Bioavailability studies of Paracetamol.
11. Pharmacokinetic and IVIVC data analysis by Winnoline^R software
12. *In vitro* cell studies for permeability and metabolism
13. DoE Using Design Expert[®] Software
14. Formulation data analysis Using Design Expert[®] Software
15. Quality-by-Design in Pharmaceutical Development
16. Computer Simulations in Pharmacokinetics
17. Computer Simulations Pharmacodynamics
18. Computational Modeling Of Drug Disposition
19. To develop Clinical Data Collection manual
20. To carry out Sensitivity Analysis, and Population Modeling.
21. Development and evaluation of Creams
22. Development and evaluation of Shampoo and Toothpaste base
23. To Incorporate herbal and chemical actives to develop products
24. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff




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ADVANCED ORGANIC CHEMISTRY-1 (MPC101T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be to understand-

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

THEORY

60 Hrs

1. Basic Aspects of Organic Chemistry

- a. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
- b. Types of reaction mechanisms and methods of determining them,
- c. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.
 - i. Aliphatic and aromatic compounds,
 - ii. Nucleophilic uni- and bimolecular reactions (SN1 and SN2)
 - iii. Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule)
 - iv. Rearrangement reaction

12Hrs

2. Study of mechanism synthetic applications of following named Reactions:

Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction

12 Hrs

3. Synthetic Reagents & Applications



Aluminiumisopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Witting reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-yloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups

- Role of protection in organic synthesis
- Protection for the hydroxyl group, including 1,2-and 1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals
- Protection for the Carbonyl Group: Acetals and Ketals
- Protection for the Carboxyl Group: amides and hydrazides, esters
- Protection for the Amino Group and Amino acids: carbamates and amides

12Hrs

4. Heterocyclic Chemistry

General methods of synthesis and applications of drugs of five, six membered and fused heterocycles such as imidazole, pyrazole, triazole, pyrimidine, quinoline, acridine, phenothiazine and purine. Synthesis of few representative drugs containing these heterocyclic nucleus

12Hrs

5. Synthon approach and retrosynthesis applications

- Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA)
- C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
- Strategies for synthesis of three, four, five and six-membered ring

12Hrs

REFERENCES

- "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
- "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.
- "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
- "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
- A guide to mechanisms in Organic Chemistry – Peter Skyes (Orient Longman, New Delhi).
- Reactive intermediates in organic chemistry – Tandom and Gowel.



7. Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik.
8. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
9. Organic synthesis-The disconnection approach, S. Warren, Wiley India
10. Principles of organic synthesis, ROC Norman and JM Coxan, Nelson thorns
11. Organic synthesis- Special techniques VK Ahluwalia and R Agarwal, Narosa Publishers
12. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar, Narosa Publishers



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ADVANCED MEDICINAL CHEMISTRY (MPC102T)

Scope

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

THEORY

60 Hrs

1. **Drug discovery:** Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets. Chemistry of prostaglandins, leukotrienes and thromboxones.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

12

Hrs

2. **Prodrug Design and Analog design:**

- **Prodrug design:** Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.
- **Combating drug resistance:** Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.



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12

Hrs

- **Analog Design:** Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

3 Chemistry of Synthetic drugs: Systematic study, SAR, Mechanism of action and synthesis of

new generation molecules of following class of drugs: Anti-hypertensive drugs, Psychoactive

drugs, Anticonvulsant drugs, H₁ & H₂ receptor antagonist, COX1 & COX2 inhibitors,

Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

12 Hrs

4. Rational Design of Enzyme Inhibitors: Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

12 Hrs

5. Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally.

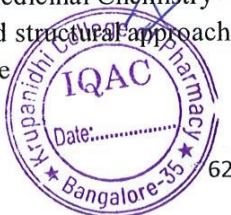
Combinatorial chemistry and High throughput screening: Different techniques, Solid phase synthesis, Solution phase synthesis, Parallel synthesis, applications of combinatorial chemistry. High Throughput Screening- general outline, importance and application.

12

Hrs

REFERENCES:

1. Medicinal Chemistry by Burger.
2. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
3. Comprehensive Medicinal Chemistry – Corwin and Hansch.
4. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore



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5. Introduction to Quantitative Drug Design by Y.C. Martin.
6. Principles of Medicinal Chemistry by William Foye.
7. Drug Design Volumes by Arienes.
8. Principles of Drug Design by Smith.
9. The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman.
10. An Introduction to Medicinal Chemistry –Graham L.Patrick, (III Edition.)
11. Biopharmaceutics and pharmacokinetics by DM.Brahmankar, Sunil B .Jaiswal.
12. Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.



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CHEMISTRY OF NATURAL PRODUCTS (MPC103T)

Scope

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

Objectives

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

THEORY

60 Hrs

1. Study of Natural products as leads for new pharmaceuticals for the following class of drugs:

- a. Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b. Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c. Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d. Neuromuscular Blocking Drugs: Curare alkaloids
- e. Chemistry of macrolid antibiotics: Erythromycine, Azithromycine, Cephalosporins(New generation)

12Hrs

2. Alkaloids- General introduction, classification, isolation, purification, stereochemistry, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids. Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

12Hrs

3. Steroids- General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, Structure elucidation of



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male & female sex hormones(testosterone, Estradiol, progesterone), Adrenocortcoids (carsisone) and contraceptive agents.

Terpenoids – Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono, di and tri terpenoids, carotinoids.

12Hrs

4. Recombinant DNA technology and drug discovery:

rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation

Active constituent of certain crude drugs used in Indigenous system.

Diabetic therapy – *Gymnema sylvestre*, *Salacia reticulate*, *Pterocarpus marsupiam*, *Swertia chirata*, *Trigonella foenum graccum*; Liver dysfunction – *Phyllanthus niruri*; Antitumor – *Curcuma longa* Linn.

12Hrs

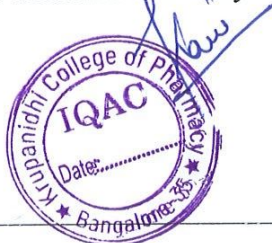
5. Structural Characterization of natural Products

Structural characterization of natural compounds using IR, ¹HNMR, ¹³CNMR and MS Spectroscopy

12Hrs

REFERENCES

1. Modern methods of plant analysis – Peech and M.V.Tracey.
2. Phytochemistry Vol. I and II by Miller, Jan Nostrant Rein Hld.
3. Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles.
4. Chemistry of natural products Vol I onwards IWPAC.
5. Natural Product Chemistry Nakanishi Gggolo.
6. Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
7. The Alkaloid Chemistry and Physiology by THF Manske.
8. Introduction to molecular Phytochemistry – CHJ Wells, Chapmanstall.
9. Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall.
10. Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal.
11. Organic Chemistry Vol I and II by I.L. Finar
12. Elements of Biotechnology by P.K. Gupta.
13. Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit.
14. Biotechnology by Purohit and Mathoor.
15. Phytochemical methods of Harborne.
16. Burger’s Medicinal Chemistry.



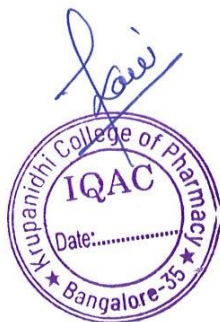
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PRACTICALS (MPC104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

To perform the following reactions of synthetic importance

7. Purification of organic solvents, column chromatography
8. Claisen-schmidt reaction.
9. Benzyllic acid rearrangement.
10. Beckmann rearrangement.
11. Hoffmann rearrangement
12. Mannich reaction
13. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
14. Estimation of elements and functional groups in organic natural compounds
15. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
16. Some typical degradation reactions to be carried on selected plant constituents



ADVANCED SPECTRAL ANALYSIS (MPC201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

At completion of this course it is expected that students will be able to understand-

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

THEORY

60Hrs

1. **UV and IR spectroscopy:** Wood ward – Fiesure rule for 1,3- butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

1

2Hrs

2. **NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.

12Hrs

3. **Mass Spectroscopy:** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

12Hrs

4. **Chromatography:** Principle, Instrumentation and Applications of the following:
a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CE-MS g)
High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography)



k)

Flash

chromatography.

12Hrs

5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA.

Raman Spectroscopy: Introduction, Principle, Instrumentation and Applications.

Radio immuno assay: Biological standardization , bioassay, ELISA,
Radioimmuno assay of digitalis and insulin

12Hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series



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ADVANCED ORGANIC CHEMISTRY -II(MPC202T)

Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

Objectives

Upon completion of course, the student shall be able to understand

- The principles and applications of Green chemistry
- The concept of peptide chemistry.
- The various catalysts used in organic reactions
- The concept of stereochemistry and asymmetric synthesis.

THEORY

60 Hrs

1. Green Chemistry

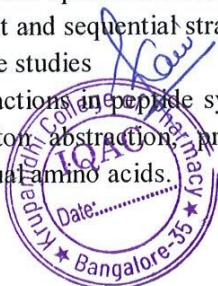
- a. Introduction, principles of green chemistry
- b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
- c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
- d. Continuous flow reactors: Working principle, advantages and synthetic applications.

12Hrs

2. Chemistry of peptides

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, over-activation and side reactions of individual amino acids.

12Hrs



3. Photochemical Reactions

Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation

Pericyclic reactions

Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

12Hrs

4. Catalysis

- Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages
- Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs
- Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- Phase transfer catalysis - theory and applications

12Hrs

5. Stereochemistry & Asymmetric Synthesis

- Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
- Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

12Hrs

REFERENCES

- "Advanced Organic chemistry, Reaction, mechanisms and structure", J March, John Wiley and sons, New York.
- "Mechanism and structure in organic chemistry", ES Gould, Hold Rinchart and Winston, New York.



3. "Organic Chemistry" Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. "Organic Chemistry" Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, R.C. Norman and J.M. Coxon, Nelson Thornes
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers
9. Organic reaction mechanisms IV edn, VK Ahluwalia and RK Parashar, Narosa Publishers



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COMPUTER AIDED DRUG DESIGN (MPC203T)

Scope

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

Objectives

At completion of this course it is expected that students will be able to understand-

- Role of CADD in drug discovery
- Different CADD techniques and their applications
- Various strategies to design and develop new drug like molecules.
- Working with molecular modeling softwares to design new drug molecules
- The *in silico* virtual screening protocols

Theory

60 Hrs

1. **Introduction to Computer Aided Drug Design (CADD):** History, different techniques and applications.

Quantitative Structure Activity Relationships: Basics

History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters (sigma), lipophilicity effects and parameters (log P, pi-substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

12 Hrs

2. **Quantitative Structure Activity Relationships: Applications**

Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations.

3D-QSAR approaches and contour map analysis.

Statistical methods used in QSAR analysis and importance of statistical parameters.

12 Hrs

3. **Molecular Modeling and Docking**

a. Molecular and Quantum Mechanics in drug design

b. Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation

Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase (AChE & BchE)

12 Hrs

4. **Molecular Properties and Drug Design**

a. Prediction and analysis of ADMET properties of new molecules and its importance in drug design.



- b. *De novo* drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
- c. Homology modeling and generation of 3D-structure of protein.

12 Hrs

5. Pharmacophore Mapping and Virtual Screening

Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques

Similarity based methods and Pharmacophore based screening, structure based *in silico* virtual screening protocols.

12 Hrs

REFERENCES:

1. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
2. Introduction to Quantitative Drug Design by Y.C. Martin.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975.
4. Principles of Drug Design by Smith and Williams.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman.
6. Medicinal Chemistry by Burger.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, (III Edition.)
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore



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PHARMACEUTICAL PROCESS CHEMISTRY (MPC204T)

Scope

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

Objectives

At completion of this course it is expected that students will be able to understand-

- The strategies of scale up process of APIs and intermediates
- The various unit operations and various reactions in process chemistry

THEORY

60 Hrs

1. Process chemistry

- Introduction, Synthetic strategy
- Stages of scale up process: Bench, pilot and large scale process.
- In-process control and validation of large scale process.
- Case studies of some scale up process of APIs.
- Impurities in API, types and their sources including genotoxic impurities

12 Hrs

2. Unit operations

- Extraction*: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
- Filtration*: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- Distillation*: azeotropic and steam distillation
- Evaporation*: Types of evaporators, factors affecting evaporation.
- Crystallization*: Crystallization from aqueous, non-aqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

12 Hrs



3. Unit Processes

- a. **Nitration:** Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
- b. **Halogenation:** Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
- c. **Oxidation:** Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H_2O_2 , sodium hypochlorite, Oxygen gas, ozonolysis.

12 Hrs

4. Unit Processes

- a. **Reduction:** Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
- b. **Fermentation:** Aerobic and anaerobic fermentation. Production of
 - i. Antibiotics; Penicillin and Streptomycin,
 - ii. Vitamins: B2 and B12
 - iii. Statins: lovastatin, simvastatin

Reaction progress kinetic analysis

- a. Streamlining reaction steps, route selection,
- b. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

12 Hrs

5. Industrial Safety

- a. MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
- b. Fire hazards, types of fire & fire extinguishers
- c. Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001 (Environmental Management System), Effluents and its management

12 Hrs

REFERENCES:

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever-Changing Climate-An Overview; K. Gadamasetti
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.



4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology
11. Clausen,Mattson: Principle of Industrial Chemistry
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Sreve: Chemical Process
16. B.K.Sharma: Industrial Chemistry
17. ICH Guidelines
18. United States Food and Drug Administration official website www.fda.gov



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PRACTICALS (MPC205P)

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
 - a. Oxidation
 - b. Reduction/hydrogenation
 - c. Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH_4 reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)
17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study
22. Virtual screening based experiment



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ADVANCED PHARMACOLOGY-I (MPL101T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, this subject helps the students to understand the concepts of drug action and mechanisms involved

Objectives

Upon completion of the course the student shall be able to:

- Discuss the pathophysiology and pharmacotherapy of certain diseases
- Explain the mechanism of drug actions at cellular and molecular level
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

THEORY

60

HOURS

UNIT-I

General Pharmacology

12 Hrs

- a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation and elimination. Concepts of linear and non-linear compartment models. Significance of Protein binding. 06 hrs
- b. Pharmacodynamics: Mechanism of drug action and the relationship between drug concentration and effect. Receptors, structural and functional families of receptors, quantitation of drug receptors interaction and elicited effects. 06 hrs

UNIT-II

12 Hrs

Neurotransmission

06 Hrs

- a. General aspects and steps involved in neurotransmission.
- b. Neurohumoral transmission in autonomic nervous system (Detailed study about neurotransmitters- Adrenaline and Acetyl choline).
- c. Neurohumoral transmission in central nervous system (Detailed study about neurotransmitters- histamine, serotonin, dopamine, GABA, glutamate and glycine).
- d. Non adrenergic non cholinergic transmission (NANC). Co-transmission

Systemic Pharmacology

06 Hrs

A detailed study on pathophysiology of diseases, mechanism of action, pharmacology and toxicology of existing as well as novel drugs used in the following systems



a. Autonomic Pharmacology

Parasympathomimetics and lytics, sympathomimetics and lytics, agents affecting neuromuscular junction

UNIT-III

12 Hrs

Central nervous system Pharmacology

General and local anesthetics	02 hrs
Sedatives and hypnotics, drugs used to treat anxiety.	02 hrs
Depression, psychosis, mania, epilepsy, neurodegenerative diseases.	05 hrs
Narcotic and non-narcotic analgesics.	03 hrs

UNIT-IV

Cardiovascular Pharmacology

12 Hrs

Diuretics, antihypertensives, antiischemics, anti- arrhythmics, drugs for heart failure and hyperlipidemia.	07 hrs
Hematinics, coagulants , anticoagulants, fibrinolytics and anti-platelet drugs	05 hrs

UNIT- V

Autocoid Pharmacology

12 Hrs

The physiological and pathological role of Histamine, Serotonin, Kinins Prostaglandins	
Opioid autocoids.	08 hrs
Pharmacology of antihistamines, 5HT antagonists.	04 hrs

REFEERENCES

1. The Pharmacological basis of therapeutics- Goodman and Gill man's
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
6. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists



PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-I (MPL102T)

Scope

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

Objectives

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY HOURS

60

Unit-I

12 Hrs

Laboratory Animals

Common lab animals: Description, handling and applications of different species and strains of animals.

02 hrs

Transgenic animals: Production, maintenance and applications

02 hrs

Anaesthesia and euthanasia of experimental animals.

03 hrs

Maintenance and breeding of laboratory animals.

02 hrs

CPCSEA guidelines to conduct experiments on animals

02 hrs

Good laboratory practice.

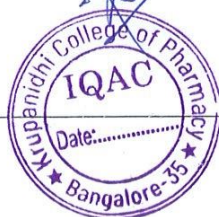
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Unit-II

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

General principles of preclinical screening. CNS Pharmacology: behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti epileptics



and nootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiple sclerosis. Drugs acting on Autonomic Nervous System.

Unit-III

12 Hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics.

Reproductive Pharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory and antipyretic agents. Gastrointestinal drugs: anti ulcer, anti -emetic, anti-diarrheal and laxatives.

Unit-IV

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Cardiovascular Pharmacology: antihypertensives, antiarrhythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antihyperlipidemic, and agents. Anti cancer agents

Unit V

12 hrs

Preclinical screening of new substances for the pharmacological activity using *in vivo*, *in vitro*, and other possible animal alternative models.

Immunosuppressants and immunomodulators

02 hrs

General principles of immunoassay: theoretical basis and optimization of immunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methods evaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulin

08 hrs

Limitations of animal experimentation and alternate animal experiments.

01 hr

Extrapolation of *in vitro* data to preclinical and preclinical to humans.

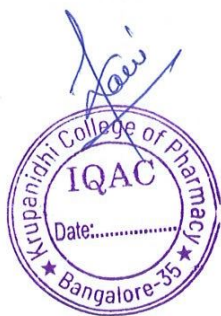
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REFERENCES

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach



5. Methods in Pharmacology by Arnold Schwartz.
6. Fundamentals of experimental Pharmacology by M.N.Ghosh
7. Pharmacological experiment on intact preparations by Churchill Livingstone
8. Drug discovery and Evaluation by Vogel H.G.
9. Experimental Pharmacology by R.K.Goyal.
10. Preclinical evaluation of new drugs by S.K. Gupta




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CELLULAR AND MOLECULAR PHARMACOLOGY (MPL103T)

Scope:

The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the receptor signal transduction processes.
- Explain the molecular pathways affected by drugs.
- Appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.
- Demonstrate molecular biology techniques as applicable for pharmacology

Unit I

12 Hrs

Cell biology

Structure and functions of cell and its organelles

Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing

Cell cycles and its regulation.

Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis.

Necrosis and autophagy.

Unit II

12Hrs

Cell signaling

Intercellular and intracellular signaling pathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

Unit III

12Hrs

Principles and applications of genomic and proteomic tools

06 hrs




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DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting,

Recombinant DNA technology and gene therapy

06 hrs

Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology.

Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy

Unit IV

12Hrs

Pharmacogenomics

08 hrs

Gene mapping and cloning of disease gene.

Genetic variation and its role in health/ pharmacology

Polymorphisms affecting drug metabolism

Genetic variation in drug transporters

Genetic variation in G protein coupled receptors

Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics

Immunotherapeutics

04 hrs

Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

Unit V

12Hrs

Cell culture techniques

Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application.

Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays

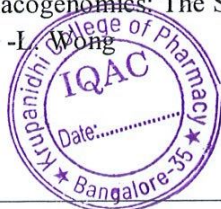
Principles and applications of flow cytometry

Unit VI

Biosimilars

References:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.
2. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong



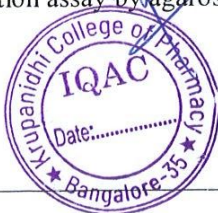
3. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
4. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
5. Basic Cell Culture protocols by Cheril D.Helgason and Cindy L.Miller
6. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
7. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
8. Current porotocols in molecular biology vol I to VI edited by Frederick M.Ausuvel et la.

Experimental Pharmacology- I (MPL104P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry

Handling of laboratory animals.

1. Various routes of drug administration.
2. Techniques of blood sampling, anesthesia and euthanasia of experimental animals.
3. Functional observation battery tests (modified Irwin test)
4. Evaluation of CNS stimulant, depressant, anxiogenics and anxiolytic, anticonvulsant activity.
5. Evaluation of analgesic, anti-inflammatory, local anesthetic, mydriatic and miotic activity.
6. Evaluation of diuretic activity.
7. Evaluation of antiulcer activity by pylorus ligation method.
8. Oral glucose tolerance test.
9. Isolation and identification of DNA from various sources (Bacteria, Cauliflower, onion, Goat liver).
10. Isolation of RNA from yeast
11. Estimation of proteins by Braford/Lowry's in biological samples.
12. Estimation of RNA/DNA by UV Spectroscopy
13. Gene amplification by PCR.
14. Protein quantification Western Blotting.
15. Enzyme based *in-vitro* assays (MPO, AChEs, α amylase, α glucosidase).
16. Cell viability assays (MTT/Trypan blue/SRB).
17. DNA fragmentation assay by agarose gel electrophoresis.



18. DNA damage study by Comet assay.
19. Apoptosis determination by fluorescent imaging studies.
20. Pharmacokinetic studies and data analysis of drugs given by different routes of administration using softwares
21. Enzyme inhibition and induction activity
22. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (UV)
23. Extraction of drug from various biological samples and estimation of drugs in biological fluids using different analytical techniques (HPLC)

References

1. CPCSEA, OECD, ICH, USFDA, Schedule Y, EPA guidelines,
2. Fundamentals of experimental Pharmacology by M.N.Ghosh
3. Handbook of Experimental Pharmacology by S.K. Kulkarni.
4. Drug discovery and Evaluation by Vogel H.G.
5. Spectrometric Identification of Organic compounds - Robert M Silverstein,
6. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman,
7. Vogel's Text book of quantitative chemical analysis - Jeffery, Basset, Mendham, Denney,
8. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L.Mille
9. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
10. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)



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ADVANCED PHARMACOLOGY-II (MPL201T)

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases. In addition, the subject helps the student to understand the concepts of drug action and mechanism involved

Objectives

Upon completion of the course the student shall be able to:

- Explain the mechanism of drug actions at cellular and molecular level
- Discuss the Pathophysiology and pharmacotherapy of certain diseases
- Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases

UNIT-I

Endocrine Pharmacology

12 Hrs

Molecular and cellular mechanism of action of hormones such as growth hormone, prolactin, thyroid, insulin and sex hormones

Anti-thyroid drugs, Oral hypoglycemic agents, Oral contraceptives, Corticosteroids.

Drugs affecting calcium regulation

UNIT-II

Chemotherapy

12 Hrs

Cellular and molecular mechanism of actions and resistance of antimicrobial agents such as β -lactams, aminoglycosides, quinolones, Macrolide antibiotics. Antifungal, antiviral, and anti-TB drugs.

UNIT-III

12 Hrs

Chemotherapy

06 Hrs

Drugs used in Protozoal Infections

Drugs used in the treatment of Helminthiasis

Chemotherapy of cancer

Immunopharmacology

06 Hrs

Cellular and biochemical mediators of inflammation and immune response. Allergic or hypersensitivity reactions, Pharmacotherapy of asthma and COPD.



Immunosuppressants and Immunostimulants

UNIT-IV

GIT Pharmacology

08 Hrs

Antiulcer drugs, Prokinetics, antiemetics, anti-diarrheals and drugs for constipation and irritable bowel syndrome.

Chronopharmacology

04 Hrs

Biological and circadian rhythms, applications of chronotherapy in various diseases like cardiovascular disease, diabetes, asthma and peptic ulcer

UNIT-V

Free radicals Pharmacology

04 Hrs

Generation of free radicals, role of free radicals in etiopathology of various diseases such as diabetes, neurodegenerative diseases and cancer.

Protective activity of certain important antioxidant

Recent Advances in Treatment:

08 Hrs

Alzheimer's disease, Parkinson's disease, Cancer, Diabetes mellitus

References

1. The Pharmacological basis of therapeutics- Goodman and Gilman's
2. Principles of Pharmacology. The Pathophysiologic basis of drug therapy by David E Golan et al.
3. Basic and Clinical Pharmacology by B.G -Katzung
4. Pharmacology by H.P. Rang and M.M. Dale.
5. Hand book of Clinical Pharmacokinetics by Gibaldi and Prescott.
6. Text book of Therapeutics, drug and disease management by E T. Herfindal and Gourley.
7. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
8. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists



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TOXICOLOGICAL SCREENING METHODS (MPL202T)

Scope:

The subject imparts knowledge on the preclinical safety and toxicological evaluation of drug & new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills required to conduct the preclinical toxicity studies.

Unit I

12 Hrs

Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive)
Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y
OECD principles of Good laboratory practice (GLP)
History, concept and its importance in drug development

Unit II

12 Hrs

Acute, sub-acute and chronic- oral, dermal and inhalational studies as per OECD guidelines.
Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
Test item characterization- importance and methods in regulatory toxicology studies

Unit III

12 Hrs

Reproductive toxicology studies, Male reproductive toxicity studies, female reproductive studies (segment I and segment III), teratogenicity studies (segment II)
Genotoxicity studies (Ames Test, *in vitro* and *in vivo* Micronucleus and Chromosomal aberrations studies)
In vivo carcinogenicity studies

Unit IV

12 Hrs

IND enabling studies (IND studies)- Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
Safety pharmacology studies- origin, concepts and importance of safety pharmacology.
Tier1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier2- GI, renal and other studies



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Unit V

12 Hrs

Toxicokinetics- Toxicokinetic evaluation in preclinical studies, saturation kinetics
Importance and applications of toxicokinetic studies.
Alternative methods to animal toxicity testing.

REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules, 2005, ministry of health and family welfare (department of health) New Delhi
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals (<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)



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PRINCIPLES OF DRUG DISCOVERY (MPL203T)

Scope:

The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the various stages of drug discovery.
- Appreciate the importance of the role of genomics, proteomics and bioinformatics in drug discovery
- Explain various targets for drug discovery.
- Explain various lead seeking method and lead optimization
- Appreciate the importance of the role of computer aided drug design in drug discovery

Unit-I

12 Hrs

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

Unit-II

12 Hrs

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure

Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

Unit-III

12 Hrs

Rational Drug Design

Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,



Unit-IV

12 Hrs

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

Unit-V

12 Hrs

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods. 3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

References

1. MouldySioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targetsand Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkellIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L . Parrill. M . Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., Hoboken, New Jeney.



CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials.

This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to,

- Explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance

UNIT-I hours

12

Regulatory Perspectives of Clinical Trials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines

Ethical Committee- Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR

Informed Consent Process: Structure and content of an Informed Consent Process
Ethical principles governing informed consent process

UNIT- II hours

12

Clinical Trials: Types and Design

Experimental Study- RCT and Non RCT,
Observation Study: Cohort, Case Control, Cross sectional



Clinical Trial Study Team

Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management

UNIT- III

12

hours

Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions; Terminologies of ADR.

UNIT-IV

12

hours

Basic aspects, terminologies and establishment of pharmacovigilance

History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance

UNIT-V

12 hours

Methods, ADR reporting and tools used in Pharmacovigilance

International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.

UNIT-VI

Pharmacoeconomics, Dermatology, pharmacoepidemiology, safety pharmacology

References:




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1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

Experimental Pharmacology-II (MPL205P)

1. To record the DRC of agonist using suitable isolated tissues preparation.
2. To study the effects of antagonist/potentiating agents on DRC of agonist using suitable isolated tissue preparation.
3. To determine to the strength of unknown sample by matching bioassay by using suitable tissue preparation.
4. To determine to the strength of unknown sample by interpolation bioassay by using suitable tissue preparation
5. To determine to the strength of unknown sample by bracketing bioassay by using suitable tissue preparation
6. To determine to the strength of unknown sample by multiple point bioassay by using suitable tissue preparation.
7. Estimation of PA₂ values of various antagonists using suitable isolated tissue preparations.
8. To study the effects of various drugs on isolated heart preparations
9. Recording of rat BP, heart rate and ECG.
10. Recording of rat ECG
11. Drug absorption studies by averted rat ileum preparation.
12. Acute oral toxicity studies as per OECD guidelines.
13. Acute dermal toxicity studies as per OECD guidelines.
14. Repeated dose toxicity studies- Serum biochemical, haematological, urine analysis, functional observation tests and histological studies.
15. Drug mutagenicity study using mice bone-marrow chromosomal aberration test.
16. Protocol design for clinical trial.
17. Protocol design for clinical trial.
18. Protocol design for clinical trial.
19. Design of ADR monitoring protocol.



20. In silico docking studies.
21. In silico pharmacophore based screening.
22. In silico QSAR studies.
23. ADR reporting
24. In silico docking studies.

References

1. Fundamentals of experimental Pharmacology-by M.N.Ghosh
2. Hand book of Experimental Pharmacology-S.K.Kulakarni
3. Text book of *in-vitro* practical Pharmacology by Ian Kitchen
4. Bioassay Techniques for Drug Development by Atta-ur-Rahman, Iqbal choudhary and William Thomsen
5. Applied biopharmaceutics and Pharmacokinetics by Leon Shargel and Andrew B.C.Yu.
6. Handbook of Essential Pharmacokinetics, Pharmacodynamics and Drug Metabolism for Industrial Scientists.



ADVANCED PHARMACEUTICAL ANALYSIS (MPA102T)

Scope

This subject deals with the various aspects of reagents, quantitative analysis of functional group used in the analytical method development. It also covers the biological testing of various vaccines and impurities

Objectives

After the completion of the course, it is expected that the student shall be able to know

- Appropriate analytical skills required for the analytical method development.
- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products.

THEORY

60 HOURS

1. **Analytical principle and procedure involved in the assay of following methods 12 Hrs with special emphasize on official drugs in IP:**
 - a) Complexometric titration b) Non aqueous titration c) Redox titration
 - d) Diazotization titration e) UV – Visible method f) HPLC g) Potentiometric titrations h) pKa and log p determination
2. **Analytical principle, procedure and applications of the following reagents: 12 Hrs**
 - a) Ninhydrin b) 3-Methyl-2- benzthiazolinone hydrazone [MBTH] c) Folin – Ciocaltau [FC] d) Para-dimethyl-amino benzaldehyde [PDAB] e) Para-dimethyl- amino cinnamaldehyde [PDAC] f) 2, 6- Dichloroquinone chlorimide
 - g) 1,2- napthaquinone-4-sulfonate h) 2,3,5-Triphenyltetrazolium i) 2,4-Dinitro Phenyl hydrazine [DNPH] j) Bratton – Marshall reagent k) 3,5- Dinitro salicylic acid [DNSA]
3. **Principles and procedure involved in quantitative estimation of following 12 Hrs functional groups in drugs and elements:**
 - a) Hydroxyl b) Amine c) Carboxyl d) Carbonyl f) Ester g) Methoxyl



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a) Sodium b) Potassium c) Calcium d) Halogens e) Phosphorus e) Sulphur

4. Biological tests and assays of the following: 12 Hrs

a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin
f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom.
PCR, PCR studies for gene regulation, instrumentation (Principles and procedures).

5. Impurities and stability studies 12 Hrs

Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines

Impurities In New Drug Products

Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products

Impurities in residual solvents

General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, Reporting levels of residual solvents

Elemental Impurities

Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N, S analysis.

Method development, Stability studies and concepts of validation

Accelerated stability testing & shelf life calculation, WHO and ICH stability testing guideline, Stability zones, Photostability testing guidelines, ICH stability guidelines for biological products

REFERENCES

1. Vogel's textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.
3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982.
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley - Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.



6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2006, 2010.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.



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PHARMACEUTICAL VALIDATION (MPA103T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

Upon completion of the subject student shall be able to

- Explain the aspect of validation
- Carryout validation of manufacturing processes
- Apply the knowledge of validation to instruments and equipments
- Validate the manufacturing facilities

THEORY

60 HOURS

1. **Introduction** -Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Qualification: User Requirement Specification, Design Qualification, Factory Acceptance Test (FAT)/ Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification, Re- Qualification (Maintaining status- Calibration Preventive Maintenance, Change management), Qualification of Manufacturing Equipments, Qualification of Analytical Instruments and Laboratory equipments.

12 Hrs

2. **Qualification of analytical instruments:** Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC, Disintegration and Dissolution

Qualification of Glassware: Volumetric flask, pipette, beakers and burette

12 Hrs

3. Validation of Utility systems - Pharmaceutical Water System & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

12 Hrs

4. History of various phases of drug development and drug approval, IND, NDA (Phase I - IV), Content and Formal ANDA

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines

12 Hrs



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5. Regulatory scenario in India:

Regulatory aspects of pharmaceutical and bulk drug manufacture and drug analysis, loan license (contract manufacture) auditing, recent amendments to drugs and cosmetics act, provisions of consumer protection act, environment protection act. **12 Hrs**

REFERENCES

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up||, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.



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FOOD ANALYSIS (MPA104T)

Scope

This course is designed to impart knowledge on analysis of food constituents and finished food products. The course includes application of instrumental analysis in the determination of pesticides in variety of food products.

Objectives

At completion of this course student shall be able to understand various analytical techniques in the determination of

- Food constituents
- Food additives
- Finished food products
- Pesticides in food
- Student shall have the knowledge on food regulations and legislations.

THEORY

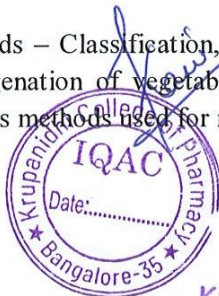
60Hrs

1. a. Carbohydrates – Chemistry & classification and properties of food carbohydrates, General methods of analysis of food carbohydrates, Changes in food carbohydrates during processing, Digestion, absorption and metabolism of carbohydrates, Dietary fibre, crude fibre and application of food carbohydrates

b. Proteins - Chemistry and classification of amino acids and proteins, Physico-Chemical properties of protein and their structure, general methods of analysis of proteins and amino acids, Digestion, absorption and metabolism of proteins

12Hrs

2. a. Lipids – Classification, general methods of analysis, refining of fats and oils; hydrogenation of vegetable oils, Determination of adulteration in fats and oils, Various methods used for measurement of spoilage of fats and fatty foods.



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b. Vitamins – classification of vitamins, methods of analysis of vitamins, Principles of microbial assay and physiological significance of vitamins of B-series.

12Hrs

3. a. Food additives – Introduction, analysis of Preservatives, antioxidants, artificial sweeteners, flavors, flavor enhancers, stabilizers, thickening and jelling agents
- b. Pigments and synthetic dyes - Natural pigments, their occurrence and characteristic properties, permitted synthetic dyes, Non-permitted synthetic dyes used by industries, Method of detection of natural, permitted and non-permitted dyes

12Hrs

4. a. General Analytical methods for milk, milk constituents and milk products like ice cream, milk powder, butter, margarine, cheese including adulterants and contaminants of milk.
- b. Analysis of fermentation products like wine, spirits, beer and vinegar.

12Hrs

5. a. Pesticide analysis - Effects of pest and insects on various food, use of pesticides in agriculture, pesticide cycle, organophosphorous and organo chlorine pesticides analysis, determination of pesticide residues in grain, fruits, vegetables, milk and milk products.
- b. Legislation regulations of food products with special emphasis on BIS, Agmark and US-FDA.

12Hrs

REFERENCES

1. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
2. Introduction to the Chemical analysis of foods – S. Nielsen, Jones & Bartlett publishers, Boston London, 1994.
3. Official methods of analysis of AOAC International, sixth edition, Volume I & II, 1997.
4. Analysis of Food Constituents – Multon, Wiley VCH.



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5. Dr. William Horwitz, Official methods of analysis of AOAC International, 18th edition, 2005.

PRACTICAL (MPL101P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Assay of official compounds by different titrations
8. Assay of official compounds by instrumental techniques.
9. Quantitative determination of hydroxyl group.
10. Quantitative determination of amino group
11. Colorimetric determination of drugs by using different reagents
12. Impurity profiling of drugs
13. Calibration of glasswares
14. Calibration of pH meter
15. Calibration of UV-Visible spectrophotometer
16. Calibration of FTIR spectrophotometer
17. Calibration of GC instrument
18. Calibration of HPLC instrument
19. Cleaning validation of one equipment



20. Determination of total reducing sugar
21. Determination of proteins
22. Determination of saponification value, Iodine value, Peroxide value, Acid value in food products
23. Determination of fat content and rancidity in food products
24. Analysis of natural and synthetic colors in food
25. Determination of preservatives in food
26. Determination of pesticide residue in food products
27. Analysis of vitamin content in food products
28. Determination of density and specific gravity of foods
29. Determination of food additives




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ADVANCED INSTRUMENTAL ANALYSIS (MPA201T)

Scope

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

Objectives

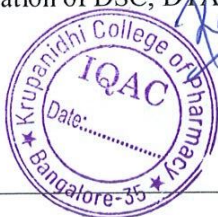
After completion of course student is able to know,

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compounds

Theory

60 Hrs

1. **UV and IR spectroscopy:** Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and α , β -carbonyl compounds and interpretation of enones. ATR-IR, IR Interpretation of organic compounds **12Hrs**
2. **NMR spectroscopy:** 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds **12 Hrs**
3. **Mass Spectroscopy:** Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, McLafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds **12 Hrs**
4. **Hyphenated analytical techniques :** Principle, Instrumentation and Applications of the following: **12 Hrs**
a) GC-MS b) LC-MS c) ICP-MS d) LC-NMR e) EC-MS f) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion-Exclusion Chromatography) k) Flash chromatography
5. **Thermal methods of analysis** – Introduction, principle, instrumentation and application of DSC, DTA and TGA. **12 Hrs**



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Radio Immuno Assay: Importance, various components, Principle, Different methods, Limitation & Applications of RIA.

Optical Rotatory Dispersion: Principle, Plain curves, Cotton effect, Circular Dichroism, Measurement of rotation angle in ORD and applications

References

8. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
9. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
10. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
11. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
12. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
13. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
14. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series



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MODERN BIO-ANALYTICAL TECHNIQUES (MPA202T)

Scope

This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objectives

Upon completion of the course, the student shall be able to understand

- Extraction of drugs from biological samples
- Separation of drugs from biological samples using different techniques
- Bioanalytical method validation
- Guidelines for BA/BE studies.
- GCP

THEORY

60 HOURS

1. Analysis of drugs in biological matrices:

Analysis of drugs in use and drugs in Research and Development

Biological matrix and Problems with analysis of biological matrices:

Properties of the biological media, small organic molecules, peptides and protein drugs, prodrugs, formulations, drug metabolites, other drugs, safety considerations.

2. Good Clinical Practice (GCP):

12 Hrs

Origin of GCP, Requirements of GCP compliance, Guidelines for GCP, guidelines of ICH, guidelines of ICMR, Ensuring GCP, Documentation of GCP practice, Audit of GCP compliance

3. USFDA & UDSCO Guidelines for BA/BE studies for orally administered drug products:

12 Hrs

Introduction, Design and conduct of studies, Facilities to conduct BA/BE studies, SPE sorbents, Retention of BA/BE samples, Maintenance of records of BA/BE studies




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4.Extraction of drugs and metabolites from biological matrices:

12 Hrs

General principle and procedure involved in the bio-analytical methods such as Protein precipitation, Liquid - Liquid extraction and Solid phase extraction and membrane filtration.

5.Separation techniques

12 Hrs

Bio molecules separation by HPLC, LC MS/MS and Gel electrophoresis

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition. CRC Press, Newyork. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercey. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, Newyork, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jercey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH guidelines




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QUALITY CONTROL AND QUALITY ASSURANCE (MPA203T)

Scope

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives

At the completion of this subject it is expected that the student will be able to know the cGMP aspects in a pharmaceutical industry

- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments

THEORY

60 HOURS

1. Concept and evolution of Quality Control and Quality Assurance, 12 Hrs
Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.
Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation.
2. cGMP guidelines according to schedule M, USFDA (inclusive of CDER and 12 Hrs
CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA
covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines.
3. Analysis of raw materials, finished products, packaging materials, in process 12 Hrs
quality control (IPQC), Developing specification (ICH Q6 and Q3)
Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures



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and secondary packing materials.

4. **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. **12 Hrs**
5. **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. **12 Hrs**
- b. NABL certification & accreditation procedure c. Patent Regime and IPR

REFERENCES

1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines



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8. ISO 9000 and total quality management
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.



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COSMETIC ANALYSIS & EVALUATION (MPA204T)

Scope

This course is designed to impart knowledge on analysis of cosmetic raw materials and finished products. Performance analysis of cosmetic products is included for the better understanding of the equipments used in cosmetic industries for the purpose.

Objectives

At completion of this course student shall be able to understand Food constituents

- Determination of physical constants of cosmetic raw materials
- Cosmetic raw materials, additives and their analysis
- Analysis of finished cosmetic products
- Principles of performance evaluation of cosmetic products.

THEORY

60Hrs

1. Determination of acid value, ester value, Saponification value, iodine value, peroxide value, rancidity, moisture, ash, volatile matter, heavy metals, fineness of powders, density, viscosity of cosmetics raw materials and finished products

12 Hrs

2. Study on the quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

12 Hrs

3. Indian standard specifications laid down for sampling and testing of various cosmetics in finished forms such as baby care powders, skin care products, dental products, personal hygiene preparations, lips sticks, hair products and skin creams by the Bureau Indian Standards.

12 Hrs

4. Principles of equipment used to measure product performance of skin and hair care products - Sebumeter, corneometer, trans-epidermal water loss, Skin color, hair tensile properties, hair combing properties.

Performance evaluation of shampoos, antiperspirants, deodorants, sunscreens, foam baths and abrasiveness of dentifrices.

12 Hrs

5. Study of specialized additives- quality parameters and analysis of rheology modifiers, preservatives, emollients, hair conditioners and fragrances

12 Hrs



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References

1. Cosmetics – Formulation, Manufacturing and Quality Control, P.P. Sharma, 4th edition, Vandana Publications Pvt. Ltd., Delhi
2. Indian Standard specification, for raw materials, BIS, New Delhi.
3. Indian Standard specification for 28 finished cosmetics BIS, New Delhi
4. Harry's Cosmeticology
5. Wilkinson, Moore, seventh edition, George Godwin. Poucher's Perfumes, Cosmetics and Soaps
6. Hilda Butler, 10th Edition, Kluwer Academic Publishers. Handbook of Cosmetic Science and Technology, 3rd Edition,




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PRACTICAL (MPL205P):

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Interpretation of organic compounds by FT-IR
3. Interpretation of organic compounds by NMR
4. Interpretation of organic compounds by MS
5. Determination of purity by DSC in pharmaceuticals
6. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
7. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis.
8. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by HPLC techniques.
9. Isolation of analgesics from biological fluids (Blood serum and urine).
10. Protocol preparation and performance of analytical/Bioanalytical method validation.
11. Protocol preparation for the conduct of BA/BE studies according to guidelines.
12. In process and finished product quality control tests for tablets, capsules, parenterals and creams
13. Quality control tests for Primary and secondary packing materials
14. Assay of raw materials as per official monographs
15. Testing of related and foreign substances in drugs and raw materials
17. Preparation of Master Formula Record.
18. Preparation of Batch Manufacturing Record.
19. Quantitative analysis of rancidity in lipsticks and hair oil
20. Determination of aryl amine content and Developer in hair dye
21. Determination of foam height and SLS content of Shampoo.
22. Determination of total fatty matter in creams (Soap, skin and hair creams)
23. Determination of acid value and saponification value.
24. Determination of calcium thioglycolate in depilatories




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QUALITY MANAGEMENT SYSTEMS (MQA101T)

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. It also aids in understanding the quality evaluation in the pharmaceutical industries.

Objectives

At completion of this course it is expected that students will be able to understand-

- The importance of quality
- ISO management systems
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

THEORY

60 Hrs

1. **Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality

Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality

Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behavior, concept of internal and external customers. Case studies.

Cost of Quality: Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, Preventing cost of quality



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12 Hrs

2. **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

12 Hrs

3. **Six System Inspection model:** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labeling system. Concept of self inspection.
Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.

12 Hrs

4. **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products.

Study of ICH Q8, Quality by Design and Process development report

Quality risk management: Introduction, risk assessment, risk control, risk review, risk management tools, HACCP, risk ranking and filtering according to ICH Q9 guidelines

12 Hrs

5. **Statistical Process control (SPC):** Definition and Importance of SPC, Quality measurement in manufacturing, Statistical control charts - concepts and general aspects, Advantages of statistical control, Process capability, Estimating Inherent or potential capability from a control chart analysis, Measuring process control and quality improvement, Pursuit of decreased process variability.

8Hrs

6. **Regulatory Compliance through Quality Management and development of Quality Culture**



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Benchmarking: Definition of benchmarking, Reasons for benchmarking, Types of Benchmarking, Benchmarking process, Advantages of benchmarking, Limitations of benchmarking

4 Hrs

REFERENCES:

1. Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
2. Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
3. Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
4. Corporate Culture and the Quality Organization By James W. Fairfield-Sonn, Quorum Books, 2001
5. The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
6. The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
7. Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
8. Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications



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QUALITY CONTROL AND QUALITY ASSURANCE (MQA102T)

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objectives:

Upon completion of this course the student should be able to

- Understand the cGMP aspects in a pharmaceutical industry
- To appreciate the importance of documentation
- To understand the scope of quality certifications applicable to Pharmaceutical industries
- To understand the responsibilities of QA & QC departments.

THEORY

60 Hrs

1. **Introduction:** Concept and evolution and scopes of Quality Control and Quality Assurance,

Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines.

Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

12 Hrs

2. **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention(PIC), WHO and EMEA covering:** Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

12 Hrs



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3. **Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3),** purchase specifications and maintenance of stores for raw materials.

In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias).

10 Hrs

4. **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non regulated markets.

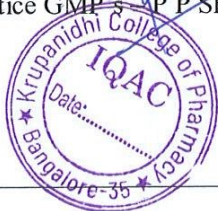
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5. **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope and importance of intellectual property rights. Concept of trade mark, copyright and patents.

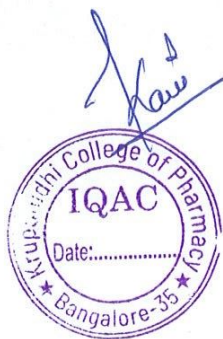
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REFERENCES

- 1 Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
- 2 Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
- 3 Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
- 4 How to Practice GMP, P P Sharma, Vandana Publications, Agra, 1991.



- 5 The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms, 3rd edition, WHO, Geneva, 2005.
- 6 Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
- 7 ICH guidelines
- 8 ISO 9000 and total quality management
- 9 The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
- 10 QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
- 11 Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
- 12 Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
- 13 Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.
- 14 Packaging of Pharmaceuticals.
- 15 Schedule M and Schedule N.



PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA103T)

Scope

This deal with technology transfer covers the activities associated with Drug Substance, Drug Product and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Objectives:

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
- To elucidate necessary information to transfer technology of existing products between various manufacturing places

THEORY

60 Hrs

1. **Principles of Drug discovery and development:** Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC), Post marketing surveillance, Product registration guidelines – CDSCO, USFDA.

12 Hrs

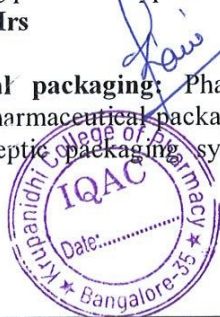
2. **Preformulation studies:** Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Preformulation protocol, Stability testing during product development.

12 Hrs

3. **Pilot plant scale up:** Concept, Significance, design, layout of pilot plant scale up study, operations, large scale manufacturing techniques (formula, equipment, process, stability and quality control) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products: opportunities and challenges.

12 Hrs

4. **Pharmaceutical packaging:** Pharmaceutical dosage form and their packaging requirements, Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing



modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials.

Quality control test: Containers, closures and secondary packing materials.

12 Hrs

5. **Technology transfer:** Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report, technology transfer plan and Exhibit.

12 Hrs

REFERENCES

1. The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3rd Edn, Lea & Febrieger, Philadelphia.
6. Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott;Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
9. The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1st Edition(Reprint 2006). Taylor and Francis. London and New York.



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QUALITY ASSURANCE PRACTICAL-I (MQA104P)

PRACTICALS

1. Analysis of pharmacopoeial compounds in bulk and in their formulations (tablet/capsules/ semisolids) by UV Vis spectrophotometer
2. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry or AAS
7. **Case studies on**
 - Total Quality Management
 - Six Sigma
 - Change Management/ Change control. Deviations,
 - Out of Specifications (OOS)
 - Out of Trend (OOT)
 - Corrective & Preventive Actions (CAPA)
 - Deviations
8. Development of Stability study protocol
9. Estimation of process capability
11. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
12. Assay of raw materials as per official monographs
13. Testing of related and foreign substances in drugs and raw materials
14. To carry out pre formulation study for tablets, parenterals (2 experiment).
15. To study the effect of pH on the solubility of drugs, (1 experiment)
16. Quality control tests for Primary and secondary packaging materials
17. Accelerated stability studies (1 experiment)
18. Improved solubility of drugs using surfactant systems (1 experiment)
19. Improved solubility of drugs using co-solvency method (1 experiment)
20. Determination of Pka and Log p of drugs.



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HAZARDS AND SAFETY MANAGEMENT (MPA201T)

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

THEORY

60Hrs

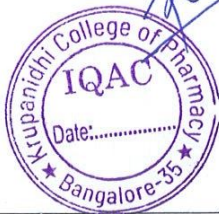
1. **Multidisciplinary nature of environmental studies:** Natural Resources, Renewable and non-renewable resources, Natural resources and associated problems, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources

Ecosystems: Concept of an ecosystem and Structure and function of an ecosystem.
Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

12 Hrs

2. **Air based hazards:** Sources, Types of Hazards, Air circulation maintenance industry for sterile area and non sterile area, Preliminary Hazard Analysis (PHA)
Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system.

12 Hrs



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3. **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards, Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, Management of over-Exposure to chemicals and TLV concept.

12 Hrs

4. **Fire and Explosion:** Introduction, Industrial processes and hazards potential, mechanical electrical, thermal and process hazards. Safety and hazards regulations, Fire protection system: Fire prevention, types of fire extinguishers and critical Hazard management system mechanical and chemical explosion, multiphase reactions, transport effects and global rates. Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, relief systems -relief valves, flares, scrubbers.

12 Hrs

5. **Hazard and risk management:** Self-protective measures against workplace hazards. Critical training for risk management, Process of hazard management, ICH guidelines on risk assessment and Risk management methods and Tools
Factory act and rules, fundamentals of accident prevention, elements of safety programme and safety management, Physicochemical measurements of effluents, BOD, COD, Determination of some contaminants, Effluent treatment procedure, Role of emergency services

12 Hrs

REFERENCES:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. "Quantitative Risk Assessment in Chemical Process Industries" American Institute of Chemical Industries, Centre for Chemical Process safety.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Hazardous Chemicals: Safety Management and Global Regulations, T.S.S. Dikshith, CRC press



PHARMACEUTICAL VALIDATION (MQA202T)

Scope

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objectives

At completion of this course, it is expected that students will be able to understand-

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments
- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

THEORY

60 Hrs

1. **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Streamlining of qualification & Validation process and Validation Master Plan.

Qualification: User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status- Calibration Preventive Maintenance, Change management).

12 Hrs

2. **Qualification of manufacturing equipment:** Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization/Tunnels, Autoclaves, Membrane filtration, Capsule filling machine.



Qualification of analytical instruments: UV-Visible spectrophotometer, FTIR, DSC, GC, HPLC, HPTLC, LC-MS.

12 Hrs

3. **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

12 Hrs

4. **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines (Q2) and USP.

12 Hrs

5. **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP).

Validation of facilities in sterile and non-sterile plant.

Computerized system validation: Electronic records and digital signature - 21 CFR Part 11 and GAMP 5.

12 Hrs

REFERENCES:

1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Michael Levin, Pharmaceutical Process Scale-Up", Drugs and Pharm. Sci. Series, Vol.

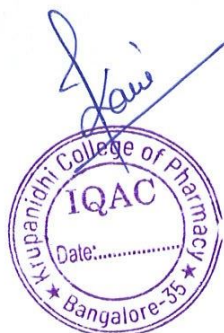


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157, 2nd Ed., Marcel Dekker Inc., N.Y.

6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press



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AUDITS AND REGULATORY COMPLIANCE (MPA203T)

Scope:

This course deals with the understanding and process for auditing in pharmaceutical industries. This subject covers the methodology involved in the auditing process of different in pharmaceutical industries.

Objectives:

Upon completion of this course the student should be able to

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

THEORY

60 Hrs

1. **Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies

12 Hrs

2. **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries.

1

2

Hrs

3. **Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.

1

2

Hrs

4. **Auditing of Microbiological laboratory:** Auditing the manufacturing process,



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Product and process information, General areas of interest in the building raw materials, Water, Packaging materials.

12 Hrs

5. **Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP.

12 Hrs

REFERENCES

1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).



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PHARMACEUTICAL MANUFACTURING TECHNOLOGY (MPA204T)

Scope

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing.

Objectives

At completion of this course it is expected that students will be able to understand-

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturing

THEORY

60Hrs

1. **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.

Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.

Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.



1

2H

rs

2. **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).

Advanced sterile product manufacturing technology : Area planning & environmental control, wall and floor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilities equipment location, engineering and maintenance.

Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).

Lyophilization technology: Principles, process, equipment.

12Hrs

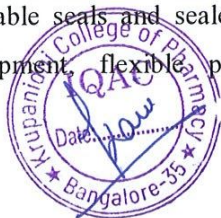
3. **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).

Advance non-sterile solid product manufacturing technology: Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered.

Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered.

12Hrs

4. **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit



worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material.

1

2H

rs

5. **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP, CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4th ed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopoeial Convention, Inc, USA,



2003.

9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1st Edition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

QUALITY ASSURANCE PRACTICAL-II(MQA204P)

PRACTICALS

1. Organic contaminants residue analysis by HPLC
2. Estimation of Metallic contaminants by Flame photometer
3. Identification of antibiotic residue by TLC
4. Estimation of Hydrogen Sulphide in Air.
5. Estimation of Chlorine in Work Environment.
6. Sampling and analysis of SO₂ using Colorimetric method
7. Qualification of following Pharma equipment
 - a. Autoclave
 - b. Hot air oven
 - c. Powder Mixer (Dry)
 - d. Tablet Compression Machine
8. Validation of an analytical method for a drug
9. Validation of a processing area
10. Qualification of at least two analytical instruments
11. Cleaning validation of one equipment
12. Qualification of Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Disintegration Tester)
13. Check list for Bulk Pharmaceutical Chemicals vendors
14. Check list for tableting production.
15. Check list for sterile production area
16. Check list for Water for injection.
17. Design of plant layout: Sterile and non-sterile
18. Case study on application of QbD
19. Case study on application of PAT



**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA
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Pharm D Revised Regulations 2008

(Effective from 2012-2013)

1. ELIGIBILITY

1.1 Qualifying Examination

i) Candidates who have passed two year P.U.C. examination of Karnataka P.U.C. Board or an equivalent examination of any other approved Board or University established by law in India with English as one of the subject and Physics, Chemistry as compulsory subjects along with one of the following subject – Mathematics or Biology or P.C.M.B. Minimum eligibility should be based on the aggregate of P.C.M. or P.C.B. The candidates shall have passed subjects of English, Physics, Chemistry and Biology / Mathematics individually also.

ii) Candidates who have passed D.Pharm course from institutions approved by Pharmacy Council of India U/S 12 of Pharmacy Act, 1948, are only eligible to be admitted to first year Pharm. D course.

1.2 Age

The candidate should have completed 17 years of age on or before 31st day of December of the year of admission to the course.

2. Duration of the course

Pharm.D: The duration of the course shall be six academic years (five years of study and one year of internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of six years duration is divided into two phases –

Phase I – consisting of First, Second, Third, Fourth and Fifth academic year.

Phase II – consisting of internship or residency training during sixth year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

Medium of Instruction and Examination Shall be English.



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PHARM.D. SYLLABUS

First Year

1.1 HUMAN ANATOMY & PHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and Objectives:** This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.
2. **Upon completion of the course the student shall be able to:**
 - a. describe the structure (gross and histology) and functions of various organs of the human body;
 - b. describe the various homeostatic mechanisms and their imbalances of various systems;
 - c. identify the various tissues and organs of the different systems of the human body;
 - d. perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
 - e. appreciate coordinated working pattern of different organs of each system; and
 - f. appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body
3. **Course materials:**

Text books

 - a. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins college New York.
 - b. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburg.

Reference books

 - a. Guyton arthur, C. *Physiology of human body*. Publisher: Holtsaunders.
 - b. Chatterjee, C.C. *Human physiology*. Volume 1&11. Publisher: medical allied agency, Calcutta.
 - c. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H.
 - d. *Gray's anatomy*. Publisher: Churchill Livingstone, London.




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4. Lecture wise program : Topics

- 1 Scope of anatomy and physiology, basic terminologies used in this subject
(Description of the body as such planes and terminologies)
- 2 Structure of cell – its components and their functions.
- 3 Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
- 4
 - a) Osseous system - structure, composition and functions of the Skeleton. (done in practical classes - 6hrs)
 - b) Classification of joints, Types of movements of joints and disorders of joints
(Definitions only)
- 5 Haemopoetic System
 - a) Composition and functions of blood
 - b) Haemopoiesis and disorders of blood components (definition of disorder)
 - c) Blood groups
 - d) Clotting factors and mechanism
 - e) Platelets and disorders of coagulation
- 6 Lymph
 - a) Lymph and lymphatic system, composition, formation and circulation.
 - b) Spleen: structure and functions, Disorders
 - c) Disorders of lymphatic system (definition only)
- 7 Cardiovascular system
 - a) Anatomy and functions of heart
 - b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
 - c) Electrocardiogram (ECG)
 - d) Cardiac cycle and heart sounds
 - e) Blood pressure – its maintenance and regulation
 - f) Definition of the following disorders
Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina,
Myocardial infarction, Congestive heart failure, Cardiac arrhythmias
- 8 Respiratory system
 - a) Anatomy of respiratory organs and functions
 - b) Mechanism / physiology of respiration and regulation of respiration
 - c) Transport of respiratory gases
 - d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia,
Dyspnea, Oxygen therapy and resuscitation.
- 9 Digestive system
 - a) Anatomy and physiology of GIT
 - b) Anatomy and functions of accessory glands of GIT
 - c) Digestion and absorption
 - d) Disorders of GIT (definitions only)



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- 10 Nervous system
 - a) Definition and classification of nervous system
 - b) Anatomy, physiology and functional areas of cerebrum
 - c) Anatomy and physiology of cerebellum
 - d) Anatomy and physiology of mid brain
 - e) Thalamus, hypothalamus and Basal Ganglia
 - f) Spinal cord: Structure & reflexes – mono-poly-planter
 - g) Cranial nerves – names and functions
 - h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system
 - a) Anatomy and physiology of urinary system
 - b) Formation of urine
 - c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
 - d) Clearance tests and micturition
- 12 Endocrine system
 - a) Pituitary gland
 - b) Adrenal gland
 - c) Thyroid and Parathyroid glands
 - d) Pancreas and gonads
- 13 Reproductive system
 - a) Male and female reproductive system
 - b) Their hormones – Physiology of menstruation
 - c) Spermatogenesis & Oogenesis
 - d) Sex determination (genetic basis)
 - e) Pregnancy and maintenance and parturition
 - f) Contraceptive devices
- 14 Sense organs
 - a) Eye
 - b) Ear
 - c) Skin
 - d) Tongue & Nose
- 15 Skeletal muscles
 - a) Histology
 - b) Physiology of Muscle contraction
 - c) Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology
 - a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - c) Drugs and athletics




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1.1 HUMAN ANATOMY & PHYSIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:

Text books

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune
Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments:

1. Study of tissues of human body
 - (a) Epithelial tissue.
 - (b) Muscular tissue.
2. Study of tissues of human body
 - (a) Connective tissue.
 - (b) Nervous tissue.
3. Study of appliances used in hematological experiments.
4. Determination of W.B.C. count of blood.
5. Determination of R.B.C. count of blood.
6. Determination of differential count of blood.
7. Determination of
 - (a) Erythrocyte Sedimentation Rate.
 - (b) Hemoglobin content of Blood.
 - (c) Bleeding time & Clotting time.
8. Determination of
 - (a) Blood Pressure.
 - (b) Blood group.
9. Study of various systems with the help of charts, models & specimens
 - (a) Skeleton system part I-axial skeleton.
 - (b) Skeleton system part II- appendicular skeleton.
 - (c) Cardiovascular system.
 - (d) Respiratory system.




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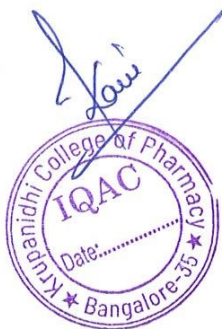
- (e) Digestive system. (f) Urinary system. (g) Nervous system. (h) Special senses.
(i) Reproductive system.

10. Study of different family planning appliances.
11. To perform pregnancy diagnosis test.
12. Study of appliances used in experimental physiology.
13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.
14. To record simple summation curve using gastrocnemius sciatic nerve preparation.
15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.
16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.
17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).




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1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. **Upon the completion of the course the student should be able to:**
 - a. know the formulation aspects of different dosage forms;
 - b. do different pharmaceutical calculation involved in formulation;
 - c. formulate different types of dosage forms; and
 - d. appreciate the importance of good formulation for effectiveness.

3. Course materials:

Text books

- a. Cooper and Gunns Dispensing for pharmacy students.
- b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Topics

1.
 - a. Introduction to dosage forms - classification and definitions
 - b. Prescription: definition, parts and handling
 - c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
2. Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.
3. Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
4. Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.
5. Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules.
6. Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.



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- 7 Biphasic dosage forms: Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- 8 Suppositories and pessaries: Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation.
- 9 Galenicals: Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.
- 10 Pharmaceutical calculations.
- 11 Surgical aids: Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- 12 Incompatibilities: Introduction, classification and methods to overcome the incompatibilities.

1.2 PHARMACEUTICS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

- 1. Syrups**
 - a. Simple Syrup I.P
 - b. Syrup of Ephedrine Hcl NF
 - c. Syrup Vasaka IP
 - d. Syrup of ferrous Phosphate IP
 - e. Orange Syrup
- 2. Elixir**
 - a. Piperizine citrate elixir BP
 - b. Cascara elixir BPC
 - c. Paracetamol elixir BPC
- 3. Linctus**
 - a. Simple Linctus BPC
 - b. Pediatric simple Linctus BPC
- 4. Solutions**
 - a. Solution of cresol with soap IP
 - b. Strong solution of ferric chloride BPC
 - c. Aqueous Iodine Solution IP
 - d. Strong solution of Iodine IP
 - e. Strong solution of ammonium acetate IP



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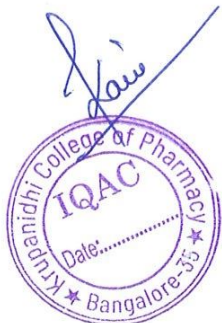
5. **Liniments**
 - a. Liniment of turpentine IP*
 - b. Liniment of camphor IP
6. **Suspensions***
 - a. Calamine lotion
 - b. Magnesium Hydroxide mixture BP
7. **Emulsions***
 - a. Cod liver oil emulsion
 - b. Liquid paraffin emulsion
8. **Powders** [□]
 - a. Eutectic powder
 - b. Explosive powder
 - c. Dusting powder
 - d. Insufflations
9. **Suppositories** [□]
 - a. Boric acid suppositories
 - b. Chloral suppositories
10. **Incompatibilities**
 - a. Mixtures with Physical
 - b. Chemical & Therapeutic incompatibilities

* colourless bottles required for dispensing [□] Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).




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1.3 MEDICINAL BIOCHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Scope of the Subject: Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases.

2. Objectives of the Subject (Know, do, appreciate) :

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. Upon completion of the subject student shall be able to –

- understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- know the metabolic process of biomolecules in health and illness (metabolic disorders);
- understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- do the qualitative analysis and determination of biomolecules in the body fluids.

Text books (Theory)

- Harpers review of biochemistry - Martin
- Text book of biochemistry – D.Satyanarayana
- Text book of clinical chemistry- Alex kaplan & Laverne L.Szabo

Reference books (Theory)

- Principles of biochemistry -- Lehninger
- Text book of biochemistry -- Ramarao
- Practical Biochemistry-David T.Plummer.
- Practical Biochemistry-Pattabhiraman.

3. Lecture wise programme:

Topics

- 1 Introduction to biochemistry:** Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.
- 2 Enzymes:** Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.
- 3 Carbohydrate metabolism.** Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose, tolerance test and their significance; hormonal regulation of carbohydrate metabolism.



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- 4 **Lipid metabolism:** Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).
- 5 **Biological oxidation:** Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;
- 6 **Protein and amino acid metabolism:** protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.
- 7 **Nucleic acid metabolism:** Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.
- 8 **Introduction to clinical chemistry: Cell;** composition; malfunction; Roll of the clinical chemistry laboratory.
- 9 **The kidney function tests:** Role of kidney; Laboratory tests for normal function includes-
 - a) Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
 - b) Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
 - c) Urine concentration test
 - d) Urinary tract calculi. (stones)
- 10 **Liver function tests:** Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.
 - a) Test for hepatic dysfunction-Bile pigments metabolism.
 - b) Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
 - c) Dye tests of excretory function.
 - d) Tests based upon abnormalities of serum proteins.
 Selected enzyme tests.
- 11 **Lipid profile tests:** Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.
- 12 **Immunochemical techniques** for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.
Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)
- 13 **Electrolytes:** Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.



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1.3 MEDICINAL BIOCHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Qualitative analysis of normal constituents of urine.*
- 2 Qualitative analysis of abnormal constituents of urine.*
- 3 Quantitative estimation of urine sugar by Benedict's reagent method.**
- 4 Quantitative estimation of urine chlorides by Volhard's method.**
- 5 Quantitative estimation of urine creatinine by Jaffe's method.**
- 6 Quantitative estimation of urine calcium by precipitation method.**
- 7 Quantitative estimation of serum cholesterol by Libermann Burchard's method.**
- 8 Preparation of Folin Wu filtrate from blood.*
- 9 Quantitative estimation of blood creatinine.**
- 10 Quantitative estimation of blood sugar Folin-Wu tube method.**
- 11 Estimation of SGOT in serum.**
- 12 Estimation of SGPT in serum.**
- 13 Estimation of Urea in Serum.**
- 14 Estimation of Proteins in Serum.**
- 15 Determination of serum bilirubin**
- 16 Determination of Glucose by means of Glucoseoxidase.**
- 17 Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
- 18 Study of factors affecting Enzyme activity. (pH & Temp.)**
- 19 Preparation of standard buffer solutions and its pH measurements (any two)*
- 20 Experiment on lipid profile tests**
- 21 Determination of sodium, calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments:

Format of the assignment

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a very good knowledge about
 - a. IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
 - b. Some important physical properties of organic compounds;
 - c. Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
 - d. Some named organic reactions with mechanisms; and
 - e. Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

2. Course materials:

Text books

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry

Reference books

- a. Organic chemistry – J.M.Cram and D.J.Cram
- b. Organic chemistry- Brown
- c. Advanced organic chemistry- Jerry March, Wiley
- d. Organic chemistry- Cram and Hammered, Pine Hendrickson

3. Lecture wise programme :

Topics

- 1 Structures and Physical properties:
 - a. Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
 - b. Acids and bases, Lowry bronsted and Lewis theories
 - c. Isomerism
- 2 Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.
- 3 Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability
- 4 Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.
- 5 Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN_2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN_1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN_1 reaction, Ion dipole bonds, SN_2 versus SN_1 solvolyses, nucleophilic assistance by the solvents.




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- 6 Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.
- 7 Electrophillic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophillic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals additon, mechanism of peroxide initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.
- 8 Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparision of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.
- 9 Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allyl cation as a resonance hybrid, nucleophyllic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allyl cation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic cation, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.
- 10 Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, friedel craft alkylation, friedel craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogination of alkyl benzene, resonance stabilization of benzyl radical.
- 11 Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of caboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.



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- 12 Mechanism of aldol condensation, claisen condensation, cannizzaro reaction, crossed aldol condensation, crossed cannizzaro reaction, benzoin condensation, perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.
- 13 Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer tieman's reactions.
- 14 Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.
- 15 Oxidation reduction reaction.
- 16 Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde, Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzyl benzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

1.4 PHARMACEUTICAL ORGANIC CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Acetanilide / aspirin (Acetylation)
2. Benzanilide / Phenyl benzoate (Benzoylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. 9, 10 – Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenone oxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

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II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives
Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones,
Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (THEORY)

**Theory : 2 Hrs.
/Week**

1. **Scope and objectives:** This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.
2. **Upon completion of the course student shall be able to:**
 - a. understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
 - b. know the analysis of the inorganic pharmaceuticals their applications; and
 - c. appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

3. Course

materials:

Text books

- a. A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- b. A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- c. Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao

Reference books

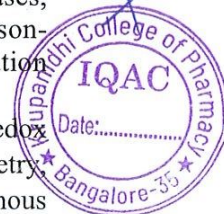
- a. Inorganic Pharmaceutical Chemistry by Anand & Chetwal
- b. Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- c. Analytical chemistry principles by John H. Kennedy
- d. I.P.1985 and 1996, Govt. of India, Ministry of health

4. Lecture wise

programme: Topics

- 1 Errors: Errors in quantitative analysis, classification of errors, concept of accuracy and precision, treatment of analytical
- 2 Volumetric analysis: Principle of volumetric analysis, different methods of analysis, different methods of expressing concentrations of solutions, Primary and secondary standards.
- 3 Acid-base titrations: Acid-base concepts, relative strength of acids and bases, law of mass action, common ion effect, ionic product of water, Henderson-Hasselbalch equation, buffer solutions, theory of indicators, neutralization curves, choice of indicators, mixed and universal indicators.
- 4 Redox titrations: Concepts of oxidation and reduction reactions. Redox reactions, theory of redox titrations, redox indicators, iodometry, iodimetry, titrations involving ceric sulphate, potassium iodate, potassium bromate, titanous chloride, Potassium permanganate.
- 5 Non aqueous titrations: Theoretical basis, types of solvents, preparations and standardization of titrant solutions, titration of weak acid, weak bases and indicators. Standardization of perchloric acid, lithium and sodium methoxide, tetra butyl ammonium hydroxide.

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- 6 Precipitation titrations: Introduction, types of precipitation titrations, end point detection.
- 7 Complexometric titrations: Introduction, principle, types of titrations, end point detection.
- 8 Theory of indicators
- 9 Gravimetry: Basic concepts, precipitation techniques, co-precipitations, post precipitation, various steps involved in gravimetric analysis, pharmaceutical applications.
- 10 Limit tests: Definition, importance, general procedure for limit test for chlorides, sulphates, iron, arsenic, lead and heavy metals.
- 11 Medicinal gases: Preparation and uses of the following oxygen, carbon dioxide, Helium, Nitrogen and Nitrous oxide.
Method of preparation, assay, storage conditions and uses of Inorganic compounds listed in IP belonging to the following categories.
- 12 Acidifiers: Dilute HCl, Sodium Phosphate, Ammonium chloride.
- 13 Antacids: Classification, qualities of an ideal antacid, side effects, advantages, combination therapy, acid neutralizing capacity, sodium bicarbonate, Potassium citrate, Aluminium hydroxide gel, Dried Aluminium hydroxide gel, magnesium hydroxide, Light and Heavy magnesium trisilicate, Light and Heavy magnesium carbonate, Calcium carbonate, Magaldrate and Bismuth carbonate.
- 14 Cathartics: Magnesium hydroxide, Magnesium sulphate, Magnesium carbonate, Sodium phosphate.
- 15 Electrolyte replenishers: Electrolytes used for replacement therapy: sodium chloride, potassium chloride, calcium chloride, calcium gluconate.
Electrolytes used in acid-base therapy: Sodium acetate, potassium acetate, sodium bicarbonate, potassium bicarbonate, sodium citrate, sodium lactate, ammonium chloride, Electrolyte combination therapy, compound sodium chloride solution, sodium chloride injection and oral rehydration salt.
- 16 Essential Trace elements: Definition, physiological role of Iron, Copper, Zinc, Chromium, Manganese, Molybdenum, Selenium, Sulphur and Iodine.
- 17 Antimicrobials: Hydrogen peroxide, Potassium permanganate, Chlorinated Lime, Iodine, Boric acid, Silver nitrate, Selenium Sulphide.
- 18 Pharmaceutical Aids: Sodium bisulphate, sodium metabisulphite, bentonite, magnesium stearate, zinc stearate, aluminium sulphate, sodium carboxy methylcellulose, purified water, water for injection and sterile water for injection.
- 19 Dental Products:
Anti-caries agents: Role of Fluorides as anti-caries agents, Sodium Fluoride.
Dentifrices: Calcium carbonate, dibasic calcium phosphate, Zinc chloride.
- 20 Miscellaneous compounds
Sclerosing agents: Hypertonic saline, Sodium tetradecyl sulphate.
Expectorants: Potassium citrate and Potassium iodide.
Sedative: Potassium bromide.
Antidotes: Sodium nitrite, Sodium thiosulphate and Charcoal.
Respiratory stimulant: Ammonium carbonate.
- 21 Radio Pharmaceuticals: Introduction, measurement of radioactivity, clinical applications and dosage, hazards and precautions.



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1.5 PHARMACEUTICAL INORGANIC CHEMISTRY (PRACTICAL)**Practical : 3 Hrs./Week****1. Limit test (6 exercises)**

- a. Limit test for chlorides
- b. Limit test for sulphates
- c. Limit test for iron
- d. Limit test for heavy metals
- e. Limit test for arsenic
- f. Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- a. Ammonium chloride- Acid-base titration
- b. Ferrous sulphate- Cerimetry
- c. Copper sulphate- Iodometry
- d. Calcium gluconate- Complexometry
- e. Hydrogen peroxide – Permanganometry
- f. Sodium benzoate – Nonaqueous titration
- g. Sodium chloride – Modified volhard's method
- h. Assay of KI – KIO_3 titration
- i. Gravimetric estimation of barium as barium sulphate
- j. Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a. Sodium hydroxide and sodium carbonate
- b. Boric acid and Borax
- c. Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a. Sodium bicarbonate
- b. Barium sulphate
- c. Ferrous sulphate
- d. Potassium chloride


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5. Test for purity (Any two exercises)

- Swelling power in Bentonite
- Acid neutralising capacity in aluminium hydroxide gel
- Ammonium salts in potash alum
- Adsorption power heavy Kaolin
- Presence of Iodates in KI

6. Preparations (Any two exercises)

- Boric acids
- Potash alum
- Calcium lactate
- Magnesium sulphate

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment 1 & 2	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).


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1.6 REMEDIAL MATHEMATICS/BIOLOGY (THEORY)

Theory : 3 Hrs. /Week

REMEDIAL MATHEMATICS :

1. **Scope and objectives:** This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.
2. **Upon completion of the course the student shall be able to : –**
 - a. Know Trigonometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
 - b. solve the problems of different types by applying theory; and
 - c. appreciate the important applications of mathematics in pharmacy.
3. **Course materials:**

Text books

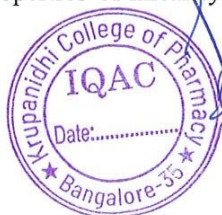
 - a. Differential calculus By Shantinakaran
 - b. Text book of Mathematics for second year pre-university by Prof.B.M.Sreenivas

Reference books

 - a. Integral calculus By Shanthinarayan
 - b. Engineering mathematics By B.S.Grewal
 - c. Trigonometry Part-I By S.L.Loney
4. **Lecture wise programme :**

Topics

- 1 **Algebra :** Determinants, Matrices
- 2 **Trigonometry :** Sides and angles of a triangle, solution of triangles
- 3 **Analytical Geometry :** Points, Straight line, circle, parabola
- 4 **Differential calculus:** Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables
- 5 **Integral Calculus:** Definite integrals, integration by substitution and by parts, Properties of definite integrals.
- 6 **Differential equations:** Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.
- 7 **Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.



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BIOLOGY :

1. **Scope and objectives:** This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

2. **Course materials:**

Text books

- a. Text book of Biology by S.B.Gokhale
- b. A Text book of Biology by Dr.Thulajappa and Dr. Seetaram.

Reference books

- a. A Text book of Biology by B.V.Sreenivasa Naidu
- b. A Text book of Biology by Naidu and Murthy
- c. Botany for Degree students By A.C.Dutta.
- d. Outlines of Zoology by M.Ekambaranatha ayyer and T.N.Ananthakrishnan.
- e. A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

3. **Lecture wise programme :**

Topic

PART – A

- 01 Introduction
- 02 General organization of plants and its inclusions
- 03 Plant tissues
- 04 Plant kingdom and its classification
- 05 Morphology of plants
- 06 Root, Stem, Leaf and Its modifications
- 07 Inflorescence and Pollination of flowers
- 08 Morphology of fruits and seeds
- 09 Plant physiology
- 10 Taxonomy of Leguminosae, umbelliferae, Solanaceae, Lilliaceae, Zinziberaceae, Rubiaceae
- 11 Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

- 01 Study of Animal cell
- 02 Study animal tissues
- 03 Detailed study of frog
- 04 Study of Pisces, Raptiles, Aves
- 05 General organization of mammals
- 06 Study of poisonous animals



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1.6 BIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title:

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination :

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.



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Second year

2.1 PATHOPHYSIOLOGY (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic Pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge of its application in other subject of pharmacy.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to –
 - a. describe the etiology and pathogenesis of the selected disease states;
 - b. name the signs and symptoms of the diseases; and
 - c. mention the complications of the diseases.

Text books (Theory)

- a. Pathologic basis of disease by- Cotran, Kumar, Robbins
- b. Text book of Pathology- Harsh Mohan
- c. Text book of Pathology- Y.M. Bhide

Reference books (Theory)

- a. Clinical Pharmacy and Therapeutics; Second edition; Roger Walker; Churchill Livingstone publication

3. Detailed syllabus and lecture wise schedule :

Chapter

- 1 **Basic principles of cell injury and Adaptation**
 - a) Causes, Pathogenesis and morphology of cell injury
 - b) Abnormalities in lipoproteinaemia, glycogen infiltration and glycogen infiltration and glycogen infiltration and glycogen storage diseases
- 2 **Inflammation**
 - a) Pathogenesis of acute inflammation, Chemical mediators in inflammation, Types of chronic inflammation
 - b) Repairs of wounds in the skin, factors influencing healing of wounds
- 3 **Diseases of Immunity**
 - a) Introduction to Tand B cells
 - b) MHC proteins or transplantation antigens
 - c) Immune tolerance
 - Hypersensitivity
Hypersensitivity type I, II, III, IV, Biological significance, Allergy due to food, chemicals and drugs
 - Autoimmunity
Criteria for autoimmunity, Classifications of autoimmune diseases in man, mechanism of autoimmunity, Transplantation and immunologic tolerance, allograft rejections, transplantation antigens, mechanism of rejection of allograft.
 - Acquired immune deficiency syndrome (AIDS)



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- Amyloidosis

- 4 **Cancer:** differences between benign and malignant tumors, Histological diagnosis of malignancy, invasions and metastasis, patterns of spread, disturbances of growth of cells, classification of tumors, general biology of tumors, spread of malignant tumors, etiology and pathogenesis of cancer.
- 5 Types of shock, mechanisms, stages and management
- 6 Biological effects of radiation
- 7 Environmental and nutritional diseases
 - i) Air pollution and smoking- SO₂, NO, NO₂, and CO
 - ii) Protein calorie malnutrition, vitamins, obesity, pathogenesis of starvation.
- 8 Pathophysiology of common diseases
 - a. Parkinsonism
 - b. Schizophrenia
 - c. Depression and mania
 - d. Hypertension,
 - e. Stroke (ischaemic and hemorrhage)
 - f. Angina, CCF, Atherosclerosis, Myocardial infarction
 - g. Diabetes Mellitus
 - h. Peptic ulcer and inflammatory bowel diseases
 - i. Cirrhosis and Alcoholic liver diseases
 - j. Acute and chronic renal failure
 - k. Asthma and chronic obstructive airway diseases
- 9 Infectious diseases :
Sexually transmitted diseases (HIV, Syphilis, Gonorrhea), Urinary tract infections, Pneumonia, Typhoid, Tuberculosis, Leprosy, Malaria Dysentery (bacterial and amoebic), Hepatitis- infective hepatitis.

4. Assignments :

Title of the Experiment

- 1 Chemical Mediators of inflammation
- 2 Drug Hypersensitivity
- 3 Cigarette smoking & its ill effects
- 4 Biological Effects of Radiation
- 5 Etiology and hazards of obesity
- 6 Complications of diabetes
- 7 Diagnosis of cancer
- 8 Disorders of vitamins
- 9 Methods in Pathology-Laboratory values of clinical significance
- 10 Pathophysiology of Dengue Hemorrhagic Fever (DHF)

Format of the assignment

- 1 Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy.
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

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2.2 PHARMACEUTICAL MICROBIOLOGY (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** Microbiology has always been an essential component of pharmacy curriculum. This is because of the relevance of microbiology to pharmaceutical sciences and more specifically to pharmaceutical industry. Pharmaceutical biotechnology is the logical extension of pharmaceutical microbiology, which is expected to change the complete drug product scenario in the future.

This course deals with the various aspects of microorganisms, its classification, morphology, laboratory cultivation identification and maintenance. It also discusses with sterilization of pharmaceutical products, equipment, media etc. The course further discusses the immunological preparations, diseases its transmission, diagnosis, control and immunological tests.

2. Objectives of the Subject :

Upon completion of the subject student shall be able to –

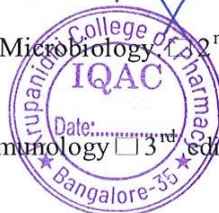
- know the anatomy, identification, growth factors and sterilization of microorganisms;
- know the mode of transmission of disease causing microorganism, symptoms of disease, and treatment aspect;
- do estimation of RNA and DNA and there by identifying the source;
- do cultivation and identification of the microorganisms in the laboratory;
- do identification of diseases by performing the diagnostic tests; and
- appreciate the behavior of motility and behavioral characteristics of microorganisms.

Text books (Theory)

- Vanitha Kale and Kishor Bhusari – Applied Microbiology ☐ Himalaya Publishing house Mumbai.
- Mary Louis Turgeon – Immunology and Serology in Laboratory Medicines ☐ 2nd edition, 1996 Mosby- Year book inc St. Louis Missouri 63146.
- Harsh Mohan, – Text book of Pathology ☐ 3rd edition, 1998, B-3 Ansari road Darya ganj N. Delhi.

Reference books (Theory)

- Prescot L.M., Jarley G.P Klein D.A –Microbiology ☐ 2nd- edition Mc Graw Hill Company Inc
- Rawlins E.A. ☐ Bentley's Text Book of Pharmaceutics ☐ B ailliere Tindals 24th edition London 1988
- Forbisher – Fundamentals of Microbiology ☐ Philadelphia W.B. Saunders.
- Prescott L.M. Jarley G.P., Klein.D.A. – Microbiology ☐ 2nd edition WMC Brown Publishers, Oxford. 1993
- War Roitt, Jonathan Brostoff, David male, – Immunology ☐ 3rd edition 1996, Mosby- year book Europe Ltd, London.
- Pharmacopoeia of India, Govt of India, 1996.



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3. Detailed syllabus and lecture wise schedule :

Title of the topic

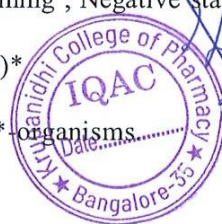
- 1 Introduction to the science of microbiology. Major divisions of microbial world and Relationship among them.
- 2 Different methods of classification of microbes and study of Bacteria, Fungi, virus, Rickettsiae, Spirochetes.
- 3 Nutritional requirements, growth and cultivation of bacteria and virus. Study of different important media required for the growth of aerobic and anaerobic bacteria & fungi. Differential media, enriched media and selective media, maintenance of lab cultures.
- 4 Different methods used in isolation and identification of bacteria with emphasis to different staining techniques and biochemical reactions. Counting of bacteria -Total and Viable counting techniques.
- 5 Detailed study of different methods of sterilization including their merits and demerits. Sterilization methods for all pharmaceutical products. Detailed study of sterility testing of different pharmaceutical preparations . Brief information on Validation.
- 6 Disinfectants- Study of disinfectants, antiseptics, fungicidal and virucidal agents factors affecting their activation and mechanism of action. Evaluation of bactericidal, bacteristatic, , virucidal activities, evaluation of preservatives in pharmaceutical preparations.
- 7 Immunology- Immunity, Definition, Classification, General principles of natural immunity, Phagocytosis, acquired immunity(active and passive) . Antigens, chemical nature of antigens structure and formation of Antibodies, Antigen-Antibody reactions. Bacterial exotoxins and endotoxins. Significance of toxoids in active immunity, Immunization programme, and importance of booster dose.
- 8 Diagnostic tests : Schick's Test, Elisa test, Western Blot test, Southern Blot PCR Widal, QBC, Mantoux Peripheral smear. Study of malarial parasite.
- 9 Microbial culture sensitivity Testing: Interpretation of results Principles and methods of different microbiological assays, microbiological assay of Penicillin, Streptomycin and vitamin B₂ and B₁₂. Standardisation of vaccines and sera.
- 10 Study of infectious diseases: Typhoid, Tuberculosis, Malaria, Cholera, Hepatitis, Meningitis, Syphilis & Gonorrhea and HIV.

2.2 PHARMACEUTICAL MICROBIOLOGY (PRACTICAL)

Practical : 3 Hrs./Week

Title of the Experiment:

- 1 Study of apparatus used in experimental microbiology*.
- 2 Sterilisation of glass ware's. Preparation of media and sterilisation*.
- 3 Staining techniques – Simple staining ; Gram's staining ; Negative staining**
- 4 Study of motility characters*.
- 5 Enumeration of micro-organisms (Total and Viable)*.
- 6 Study of the methods of isolation of pure culture.*
- 7 Bio chemical testing for the identification of micro* organisms.



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- 8 Cultural sensitivity testing for some micro-organisms.*
- 9 Sterility testing for powders and liquids.*
- 10 Determination of minimum inhibitory concentration.*
- 11 Microbiological assay of antibiotics by cup plate method.*
- 12 Microbiological assay of vitamins by Turbidometric method**
- 13 Determination of RWC.**
- 14 Diagnostic tests for some common diseases, Widal, malarial parasite.**

* Indicate minor experiment & ** indicate major experiment

Assignments:

- 1 Visit to some pathological laboratories & study the activities and equipment/instruments used and reporting the same.
2. Visit to milk dairies (Pasturization) and microbial laboratories (other sterilization methods) & study the activities and equipment/instruments used and reporting the same.
3. Library assignments
 - a. Report of recent microbial techniques developed in diagnosing some common diseases.
 - b. Latest advancement developed in identifying, cultivating & handling of microorganisms.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. It shall be computer draft copy.
3. Reference(s) shall be included at the end.
4. Name and signature of the student.
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (THEORY)

Theory : 3 Hrs. /Week

1. **Scope and objectives:** This subject has been introduced for the pharmacy course in order to make the student aware of medicinal uses of various naturally occurring drugs its history, sources, distribution, method of cultivation, active constituents, medicinal uses, identification tests, preservation methods, substitutes and adulterants.
2. **Upon completion of the course student shall be able to:**
 - a. under stand the basic principles of cultivation, collection and storage of crude drugs;
 - b. know the source, active constituents and uses of crude drugs; and
 - c. appreciate the applications of primary and secondary metabolites of the plant.

3. Course materials:

Text books

- a. Pharmacognosy by G.E. Trease & W.C.Evans.
- b. Pharmacognosy by C.K.Kokate,Gokhale & A.C.Purohit.

Reference books

- a. Pharmacognosy by Brady & Tyler.E.
- b. Pharmacognosy by T.E.Wallis.
- c. Pharmacognosy by C.S. Shah & Qadery.
- d. Pharmacognosy by M.A. Iyengar.

4. Lecture wise programme:

Topics

- 1 Introduction.
- 2 Definition, history and scope of Pharmacognosy.
- 3 Classification of crude drugs.
- 4 Cultivation, collection, processing and storage of crude drugs.
- 5 Detailed method of cultivation of crude drugs.
- 6 Study of cell wall constituents and cell inclusions.
- 7 Microscopical and powder Microscopical study of crude drugs.
- 8 Study of natural pesticides.
- 9 Detailed study of various cell constituents.
- 10 Carbohydrates and related products.
- 11 Detailed study carbohydrates containing drugs.(11 drugs)
- 12 Definition sources, method extraction, chemistry and method of analysis of lipids.
- 13 Detailed study of oils.
- 14 Definition, classification, chemistry and method of analysis of protein.
- 15 Study of plants fibers used in surgical dressings and related products.
- 16 Different methods of adulteration of crude drugs.



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2.3 PHARMACOGNOSY & PHYTOPHARMACEUTICALS (PRACTICAL)

Practical : 3 Hrs./Week

General Requirements: Laboratory Napkin, Observation Book 150 pages Zero brush, Needle, Blade, Match box.

List of experiments:

- 1 Introduction of Pharmacognosy laboratory and experiments.
- 2 Study of cell wall constituents and cell inclusions.
- 3 Macro, powder and microscopic study of Datura.
- 4 Macro, powder and microscopic study of Senna.
- 5 Macro, powder and microscopic study of Cassia.cinnamon.
- 6 Macro, powder and microscopic study of Cinchona.
- 7 Macro, powder and microscopic study of Ephedra.
- 8 Macro, powder and microscopic study of Quassia.
- 9 Macro, powder and microscopic study of Clove
- 10 Macro, powder and microscopic study of Fennel.
- 11 Macro, powder and microscopic study of Coriander.
- 12 Macro, powder and microscopic study of Isapgol.
- 13 Macro, powder and microscopic study of Nux vomica.
- 14 Macro, powder and microscopic study of Rauwolfia.
- 15 Macro, powder and microscopic study of Liquorice.
- 16 Macro, powder and microscopic study of Ginger.
- 17 Macro, powder and microscopic study of Podophyllum.
- 18 Determination of Iodine value.
- 19 Determination of Saponification value and unsaponifiable matter.
- 20 Determination of ester value.
- 21 Determination of Acid value.
- 22 Chemical tests for Acacia.
- 23 Chemical tests for Tragacanth.
- 24 Chemical tests for Agar.
- 25 Chemical tests for Starch.
- 26 Chemical tests for Lipids.(castor oil,sesame oil, shark liver oil,bees wax)
- 27 Chemical tests for Gelatin.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04Hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance.



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2.4 PHARMACOLOGY – I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, apart from general pharmacology, drugs acting on autonomic nervous system, cardiovascular system, central nervous system, blood and blood forming agents and renal system will be taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject :** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters;
 - b. handle and carry out the animal experiments;
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics; and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory) (Author, Title, Edition, Publication Place, Publisher, Year of Publication)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th Ed, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. & Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)(Author, Title, Edition, Publication Place, Publisher, Publication Year)

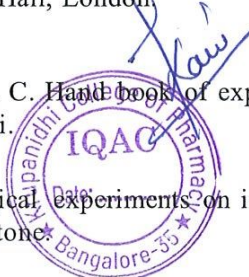
- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th Ed, 1996. Publisher Mc Graw Hill, Pergamon press.
- b. Craig, C.R.&Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown.Co
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, Int.
- d. Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher: Prentice Hall, London

Text books (Practical) :

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical)

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone



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- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule :

Title of the topic

1. General Pharmacology

- a) Introduction, definitions and scope of pharmacology
- b) Routes of administration of drugs
- c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
- d) Pharmacodynamics
- e) Factors modifying drug effects
- f) Drug toxicity - Acute, sub- acute and chronic toxicity.
- g) Pre-clinical evaluations
- h) Drug interactions

Note: The term Pharmacology used here refers to the classification, mechanism of action, pharmacokinetics, pharmacodynamics, adverse effects, contraindications, Therapeutic uses, interactions and dose and route of administration.

2. Pharmacology of drugs acting on ANS

- a) Adrenergic and antiadrenergic drugs
- b) Cholinergic and anticholinergic drugs
- c) Neuromuscular blockers
- d) Mydriatics and miotics
- e) Drugs used in myasthenia gravis
- f) Drugs used in Parkinsonism

3. Pharmacology of drugs acting on cardiovascular system

- a) Antihypertensives
- b) Anti-anginal drugs
- c) Anti-arrhythmic drugs
- d) Drugs used for therapy of Congestive Heart Failure
- e) Drugs used for hyperlipidaemias



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4. **Pharmacology of drugs acting on Central Nervous System**

- a) General anesthetics
- b) Sedatives and hypnotics
- c) Anticonvulsants
- d) Analgesic and anti-inflammatory agents
- e) *Psychotropic drugs*
- f) Alcohol and methyl alcohol
- g) CNS stimulants and cognition enhancers
- h) Pharmacology of local anaesthetics

5. **Pharmacology of Drugs acting on Respiratory tract**

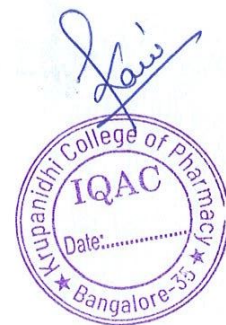
- a) Bronchodilators
- b) Mucolytics
- c) Expectorants
- d) Antitussives
- e) Nasal Decongestants

6. **Pharmacology of Hormones and Hormone antagonists**

- a) Thyroid and Antithyroid drugs
- b) Insulin, Insulin analogues and oral hypoglycemic agents
- c) Sex hormones and oral contraceptives
- d) Oxytocin and other stimulants and relaxants

7. **Pharmacology of autocooids and their antagonists**

- a) Histamines and Antihistaminics
- b) 5-Hydroxytryptamine and its antagonists
- c) Lipid derived autocooids and platelet activating factor




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2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

- | | |
|---|----|
| 1. Synopsis | 10 |
| 2. Major Experiment
(Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion) | 30 |
| 3. Minor Experiment (Ability to measure B.P / CBG / Lung function) | 15 |
| 4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management) | 15 |
| 5. Viva – Voce | 10 |


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4. Lecture wise programme :

Topics

- 1 **Definition, scope, of community pharmacy**
Roles and responsibilities of Community pharmacist
- 2 **Community Pharmacy Management**
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 3 **Prescriptions** – parts of prescription, legality & identification of medication related problems like drug interactions.
- 4 **Inventory control in community pharmacy**
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- 5 **Pharmaceutical care**
Definition and Principles of Pharmaceutical care.
- 6 **Patient counselling**
Definition, outcomes, various stages, barriers, Strategies to overcome barriers
Patient information leaflets- content, design, & layouts, advisory labels
- 7 **Patient medication adherence**
Definition, Factors affecting medication adherence, role of pharmacist in improving the adherence.
- 8 **Health screening services**
Definition, importance, methods for screening
Blood pressure/ blood sugar/ lung function
and Cholesterol testing
- 9 **OTC Medication- Definition, OTC medication list & Counselling**
- 10 **Health Education**
WHO Definition of health, and health promotion, care for children, pregnant & breast feeding women, and geriatric patients.
Commonly occurring Communicable Diseases, causative agents,
Clinical presentations and prevention of communicable diseases – Tuberculosis, Hepatitis, Typhoid, Amoebiasis, Malaria, Leprosy, Syphilis, Gonorrhea and AIDS
Balance diet, and treatment & prevention of deficiency disorders
Family planning – role of pharmacist
- 11 **Responding to symptoms of minor ailments**
Relevant pathophysiology, common drug therapy to,
Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia, Ophthalmic symptoms, worms infestations.
- 12 **Essential Drugs concept and Rational Drug Therapy**
Role of community pharmacist
- 13 **Code of ethics for community pharmacists**



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2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.



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3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias, Electrophysiology of heart and Arrhythmias
- 2 **Respiratory system :** Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 3 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 4 **Ophthalmology:** Glaucoma, Conjunctivitis- viral & bacterial
- 5 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.



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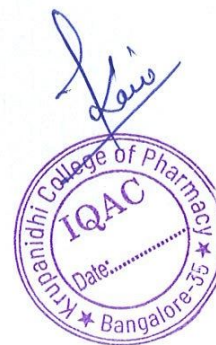
Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
2. **Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.


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Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:**Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
3. **Chemotherapy**
 - a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolones
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity



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6. **The dynamic cell: The structures and functions of the components of the cell**

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts. K. and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1995)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)



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3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

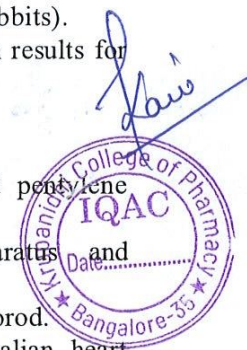
List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylene tetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotorod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. Quality Assurance:

- Introduction, sources of quality variation, control of quality variation.
- Concept of statistical quality control.
- Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- GLP, ISO 9000.
- Total quality management, quality review and documentation.
- ICH- international conference for harmonization-guidelines.
- Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- TLC:** Introduction, principle, techniques, R_f value and applications.
- PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- HPLC:** Introduction, theory, instrumentation, and applications.
- HPTLC:** Introduction, theory, instrumentation, and applications.
- Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- Gel filtration and affinity chromatography:** Introduction, technique, applications.



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3. Electrometric Methods:

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. Spectroscopy:

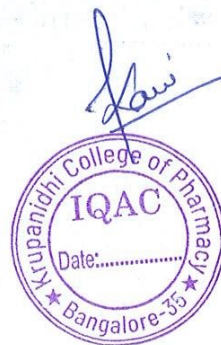
Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. Absorption Spectroscopy:

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation-IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors- Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.



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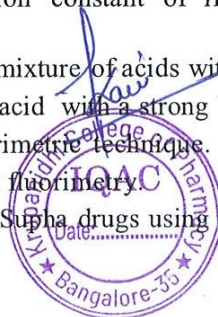
- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.

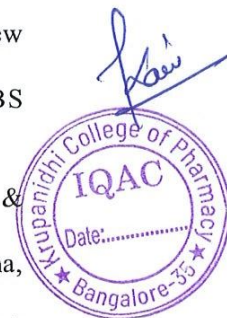


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11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.



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Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*
- 13 To study the effects of drugs on vas deferens of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection - Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
2. **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
3. **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders



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- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

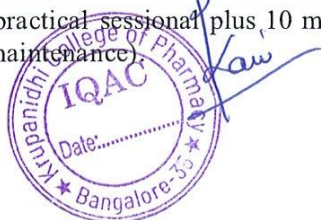
Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

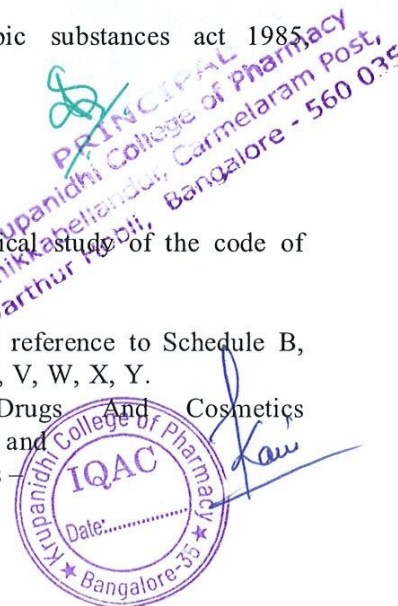
Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985 Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics
Provisions Relating to Indigenous Systems. Constitution and Functions of DTAB, DCC, CDL. Qualification and duties – Govt. analyst and Drugs Inspector.



4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

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3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids



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3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.


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3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular



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3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

1. **Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
2. **Formulation and filling of hard gelatin capsules**
3. **Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
4. **Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules
 - c. Injections
5. **Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
6. **Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
7. **Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
8. **Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance)

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Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.



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4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

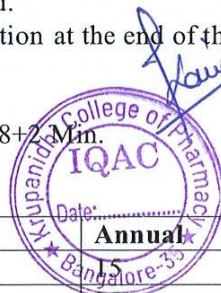
Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication Newsletter



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5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging**9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)**

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.



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Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).



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4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- monitor drug therapy of patient through medication chart review and clinical review;
- obtain medication history interview and counsel the patients;
- identify and resolve drug related problems;
- detect, assess and monitor adverse drug reaction;
- interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

- Definitions, development and scope of clinical pharmacy**
- Introduction to daily activities of a clinical pharmacist**
 - Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - Ward round participation
 - Adverse drug reaction management
 - Drug information and poisons information
 - Medication history
 - Patient counseling
 - Drug utilisation evaluation (DUE) and review (DUR)
 - Quality assurance of clinical pharmacy services



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3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)



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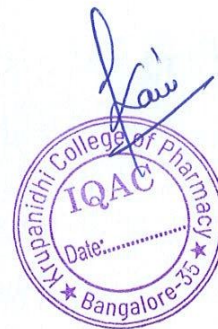
Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.




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4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation co-efficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.


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2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006


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4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability



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4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Mercel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott By ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebert F Notari Marcel Dekker Inn, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.



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4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Wilkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad



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Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.




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References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.


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5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. Pharmacoepidemiology :

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. Pharmacoeconomics:

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. Applications of Pharmacoeconomics

Software and case studies

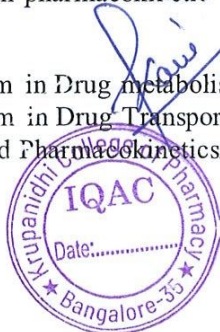


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5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

1. **Introduction to Clinical pharmacokinetics.**
2. **Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
3. **Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
4. **Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
5. **Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
6. **Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
7. **Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations



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**RAJIV GANDHI UNIVERSITY OF HEALTH SCIENCES, KARNATAKA
(RGUHS), BANGALORE – 560 041**

**Pharm D (Post Baccalaureate) Revised Regulations 2008
(Effective from 2012-2013)**

1. Eligibility

1.1 Qualifying Examination

For Pharm D Post (Baccalaureate), a pass in B Pharm degree examination of Rajiv Gandhi University of Health Sciences or B Pharm examination of any other recognized Indian University established by law in India or any other degree courses in Pharmacy recognized as equivalent by RGUHS and Pharmacy Council of India.

1.2 Eligible candidates are directly joining to fourth year Pharm D course as lateral entry.

2. Duration of the course

Pharm D. (Post Baccalaureate): The duration of the course shall be for three academic years (two years of study and one year internship or residency) full time with each academic year spread over a period of not less than two hundred working days. The period of three years duration is divided into two phases –

Phase I – consisting of First and Second academic year.

Phase II – consisting of Internship or residency training during third year involving posting in speciality units. It is a phase of training wherein a student is exposed to actual pharmacy practice or clinical pharmacy services, and acquires skill under supervision so that he or she may become capable of functioning independently.

3. Medium of Instruction

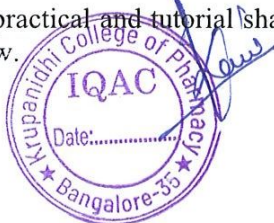
Medium of Instruction and Examination Shall be English.

4. Attendance and Progress

A candidate is required to put in at least 80% attendance in theory and practical subjects separately in a recognized institution approved by Pharmacy council of India and affiliated to Rajiv Gandhi University of Health Sciences, Karnataka. The candidate shall complete prescribed course satisfactorily to be eligible to appear for the respective examination.

5. Course of study

The course of study for Pharm.D.(Post Baccalaureate) shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.




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18. SYLLABUS FOR PHARM. D. Post-Baccalaureate

FIRST YEAR

1.1 PHARMACOTHERAPEUTICS – I & II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- 1 **Cardiovascular system:** Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias

- 2 **Respiratory system** : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
- 3 **Endocrine system** : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis
- 4 **General prescribing guidelines for**
 - a. Paediatric patients
 - b. Geriatric patients
 - c. Pregnancy and breast feeding
- 5 **Ophthalmology**: Glaucoma, Conjunctivitis- viral & bacterial
- 6 **Introduction to rational drug use**
Definition, Role of pharmacist Essential drug concept Rational drug formulations
- 7 **Infectious disease**: Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 8 **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 9 **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders
- 10 **Oncology**: Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
11. **Dermatology**: Psoriasis, Scabies, Eczema, Impetigo

1.1 PHARMACOTHERAPEUTICS – I & II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).




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1.2 HOSPITAL AND COMMUNITY PHARMACY (THEORY)

Theory: 3 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a) Hospital pharmacy by William .E. Hassan
- b) A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh
- c) Health Education and Community Pharmacy by N.S.Parmar.
- d) WHO consultative group report.
- e) Drug store & Business management by Mohammed Ali & Jyoti.

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- d. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

3. Lecture wise programme:

Topics

A. HOSPITAL PHARMACY

- 1 Hospital - its Organization and functions
- 2 Hospital pharmacy-Organization and management
 - a) Organizational structure-Staff, Infrastructure & work load statistic
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 Hospital drug policy
 - a) Pharmacy and Therapeutic Committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee




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- d) Developing therapeutic guidelines
- e) Hospital pharmacy communication - Newsletter
- 4 Hospital pharmacy services
 - a) Procurement & warehousing of drugs and Pharmaceuticals
 - b) Inventory control
 - Definition, various methods of Inventory Control
 - ABC, VED, EOQ, Lead time, safety stock
 - c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
 - d) Distribution of Narcotic and other controlled substances
 - e) Central sterile supply services – Role of pharmacist
- 5 Enteral and parenteral nutrition preparations
 - Total Parenteral Nutrition and I.V. admixtures
- 6 Continuing professional development programs
 - Education and training
- 7 Radio Pharmaceuticals – Handling and packaging
- 8 Professional Relations and practices of hospital pharmacist

B. COMMUNITY PHARMACY

- 1 Definition, scope, of community pharmacy
 - Roles and responsibilities of Community pharmacist
- 2 Community Pharmacy Management
 - a) Selection of site, Space layout, and design
 - b) Staff, Materials- coding, stocking
 - c) Legal requirements
 - d) Maintenance of various registers
 - e) Use of Computers: Business and health care soft wares
- 3 Responding to symptoms of minor ailments
 - Relevant pathophysiology, common drug therapy to,
 - Pain, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhea, constipation), Pyrexia,
 - Ophthalmic symptoms, worm's infestations.
- 4 Code of ethics for community pharmacists
- 5 Good Pharmacy Practice




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1.2 HOSPITAL AND COMMUNITY PHARMACY (PRACTICALS)

Practical : 3 Hrs./Week

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Inventory control
4. Prescription Analysis (Analyzing the prescriptions for probable drug interactions and ability to tell the management)

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 300 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
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Minor Experiment	03	15
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