1.2.1. Number of Programmes in which CBCS / Elective course system implemented

JNCET'S
GRY INSTITUTE OF PHARMACY
(Approved by AICTE & PCI; Affiliated to RGPV; Recognized by Govt. of M.P.)
Vidya Vihar, Borawan (Khargone) MP – 451 228
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Visit us at:gryip.com; principalgry@gmail.com

Ref no:..015.... Date: 12.05.2015

Meeting for CBCS system implementation

Venue: Conference Room **Time: 12:30 PM**

Meeting Agenda:

1. Implementation of CBCS system
2. lab preparation as per CBCS scheme
3. Books as per CBCS
4. Time table and credit system as per CBCS

Name	Designation composition	Signature
Dr. Sujit Pillai	Principal	
Mr. Rakesh Punasiya	Academic In charge	
Mr. Rampal Mandloi	Exam In charge	
Mr. Narendra Singh Badore	Admission I/c	
Mr. Vijay Salvekar	Member	
Mr. Nikhilesh Birla	Exam Supt.	
Mr. Nitin Deshmukh	Store/Practical In charge	
Mr. Deepak Rathore	Librarian	

1. Dr. Sujit Pillai started the meeting.
2. Academic in-charge Mr. Rakesh Punasiya given presentation on CBCS implementation by RGPV university as per the circular.
3. Academic in charge Mr. Rakesh Punasiya Instructed the librarian to prepare the list of books as per the CBCS syllabus.
4. Academic in charge Mr. Rakesh Punasiya instructed to exam Supt. and exam in charge to understand the credit system and inform the students regarding same.
5. The academic in charge was also instructed to store in charge for preparation of lab according to CBCS scheme.

Academic In charge

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Principal
Principal,
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RAJIV GANDHI PROUDYOGIKI VISHWAVIDYALAYA

(University of Technology of Madhya Pradesh)
Airport Road, Gandhi Nagar, Bhopal- 462033 (M.P.)

Tel No. 0755-2678866 Fax No. 0755-2742006

Ref. No.: F-5/Acad./ RGPV/2015/ 1810 Date: 06/05/15

To,
The Principals/Directors/Heads,
Affiliated Colleges / Institutions
Madhya Pradesh.

Subject:- Implementation of **Choice Based Credit System (CBCS)** for University UG and PG Courses.

It is our pleasure to inform you that Rajiv Gandhi Proudhyogiki Vishwavidyalaya, Bhopal is going to implement Choice Based Credit System for its all courses running at UG and PG levels.
The CBCS is designed as per the guidelines of UGC and aligned with the structure of top ranked institutions globally.

Initially the CBCS shall be implemented from III to VIII semester of BE. Outline of CBCS scheme is as follows:

i. Three compulsory Departmental subjects, designated as **Core Departmental Subjects**.
ii. One Departmental elective subject, which will be designated as **Departmental major Elective.**
iii. Open Elective Subject, designated as **Open Elective**. In this elective, the students will have choice to take one subject as **Major credit** or two subjects as **Minor credits.**
iv. One optional subject, designated as **Audit Subject**.

For sr. no. (ii) & (iii) the university seeks suggestions and feedback from teachers, students, & industry, i.e. suggestion for list of departmental elective subjects in each semester and list of open elective subjects, list of audit subjects, & total credits for each semester etc.

You are requested to mail us your suggestions in terms of separate lists of subjects those can be included as departmental elective and open elective for each semester (III-VIII) along with their rationales and course content to **cbcs@rgtu.net**, so that a broad discussion could be made in respective board of studies to finalize the guidelines for adaption.

Looking forward for your valuable suggestions.

Existing schemes and syllabi can be accessed at
https://www.rgpv.ac.in/UploadContent/frm_ViewScheme.aspx

Thanking you,

Principal,
Institute of Pharmacy,
BARWAN (Khargone) 451228

Registrar,
RGPV, Bhopal.

Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal(M.P.)

Scheme of Examination

Third Semester- Master of Pharmacy (Pharmaceutics)

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)			Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Tests (Two)	Assignments /Quiz	End Sem. Practical/Viva	Practical Record/ Assignment/Quiz /Presentation	
1	MPY 301 PCS -	Elective -I	4	-	-	4	70	20	10	-	-	100
2	MPY 302 PCS	Elective -II	4	-	-	4	70	20	10	-	-	100
3	MPY 303 PCS	Dissertation Part –I (Synopsis, Literature Review, Experimental Work, Seminar Presentation)	-	-	24	12	-	-	-	180	120	300
			8	-	24	20	140	40	20	180	120	500

L: Lecture - T: Tutorial - P: Practical

w.e.f. June-2012

Electives

A) MODULATED RELEASE ORAL DRUG DELIVERY SYSTEMS
B) PARENTERAL, INHALATION & INTRANASAL DRUG DELIVERYTECHNOLOGY
C) NANO DRUG DELIVERY SYSTEMS
D) BIOMATERIALS FOR DRUG DELIVERY

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- **Applicable from 2011-12 Batch**
- **Candidate can opt for any of the electives from the given list for MPY301 & MPY302 (Subjects for both electives should be different)**

Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal(M.P.)

Scheme of Examination

Third Semester- Master of Pharmacy (Pharmaceutical Chemistry)

S.No.	Subject Code	Subject Name	Periods per week			Credits	Maximum Marks (Theory Slot)			Maximum Marks (Practical Slot)		Total Marks
			L	T	P		End Sem. Exam.	Tests (Two)	Assignments /Quiz	End Sem. Practical/Viva	Practical Record/ Assignment/Quiz /Presentation	
1	MPY 301 PCH	Elective -I	4	-	-	4	70	20	10	-	-	100
2	MPY 302 PCH	Elective -II	4	-	-	4	70	20	10	-	-	100
3	MPY 303 PCH	Dissertation Part –I (Synopsis, Literature Review, Experimental Work, Seminar Presentation)	-	-	24	12	-	-	-	180	120	300
			8	-	24	20	140	40	20	180	120	500

L: Lecture - T: Tutorial - P: Practical

w.e.f. June-2012

Electives

A)DRUG DESIGN & DISCOVERY
B) IMPURITY PROFILING
C) SYNTHETIC ORGANIC CHEMISTRY
D) BIOANALYSIS

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Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal

Choice Based Credit System (CBCS)

Scheme of Examination w.e.f. September 07, 2015

Bachelor of Pharmacy (B.Pharm.)

SEMESTER: I SEMESTER

S. No.	Subject Code	Subject Name	Maximum Marks Allotted						Hours/Week			Total Credits	
			Theory			Practical							
			End Sem.	Mid Sem. Test	Quiz, Assignment	End Sem.	Lab work	Assignment /Quiz	L	T	P		
1	PY110	Biology	60	30	10	10	20	20	3	0	4	5	
2	PY111	Physical Pharmacy-I	60	30	10	10	20	20	3	0	4	5	
3	HU110	English	60	30	10	10	20	20	3	0	2	4	
4	PY112	Pharmaceutical Chemistry-I (Inorganic Chemistry)	60	30	10	10	20	20	3	0	4	5	
5	PY113	Introduction to Pharmacy	60	30	10	0	0	0	3	0	0	3	
6	ML110	Environmental Sciences	0	0	0	0	0	100	1	0	2	2*	
7	HU111	Communication	0	0	0	0	0	100	0	2	0	2*	Total Marks
			300	150	50	40	80	280	16	2	16	26	900

L: Lecture T: Tutorial P: Practical

Note: * For ML110 and HU111 there will be no examination and credits will be awarded only on the basis of internal assessment.

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HU110ENGLISH

HU110	ENGLISH	3-0-2

COURSE OBJECTIVE:

The objective of this foundational course is to develop the second language learners' ability to use the four fundamental language skills – listening, speaking, writing and reading. The objective of this laboratory is to practice English phonetics through audio & visual aids and computer software. It intends to enable student to speak English correctly with confidence.

COURSE CONTENT:

Unit I

Grammar – Applied Grammar and usage, Parts of Speech, Articles, Tenses, Subject-Verb Agreement, Prepositions, Active and Passive Voice, Reported Speech: Direct and Indirect, Sentence Structure, Punctuations.

Unit II

Vocabulary Development – Using Dictionaries and Thesaurus, Synonyms, Antonyms, Homophones, One Word Substitution, Affixation: Prefixes & Suffixes, Derivation from root words, Jargon, Scientific Jargon.

Unit III

Developing Reading Skills – Reading Comprehension, Process, Active & Passive Reading, Reading Speed Strategies, Benefits of effective reading, note-making, note- taking, Reading comprehension of technical material and SQ3R reading technique

Unit IV

Developing Writing Skills – Planning, Drafting & Editing, Writing with style, right-words selection, writing effective sentences, developing logical paragraphs, art of condensation, précis, essay, technical definition and technical description

Unit V

Business Correspondence – Business Letters, Parts & Layouts of Business Letters, Writing Resume/ Application Calling/ Sending Quotations/ Orders/ Complaints and E-mails

Topics for the Laboratory:

1. Basic Grammar & Vocabulary Practice (Synonyms, Antonyms, Analogies, Sentence Completion, Correctly Spelt Words, Idioms, Proverbs, Common Errors.
2. Phonetic Symbols, Pronunciations
3. Listening Skills – Including Listening Comprehension
4. Extempore and JAM (Just a Minute Session)
5. Role Play – I
6. Role play – II
7. Body Language
8. Debate
9. Oral Presentation – Preparation & Delivery using Audio – Visual Aids with stress on body language and voice modulations. (Topics to be selected by the Instructor)

COURSE OUTCOMES

Student after successful completion of course must possess sound language skills. They must also feel confident in communicating their ideas and feelings.After laboratory exercises, students must possess sound language skills. They must also feel confident in communicating their ideas to others.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment. Laboratory assessment will be based on assignments, presentations, and interview of each candidate.

REFERENCES

A.J. Thomson and A.V. Martinet, A Practical English Grammar, Oxford IBH Pub
Sanjay KumarmPushpLata, English for Effective Communication, Oxford

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HU111COMMUNICATION

HU111	COMMUNICATION	0-2-0

COURSE OBJECTIVE:

The objective of this course is to help students to acquire reading and writing skills in a self-learning mode.

COURSE CONTENT:

Exercises to be performed by students:

- Reading text selection from the list given below
- To write a book-review

COURSE OUTCOMES

Student after successful completion of course must possess sound comprehension skills. They must also feel confident in writing reviews and comments on the read material.

EVALUATION

Evaluation will be continuous an integral part of the class. Assessment will be based on assignments, presentations, and interview of each candidate.

REFERENCES

1. My Experiments with Truth by Mahatma Gandhi
2. Wings of Fire by Dr. APJ Abdul Kalam
3. History of Everything by Stephen Hawkings
4. A Passage to India by E.M. Forster
5. The Argumentative Indian by Amartya Sen
6. The Old Man and the Sea by Ernest Hemingway
7. Life of Pi by William Dalrymple
8. The Alchemist by Paulo Coehlo
9. The Eighth Habbit by Stephen Covey
10. The Road Less Travelled by M.Scott Peck

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ML110	ENVIRONMENTAL SCIENCES	2-0-0

COURSE OBJECTIVE:

This course introduces students to environment concerns. Students are expected to learn about environment, factors affecting it, environmental ethics and its protection through lectures, presentations, documentaries and field visits.

COURSE CONTENT:

Unit I

Introduction: Domestic and Global Environmental concerns, principles of sustainable development, Sustainable agriculture, organic farming, bio-fuels, Threats for sustainability

Unit II

Environmental Ethics & Legislations: Enforcement of Environment laws in India – The water act, The Air (Prevention and Control of Pollution) Act, 1981, The Environment (Protection) Act, 1986, Environmental Auditing

Unit III

Environmental Pollution: Air Pollution – sources, types of air pollutants, National Ambient Air Quality Standards,Controlling Air Pollution. Water pollution – sources, types of water pollutants, water quality indicators, water quality standards. Soil Pollution - types of soil pollutants: industrial wastes, pesticides, fertilizers and manures, salination of soil, Controlling Soil Pollution.

Unit IV

Environmental Challenges: Local Challenges - Solid Waste – Impact of solid waste on natural resources, Deforestation; Global Challenges - climate change and global warming, Kyoto Protocol, Greenhouse Gases, Ways to reduce Greenhouse gases emissions, Carbon Footprint, ways to reduce carbon footprint, Carbon Trading.

Unit V

Sustainable habitat, industrialisation and urbanization: Concept of Green Building, Volatile Organic Compounds (VOC), GRIHA Rating, LEED Rating, HVAC, Hybrid Car Technology, Industrial ecology, India's renewable energy capacity.*Green Technology & Green Business:* Green Business, Green Computing, E-waste management.

COURSE OUTCOMES

Student after successful completion of course must possess an understanding of environment, eco-system and its consequences of unbalancing the environment. After successful completion of this course, student will earn 2 credits.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment.

REFERENCES

R. Rajagopalan, Environmental Studies, Oxford IBH Pub, 2011.
Kogent Learning Solutions Inc., Energy, Environment, Ecology and Society, Dreamtech, 2012.
Rag, R. L, Ramesh, LekshmiDinachandran, Introduction to sustainable engineering

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PY110BIOLOGY

PY110	BIOLOGY	3-0-4

COURSE OBJECTIVE:

To provide students with a basic foundation in the fundamental concepts and knowledge base of modern biology and help students develop the skills that are integral to the process of various disciplines of pharmaceutical sciences. This course provides a coherent framework for understanding basics of botany and zoology and prepares students for their upper-level subjects like pharmacognosy, biotechnology, microbiology, and human anatomy and physiology.

COURSE CONTENT:

Theory:

Significance of basics of biology in pharmaceutical science. Cell (Plant and animal): its structure, living and non-living inclusions, cell cycle and cell division, stages of mitosis, meiosis and their significance.

Elementary tissues of the human body: epithelial, connective, muscular and nervous tissues. Different types of plant tissues and their functions.

Morphology and histology of plant parts: root, stem, bark, wood, leaf, flower, fruit and seed. Modifications of roots and stems.

Physiology of plants: photosynthesis, respiration and transpiration.

Plant Taxonomy: Classification of plant kingdom. Study of the following families with special reference to medicinally important plants: apocynaceae, solanaceae, umbelliferae, labiatae, leguminosae, and liliaceae.
Introduction to plant products of economic importance like plant drugs, dyes, fibers, spices, scents, beverages, resins.

Introduction to animal products of economic importance like animal biological products, honey, pearl, lac, silk, lather, etc.

Animal kingdom: Classification and its basis. Fundamentals of parasitology, general morphology and life history of internal parasites like plasmodium, taeniasolium(tapeworm). General structure and life history of insects like mosquito.

Basic study of the following systems of frog: Gastro Intestinal (Digestive enzymes), nervous, cardiovascular: genitourinary (glands and hormones), musculo-skeletal, respiratory systems.

Simple and compound microscopes used in biology. Origin and evolution of life: an outline.
Fundamental laws of inheritance: Mendel's law. Molecular basis of inheritance – DNA, RNA, replication, transcription, genetic code and translation.

Practical: **Experiments based on theory**

COURSE OUTCOMES

After completion of course, student should be able to:

- Understand the structures and functions of basic components of prokaryotic and eukaryotic cells.
- Understand the process of cell division in both somatic and germ cells.

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- Understand general terminology of plant structures, morphology, internal anatomical features and families.
- Understand the economical importance of products of animals and plants.
- Understand formation of RNA, DNA, proteins and process of inheritance.
- Understand the organ systems of frog and human parasites.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment.

REFERENCES:

1. *Dutta A.C., "Botany for Degree students", 20th edition, Oxford university press publisher, 2006.*
2. *Vidyarthi R.D., Pandey P. N., "A Text Book of Zoology", 1st edition, S Chand & Co. Pvt. Ltd. Publisher, 2006.*
3. *John E. Hall, Guyton & Hall: "Textbook of Medical Physiology", 13th edition, WB Saunders Company, 2015.*
4. *Bhatia K.N., "Truemans: Elementary Biology", Vol. II, 27th edition, Trueman book company-New Delhi, 2014.*
5. *Evans W. C., "Trease and Evans Pharmacognosy", 16th edition, Saunders Ltd, 2009.*
6. *NaliniChandar, Cell and Molecular Biology (Lippincott's Illustrated Reviews Series), Lippincott Williams & Wilkins publisher, 2012.*

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PY111	PHYSICAL PHARMACY-1	3-0-4

COURSE OBJECTIVE:

To develop an understanding of some basic principles of physical chemistry having applications in various pharmaceutical operations, drug properties and drug formulations.

COURSE CONTENT:

Theory:

States of Matter: Binding forces between molecules. Gaseous State: Ideal Gas law; kinetic molecular theory. Liquid state: Liquefaction of gases, vapor pressure of liquids, boilingpoint.Crystalline and amorphous solids and polymorphism, melting point and heat of fusion.Liquid crystalline state, supercritical fluid state.

Phase equilibria and phase rule: Two component systems, Eutectic mixtures; solid dispersions; phase equilibria in three component systems; rules relating to triangular diagram.

Thermodynamics: Basics of Thermodynamics. First, second and third laws of thermodynamics with special emphasis to their applications in pharmacy.

Nonelectrolytes: Types of solutions; Ideal and real solutions. Colligative properties: Lowering of the vapor pressure, elevation of the boiling point, depression of the freezing point; osmotic pressure. Molecular weight determination.

Solutions of electrolytes: Electrolysis, strong and weak electrolytes, colligative properties of electrolytic solutions and concentrated solutions of non-electrolytes. Arrhenius theory of electrolytic dissociation: Drugs and ionization; degree of Dissociation. Osmolality.

Ionic Equilibria: ionization of water; ampholytes. Sorensen's pH: Conversion of hydrogen ion concentration to pH, pK and pOH.

Buffered and isotonic solutions: Common Ion Effect and the buffer equation. Drugs as Buffers.Buffer capacity.Buffers in pharmaceutical system and biological system.Buffered isotonic solutions.

Solubility and distribution phenomena: General principles. Solvent-solute interactions: Solubility of gases in liquids, liquids in liquids and solids in liquids. The influence of solvents on the solubility of drugs; combined effect of pH and solvents; hydrotropic solubilization; influence of surfactants. Distribution of solutes between immiscible solvents.

Practical:

1. *Determine the Molecular weight of the given substance with Freezing Point Depression Method (Rast camphor method)*
2. *Perform the identification and characterization of polymorphs of the given drug* **or** *Studies on polymorphs, their identification and properties.*
3. *Construct the ternary phase diagram for three-component system (oil-water-surfactant/alcohol, water and benzene).*
4. *Determine the Critical solutjon temperature of phenol water system.*
5. *Prepare the pharmaceutical buffers and determine its buffer capacity.*
6. *Prepare acetate buffer and compare theoretical pH value with the experimental value.*
7. *Determine the ionization constant by conductivity method/ distribution method.*
8. *Perform experiments involving tonicity adjustments*
9. *Determine critical solution temperature of phenol water system.*

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10. *Determine the effect of addition of electrolyte on critical solution temperature of phenol- water system.*
11. *Determine partition coefficient of given compound between carbon tetrachloride/ benzene/ octanol and water system*
12. *Determination of distribution coefficient of given substance between two immiscible liquids . (benzoic acid /succinic acid between ether / benzene and distilled water).*
13. *Determine the heat of solution of Salicylic/benzoic/oxalic acid*
14. *Determine the saturation solubility of given drug in water.*
15. *Determine the solubility of given compound in different solvents.*
16. *Determination of effect of pH on solubility.*
17. *Determine the effect of co solvents on solubility of given drug in water*
18. *Determine the effect of temperature on solubility of solid in liquid.*
19. *Determine the solubility of given substance at different temperatures.*
20. *Determine the effect of salt on the solubility of given drug.*

COURSE OUTCOMES

Students achieve knowledge related to states of matter, thermodynamics, phase rules, electrolytes, solutions and chemical reaction.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment.

REFERENCES:

1. *Patrick J. Sinko, Martin's Physical Pharmacy and Pharmaceutical Sciences, Sixth Edition, 2011, Lippincott Williams & Wilkins.*
2. *Rawlins, E.A., Bentley's Text Book of Pharmaceutics, Eighth Edition, 2010, Elsevier/BSP Books Pvt. Ltd.*
3. *Joseph, K. H. Ma, Hadzija, B., Basic Physical Pharmacy, 2012, Jones &Bartlette.*
4. *P W Atkins, the Elements of Physical Chemistry, 2nd Ed., OUP, 1996*
5. *P W Atkins, Physical Chemistry 7th Ed., OUP, 2002*
6. *B G Cox, Modern Liquid Phase Kinetics, Oxford Science Publications, 1994.*
7. *J.R. Barrante: Physical Chemistry of Life Sciences, Printeil.*
8. *K.J. Laidler: Physical Chemistry with Biological Applications, Benjamin.*
9. *S.C. Wallwork: Physical Chemistry for Students of Pharmacy and Biology, Longman.*
10. *L. M. Atherden: Bentley and Driver's-Textbook of Pharmaceutical Chemistry, Oxford University Press, Delhi.*
11. *A.J. Mce: Physical Chemistry, E.L. B.S., London.*
12. *H.H.Willard, L.L. Merritt and J.A. Dean: Instrumental Methods of Analysis, Van Nostrand Reinhold, New York.*
13. *Samuel Glasstone and David Lewis: Elements of Physical Chemistry, Macmiilan Press, London.*
14. *A.H. Beckett and J.B. Staenlake: Practical Pharmaceutical Chemistry, Vol. I and II. The Athlone Press of the University of London.*
15. *Gross J.M. and Wiseall B. Principle of Physical Chemistry, Macdonald and Evans Plymouth, England.*
16. *Gareth Morris J. A Biologists Physical Chemistry, Edward Arnold, London.*
17. *Chang R. Physical Chemistry with Application to Biological System. Collier Macmilliar Publisher, London.*
18. *Barrow G.M. Physical Chemistry. McGraw-Hill, London.*

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PY112	PHARMACEUTICAL CHEMISTRY-1 (INORGANIC CHEMISTRY)	3-0-4

COURSE OBJECTIVE:

Pharmaceutical Chemistry-I provides the systematic study of a selection of elements of the periodic table; in addition, the students will become familiar with the most important general principles applied to the chemistry of transition elements. They will also be provided with a general understanding of Bioinorganic Chemistry, pharmaceutical inorganic chemistry and physiological inorganic chemistry.

COURSE CONTENT:

Theory:

Elements and periodicity: Modern periodic law and present form of the periodic table, s, p, d and f block elements, periodic trends in properties of elements- atomic and ionic radii, ionization enthalpy, electron gain enthalpy, valence, oxidation states and chemical reactivity.

Sources of impurities in pharmaceutical substances: Importance of limit test and general principles and procedure for limit tests of chloride, sulphate, iron, arsenic, lead and heavy metals.

Inorganic Agents: Occurrence, preparation, physical characteristics, chemical properties, purity test, incompatibilities, assay and pharmaceutical uses of inorganic official compounds (IP) of the following elements; Aluminum, Sodium, Potassium, Calcium, Magnesium, Lithium, Iron, Copper, Silver, Antimony, Iodine, Boran, Zinc, Mercury, Selenium.

Reagents: Preparation, properties and uses of the following reagents; Nesslers reagent, boron trifluoride, Grignard reagent, Potassium permanganate, potassium dichromate, Hydrogen peroxide, Iodine solution.

Bioinorganic Chemistry: The essential trace metals, Introduction to Inorganic Biochemistry. Metal ion transport and storage. Oxygen transport and storage. Biological redox processes. Zn(II): natural Lewis acid.

Major Intra and extra cellular electrolytes: Major physiological ions, electrolytes used in replacement therapy, physiological acids-base balance, electrolytes used in acid-base therapy, electrolyte combination therapy.

Radiopharmaceuticals: Basic properties, production, quality control, stability, clinical and medicinal applications of radioisotopes used in pharmacy and medicine preparations of diagnostic and therapeutic agents.

Practical:

1. Perform limit test for chloride insomepharmacopoeialcompounds.
2. Perform limit test for sulphate insomepharmacopoeialcompounds.
3. Perform limit test for lead insomepharmacopoeialcompounds.
4. Perform limit test for arsenic insomepharmacopoeialcompounds.
5. Perform limit test for heavy metals insomepharmacopoeialcompounds.
6. Perform limit test for iron insomepharmacopoeialcompounds.
7. Prepare and identification test of ferrous sulphate.
8. Prepare and identification test of ferric ammonium citrate.
9. Prepare and identification test of light and heavy magnesium oxide.
10. Prepare and identification test of magnesium carbonate.
11. Prepare and identification test of calcium carbonate.
12. Prepare and identification test of zinc sulphate.
13. Prepare and identification test of alum.
14. Prepare and identification test of Boric acid.
15. Prepare and identification test of Aluminium hydroxide gel.
16. Prepare and identification test of yellow mercuric oxide.
17. Prepare and identification test of magnesium triclicate.
18. Prepare and identification test of copper sulphate.
19. Prepare and identification test of sodium thiosulphate.

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20. Prepare and identification test of Disodium hydrogen citrate.
21. Prepare and identification test of magnesium sulphate.

COURSE OUTCOMES

- Know descriptive chemistry of some of the representative elements and their official compounds, with special emphasis on their reactions and its applications, mainly those of pharmaceutical interest.
- Preparation and application of important reagents for analysis of pharmaceutical compounds and identification of impurities present in formulations.
- Know the role of elements and compounds in the processes of life.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment.

REFERENCES:

1. *Bentley & Driver's Text Book of Pharmaceutical Chemistry Revised by L. M. Atherden, 8th edition, Oxford Medical Publications.*
2. *Pharmacopoeia of India, Govt. of India, Ministry of Health, Delhi.*
3. *J.H. Block, E. Roche, T.O. Soine and C. O. Wilson: Inorganic Medicinal and Pharmaceutical chemistry, Lee Febiger, Philadelphia. PA.*
4. *Roger's Inorganic Pharmaceutical Chemistry of Lea and Febiger, Philadelphia, USA.*
5. *M. Ali: Text book of Pharmaceutical Inorganic chemistry, CBS, New Delhi.*
6. *Mellor's Modern Inorganic Chemistry, Longman Green and Co., Ltd., London.*
7. *Beckett &Stenlake, Practical Pharmaceutical Chemistry*
8. *Liptrot G.F. Modern Inorganic Chemistry, Blantyre Printing*
9. *British Pharmacopoeia, Stationary Press, Royal Society of Pharmaceutical Press, London.*
10. *United State Pharmacopoeia, United State Pharmacopoeial Convention, Inc., 12601. Twinbrook Parkway, Rockyville M.D. 20852 USA.*
11. *Lovis F. Fiesev D.C. Experiments in Inorganic Chemistry, Health and Company, Boston.*
12. *Vogel Text Book of Quantitative Chemical Analysis, Longman, London.*
13. *Vogel's Text Book of Quantitative Analysis, 5th Ed.*
14. *Vogel's Quantitative Inorganic Analysis.*
15. *Wilson &Gisvold's Principles of Organic and Medicinal Chemistry.*
16. *Remington Practical of the Science and Pharmacy, Mack Publishing Company, Eston, Pennsylvania, USA.*

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PY113	INTRODUCTION TO PHARMACY	3-0-0

COURSE OBJECTIVE:

This course provides the students an overview of Pharmacy and its allied disciplines. The students will be introduced to the history and evolution of pharmacy education and its contribution to modern pharmacy profession. The course will also impart knowledge on major disciplines of pharmaceutical sciences and familiarize them to official/compendial literature of pharmacy, alternative systems of medicines and also the terminology employed in various pharmacy subjects. The Students are also expected to learn about scope, current and future trends of pharmacy profession, jobs, innovations & research opportunities in the field of Pharmacy. Course content will be covered through lectures, assignments, case-studies, presentations, documentaries and field visits.

COURSE CONTENT:

INTRODUCTION

General overview of pharmacy profession.Brief history of pharmacy education and pharmacy profession from ancient period to evolution of modern pharmacy practice, Introduction to various alternative systems of medicine.

PHARMACY EDUCATION

Introduction to major branches/disciplines of Pharmaceutical sciences: Pharmaceutics, Pharmaceutical Chemistry & Pharmaceutical Analysis, Pharmacology, Pharmacognosy, Pharmacy practice, Pharmaceutical Biotechnology, Cosmetic Technology, Pharmaceutical Management & other related subjects. Brief overview of all these disciplines and importance in pharmaceutical education and profession.

Literature & Terminologies

General understanding of compendial books and official Literatures of Pharmacy: Indian Pharmacopoeia, United States Pharmacopoeia, British Pharmacopoeia, British Pharmacopoeial Codex, European Pharmacopoeia, Ayurvedic Pharmacopoeia, Herbal Pharmacopoeia, National Formulary and other Formularies. Various reference textbooks like Remington's Pharmaceutical sciences, Encyclopedia, etc. and active websites.

Glossary and technical terminologies of Pharmacy. Latin terms used for drug prescription. Meaning of various symbols and terms of pharmaceutical & allied sciences.Definitions of common pharmacological drug categories.

SCOPE & OPPORTUNITIES

Pharmaceutical Industries (Manufacturing & Service)

Overview of Pharma Industries in India (Manufacturing & Service); Current status, contribution to GDP, export and growth potential, organizational structure, manpower requirement, and future prospects. Employment opportunities, Nature of Job, risks and challenges involved, new job avenues in emerging & interdisciplinary areas of pharma manufacturing.

Health Sector

Overview of Indian healthcare sector, current status & growth potential.Role & importance of pharmacists in healthcare management system, Code of ethics of Pharmacy profession, Pharmacist's oath. Present & future job prospects in Indian Healthcare sector.

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Innovation and Research

Overview of notable National Research Organizations/ Authorities/ Societies/ Forums such as CDRI, IICTE, NCL, IIIM, ICGEB, IISC, NIPER, CCMB, CSIR, ICMR etc. Emerging areas and new technologies in pharmaceutical sciences.

REGULATORY AGENCIES OF PHARMA EDUCATION & INDUSTRIES

Introduction to regulatory body of Pharmacy education and industries like- PCI, AICTE, FDA, WHO, CDSCO, Ministry of AYUSH, Ministry of Chemicals & Fertilizers, Dept. of Pharmaceuticals. Career opportunities in drug control & administration.

COURSE OUTCOMES

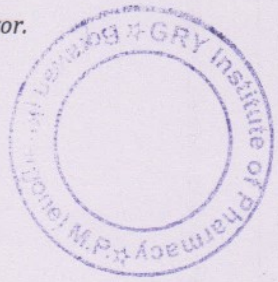
After successful completion of course, students are expected to possess an in-depth understanding and knowledge about the scope of pharmaceutical education &pharmacy profession, terminologies, learning resources and career-opportunities in field of pharmacy and its allied disciplines.

EVALUATION

Evaluation will be continuous an integral part of the class as well through external assessment.

REFERENCES:

All other course materials will be provided by the instructor.



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Choice Based Credit System (CBCS)

Scheme of Examination w.e.f. September 07, 2015

Bachelor of Pharmacy (B.Pharm.)

SEMESTER: II SEMESTER

S. No.	Subject Code	Subject Name	Maximum Marks Allotted						Hours/Week			Total Credits	
			Theory			Practical							
			End Sem.	Mid Sem. Test	Quiz, Assignment	End Sem.	Lab work	Assignment /Quiz	L	T	P		
1	MA112	Mathematics	60	30	10	0	0	0	3	1	0	4	
2	PY114	Pharmaceutical Chemistry-II (Organic Chemistry-I)	60	30	10	10	20	20	3	0	4	5	
3	PY115	Pharmaceutical Dosage Form	60	30	10	10	20	20	3	0	4	5	
4	PY116	Human Anatomy and Physiology-I	60	30	10	10	20	20	3	0	4	5	
5	PY117	Phamacognosy-I	60	30	10	10	20	20	3	0	4	5	
6	HU112	Rural Outreach	0	0	0	0	0	150	0	0	4	2*	Total Marks
			300	150	50	40	80	230	15	1	20	26	850

L: Lecture T: Tutorial P: Practical

Note: * For HU112 there will be no examination and credits will be awarded only on the basis of internal assessment.

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MA 112: MATHEMATICS

Algebra: Solving Linear Equations and Quadratic Equations, Simultaneous Linear Equation, Function and their types, Introduction to logarithms and its application in pharmaceutical science, Determinants (meaning), Matrices and its type, Arithmetic Operations on matrices.

Differential Calculus : Introduction to Limits, Methods to solve limits, differential coefficient, Differentiation of standard functions, Product rule, Quotient rule, Differentiation of function of a function (Chain rule). Logarithmic differentiation, Parametric differentiation, Successive differentiation.

Integral Calculus: Introduction to Integration, integration of standard forms, Integration of Algebraic Expression, integration by parts, Method of Substitution, Integration by Partial fractions.

Differential Equations : Definition and Formation of differential equations, equations of first order and first degree, variable separable method, Linear differential equations.

Statistics: Data and Diagrammatic representation of Data : Bar and Pie Chart, Histogram and Frequency Curve, Measures of central tendency : Mean, Mode, Median, Geometric Mean. Measures of Dispersion – Mean deviation, Standard deviation, coefficient of variations. Introduction to Correlation and Regression, Applications of Statistical Concept in Pharmaceutical Science.

Probability : Basic Concept of Probability and Preliminary ideas, Definition of probability with simple numerical examples, Addition and Multiplication Theorems, Probability Distributions – Fitting of Binomial and Poisson distribution, Normal distribution (Basic Concept).

Books & References Recommended:

1. Calculus, Volumes 1, T. M. Apostol, Wiley Eastern.
2. Ray M., Algebra
3. Pathak. H.K, Calculus and Statistical Methods, Shikha Sahitya Prakashan, Merrut.
4. Gupta S.P. Statistical Methods, Sultan Chand and Co., New Delhi.
5. Ramana B V, Higher Engineering Mathematics , Tata McGraw Ltd., New Delhi, 2006
6. Narayan Shanti, Integral calculus , Sultan Chand & Co.
7. Greval B.S., Higher Engineering Mathematics, Khanna Publication, New Delhi

PY 114: PHARMACEUTICAL CHEMISTRY-II (ORGANIC CHEMISTRY-I)

Fundamentals of organic reaction mechanism: Classification of organic reactions, bond- breaking and bond-making processes, concerted and stepwise reactions, reactivity and orientation, electrophiles and nucleophiles, aromatic, role of solvent, polarity of solvent.

Free Radical Reactions: Stability and structure generation and fate of free radicals, free radical substitution reaction.

Reaction involving Carbenes: Carbenes, its stability and structure generation and fate of carbenes.

Reaction involving Nitrenes: Nitrenes, its stability and structure generation and fate of nitrenes.

Stereochemistry:

Optical activity, Cause of optical activity, Enantiomers, Racemic modifications, Configuration: D and L System (carbohydrate and amino acids), Cahn Ingold Prelog system, diastrereoisomers, asymmetric synthesis, method of resolution and optical purity, cis-trans isomerism resulting from double bond.

Chemistry of Aliphatic Compounds:

(Carbonyl compounds, alcohols, phenol, ethers, esters and amides)

Reaction involving Carbocations: Structure generation and stability and fate of carbocataions, SN1, SN2

Reaction involving Carbanions: Stability and structure generation and fate of carbanions,

Elimination Reactions: 1,2 Elimination reactions, dehydrohalogenation of alkyl halides, E1, E2

PRACTICALS: Minimum 15 experiments based on following

- Qualitative analysis of organic compounds and preparation of their derivatives
- Synthesis of organic compounds
- Characterization of synthesized compounds
- Use of stereo models.

BOOKS & REFERENCES RECOMMENDED

Text books

1. Robert T. Morrison and Robert N. Boyd (1992) Organic Chemistry: 6th ed. Printice Hall
2. Finar I. L., Organic Chemistry (1963) vol. 1, Organic Chemistry: 4th ed. Longman
3. Finar I. L., Organic Chemistry (1964) vol.2, Organic Chemistry: 4th ed. Longman
4. Cleyden J., Greeves N., Warren S., and Wothers P., (2001) organic chemistry: 1st ed. Oxford university press

PY 115: PHARMACEUTICAL DOSAGE FORM

Introduction to dosage forms: Classification, significance of classification, classification of dosage forms based on: physical state, method of preparation, sterile and non-sterile preparations, classification as per mode of application, classification according to drug release pattern, pharmacological classification.

Routes of drug administration: types, criteria for selection and their merits and demerits.

Pharmaceutical Calculation: Different systems of weights and measures, Interconversion of different measuring units, Dilution and concentration of solutions, Percentage solutions, Calculation by alligation method. Dose calculation.

Liquid Formulation Additives: Types and properties of additives- Vehicles, Solvents & Co-solvents, Preservatives, Antioxidants, Suspending agents, Emulsifying agents, Solubilizers, Colours, Flavours and sweetners.

Liquid Dosage Forms: Definition, general formulation, principles and method of preparation, storage and official products of the following categories of dosage forms:

Solutions, Syrups, Elixirs, Spirits, Linctuses, Gargles, Mouth washes, Suspension, Emulsions, Lotions, Liniments, Milks and Magmas, Jellies.

Packaging of pharmaceutical dosage forms: Introduction, objective and functions of packaging, packaging components, containers and closures, blister and strip packaging.

List of Practical

01 Prepare and submit Aqueous Iodine Solution

02 Prepare and submit Weak Iodine Solution

03 Prepare and submit Strong Iodine Solution

04 Prepare and submit Strong Ammonium Acetate Solution

05 Prepare and submit Cresol with Soap Solution

06 Prepare and submit Chloroxylenol solution

07 Prepare and submit Simple Syrup IP

08 Prepare and submit Simple Syrup USP

09 Prepare and submit Compound Ferrous Phosphate Syrup

10 Prepare and submit Simple Elixir

11 Prepare and submit Piperazine Citrate Elixir

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PY 115: PHARMACEUTICAL DOSAGE FORM

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12 Prepare and submit Chloroform Spirit

13 Prepare and submit Aromatic Spirit of Ammonia

14 Prepare and submit Simple Linctus

15 Prepare and submit Phenol Gargle

16 Prepare and submit Compound Sodium Chloride Mouth Wash

17 Prepare and submit Calamine Lotion

18 Prepare and submit Soap Liniment

19 Prepare and submit Turpentine Liniment

20 Prepare and submit Milk of Magnesia

21 Prepare and submit Aluminium Hydroxide Gel

22 Prepare and submit Bentonite Magma.

23 Prepare and submit Liquid Paraffin Emulsion

24 Prepare and submit Turpentine oil Emulsion

25 Prepare and submit Paracetamol Oral Suspension

26 Prepare and submit dilute hydrochloric acid solution from concentrated Hydrochloric acid

27 Prepare and submit 50 % v/v alcohol from 90 % v/v alcohol after calculating by Alligation method

BOOKS & REFERENCES RECOMMENDED

Textbooks:

1. Ansel H.C., Ansel's Pharmaceutical Dosage Forms & Drug Delivery Systems, 8th Ed., Lippincot Williams & Wilkins
2. L. Lachman, H.A. Lieberman and J.L.Kanig, The theory and practice of industrial pharmacy, 4th ed., 1991, Varghese publishing house.

Reference books:

1. Remington's The Science and Practice of pharmacy, 21st ed., 2005, Lippincott williams & Wilkins
2. Ansel H.C., Pharmaceutical calculations, 14th ed., 2015, Lippincott Williams & Wilkins, India

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PY 116 : HUMAN ANATOMY AND PHYSIOLOGY-I

1. Introduction to anatomy and physiology: Scope and basic terminology, introduction to human body. Cellular organization: Structure of cell, its components and their function. Elementary Tissues of the Human Body: Epithelial, connective, muscular and nervous tissues; their sub-types and characteristics.

2. Skeletal System: Structure, composition and functions of skeleton, Classification of joints, Types of movement at joint, Arthritis.

3. Skeletal Muscles: Their gross anatomy, physiology of muscle contraction, physiological properties of skeletal muscle, Myasthenia gravis.

4. Cardiovascular System: Composition and functions of blood and its elements, blood groups and their significance, mechanism of coagulation, Anemia, Hemophilia, Erythroblastosis fetalis. Basic anatomy of the heart, physiology of heart, blood vessels and circulation. Cardiac cycle, heart sounds and electrocardiogram. Blood pressure and its regulation, hypertension, angina, myocardial infarction, congestive heart failure.

5. Lymph and lymphatic system: Structure and function of lymphatic vessels and lymph circulation, lymphatic organs and tissues, general principles of immunity.

6. Respiratory System: Anatomy of respiratory organs, mechanism and regulation of respiration, Respiratory volumes and vital capacity, Asthma, tuberculosis, COPD.

List of Practical:

- Determine RBC count of the given blood sample
- Determine WBC count of the given blood sample
- Determine differential WBC count of the given blood sample
- Determine hemoglobin count of the given blood sample
- Determine clotting and bleeding time of the given blood sample.
- Determine blood group.
- Study of epithelial, connective, muscular and nervous tissue using slide.
- Study human skeletal system with the help of chart, model and histological slides.

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- Study of human cardiovascular system with the help of chart, model and histological slides.
- Record of blood pressure.
- Study of human respiratory system with the help of chart, model and histological slides.
- Study of lymphatic system with the help of chart, model and histological slides

Books Recommended

- Gerard J. Tortora and Byran Derrickson, Principles of Anatomy and physiology. International student version Vol-I and II, John Wiley and Sons (Asia)
- Kathleen J.W., Wilson Ross and Wilson: Anatomy and Physiology in Health and Illness
- Arthur C. Guyton: Textbook of Medical Physiology.
- Cyril A. Keele, Erie Neil, Norman Joels and Samson Wrights: Applied Physiology
- Chatterjee, C.C, Human Physiology, Medical allied agency, Calcutta.
- Ross and Wilson, Human anatomy and Physiology, Churchill Livingstone London.

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PY 117 : Pharmacognosy-I

Definition, history, scope and development of the Pharmacognosy. : Sources of crude drugs and methods of their classification with examples

Exogenous and endogenous factors affecting production of crude drugs

a. Environmental conditions
b. Cultivation, collection, drying and storage
c. Natural pest control agents

Quality control of crude drugs

Organoleptic, physical, chemical, microscopic and biological evaluation

Quantitative Microscopy: Vein islet no. stomatal Index, palisade ratio, vein termination no.

Deterioration of stored crude drugs

Primary factors
Control of infestation

Carbohydrates and related drugs: Definition, properties, classification, chemical constituents, chemical test and uses
Tragacanth, Acacia, Honey, Agar, Pectin, Plantago and Starch

Tannins & resins and related drugs: definition, properties, classification, chemical constituents, chemical tests and uses
Ashoka, Amla, Arjuna, Myrobalan, Bahera
Ginger, turmeric, Asafoetida, Tolu balsam, benzoin

Traditional system of medicine: Introduction, basic concept, formulations used in Ayurvedic system of medicine, Asava, Arista,Churna, Bhasma

Biological sources, active constituents and uses of the following traditional drugs
Neem, Apamarga, Methi, Guduchi, Bramhi, satavari

List of Practical

1. Perform morphological and chemical Evaluation of Honey, Agar and Isabgol husk
2. Perform morphological Evaluation of Ashoka bark, Amla fruit, Arjuna bark, Myrobalan fruit and Bahera fruit
3. Perform morphological and chemical Evaluation of Asafoetida, Tolu Balsam and Benzoin
4. Perform morphological Evaluation of Neem leaves, Apamarga root, and Shatavari root
5. Perform morphological and chemical evaluation of Tragacanth gum, Agar and Acacia gum
6. Perform the Morphological Evaluation of Ginger rhizome

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7. Perform the Morphological and Chemical Evaluation of Turmeric rhizome
8. Perform the Morphological Evaluation of Methi seed and Brahmi leaves
9. Isolate starch from potato/rice/maize/wheat and perform its powder microscopy.
10. Perform standardization of Asava/Arishta on basis of Organoleptic, Physical and Chemical parameters
11. Perform standardization of Churnas on basis of Organoleptic, Physical and Chemical parameters

Refrences

1. Text Book of Pharmacognosy – T.E. Wallis
2. Pharmacognosy – Trease & Evans
3. Pharmacognosy – Brady & Taylor
4.. Pharmacognosy – C.K.Kokate, A.P.Purohit, S.B.Gokhale.

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Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal
Choice Based Credit System (CBCS)
Scheme of Examination

For Students admitted in Academic Session 2015-16

(With effect from academic year 2016-2017)

Bachelor of Pharmacy (B.Pharm.) Semester-III

S.No.	Subject Code	Subject Name	Maximum Marks Allotted						Hrs/Week			Total Credits	Total Marks
			Theory			Practical							
			End Sem	Mid Sem. test	Quiz/ Assignment	End Sem	Lab Work	Quiz/ Assignment	L	T	P		
1	PY-301	Pharm. Chem.-III (Organic Chem.-II)	75	15	10	35	10	05	03	0	04	5	
2	PY-302	Physical Pharmaceutics-II	75	15	10	35	10	05	03	0	04	5	
3	PY-303	Human Anatomy and Physiology-II	75	15	10	35	10	05	03	0	04	5	
4	PY-304	Pharmaceutical Microbiology	75	15	10	35	10	05	03	0	04	5	
5	PY-305	Biochemistry	75	15	10	35	10	05	03	0	04	5	
6	PY-306	Computer Applications in Pharmacy	50	15	10	15	05	05	03	0	02	4	850
			425	90	60	190	55	30	18	0	22	29	

PHARMACEUTICAL CHEMISTRY-III(ORGANIC CHEMISTRY –II) (Theory)

General methods of preparation and reaction of compounds superscripted with (*) to be explained.
To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences:

Benzene and its derivatives

Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule.

Reactions of benzene - nitration, sulphonation, halogenation- reactivity, Friedel crafts alkylation-reactivity, limitations, Friedel crafts acylation.

Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction .

Structure and uses of DDT, Saccharin, BHC and Chloramine

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

Fats and Oils

Fatty acids – reactions.

Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils.

Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value, Reichert Meissl (RM) value – significance and principle involved in their determination.

Polynuclear hydrocarbons

Synthesis, reactions

Structure and medicinal uses of Naphthalene, Phenanthrene, Anthracene, Diphenylmethane, Triphenylmethane and their derivatives

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.

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

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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.

PHARMACEUTICAL CHEMISTRY-III(ORGANIC CHEMISTRY –II) (Practical)

1. **Experiments involving laboratory techniques**
   Recrystallization
   Steam distillation
2. **Determination of following oil values (including standardization of reagents)**
   Acid value
   Saponification value
   Iodine value
3. **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-napthol from Aniline by diazotization and coupling reactions.
   Benzil from Benzoin by oxidation reaction.
   Dibenzal acetone from Benzaldehyde by Claison Schmidt reaction
   Cinnammic acid from Benzaldehyde by Perkin reaction
   p-Iodo benzoic acid from *p*-amino benzoic acid

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PHYSICAL PHARMACEUTICS-II (Theory)

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 dating of pharmaceutical dosage forms. Photolytic degradation and its prevention

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

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

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.

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.

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.

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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

PHYSICAL PHARMACEUTICS- II (Practical)

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

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HUMAN ANATOMY AND PHYSIOLOGY-II (Theory)

Body fluids and blood

Body fluids, composition and functions of blood, hemopoeisis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance and disorders of blood.

Lymphatic system

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

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.

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, Lung volumes and capacities, transport of respiratory gases, artificial respiration, 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.

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

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, Newyork

3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co,Riverview,MI USA
4. Text book of Medical Physiology- Arthur C,Guyton andJohn.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. Chatterrje ,Academic Publishers Kolka

HUMAN ANATOMY AND PHYSIOLOGY (Practical)

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 and clotting 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 analyzer.
16. Permanent slides of vital organs and gonads.

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PHARMACEUTICAL MICROBIOLOGY (Theory)

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 microscopy, dark field microscopy and electron microscopy.

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.
Equipments employed in large scale sterilization.
Sterility indicators.

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

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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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. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan

7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.

8. Peppler: 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

PHARMACEUTICAL MICROBIOLOGY (Practical)

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).
5. Staining methods- Simple, Grams staining and acid fast staining (Student Practical)
6. Isolation of pure culture of micro-organisms by multiple streak plate technique.
7. Microbiological assay of antibiotics by cup plate method.
8. Motility determination by Hanging drop method.
9. Sterility testing of pharmaceuticals.
10. Bacteriological analysis of water
11. Biochemical test (IMViC reactions)
12. Revision Practical Class

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BIOCHEMISTRY (Theory)

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

Lipid metabolism

- β-Oxidation of saturated fatty acid (Palmitic acid)
- 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

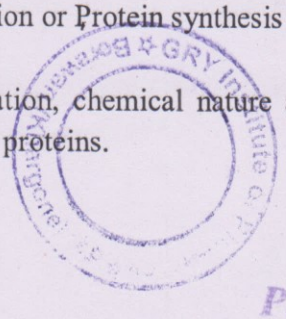
- General reactions of amino acid metabolism: Transamination, deamination and decarboxylation, urea cycle and its disorders
- Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia)
- Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline
- Catabolism of heme; hyperbillirubinemia and jaundice

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

Biomolecules

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



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Bioenergetics

- Concept of free energy, undergone and exergonic reaction, Relationship between free energy, enthalpy and entropy, Redox potential.
- Energy rich compounds; classification; biological significances of ATP and cyclic AMP

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

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.

BIOCHEMISTRY (Practical)

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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COMPUTER APPLICATIONS IN PHARMACY (Theory)

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.

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.

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.

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

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

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-Intescience, A John Willey and Sons, INC., Publication, USA

3. Bioinformatics (Concept,' Skills and Applications) – S. C. Rastogi-CBS Publishers and Distributiors 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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COMPUTER APPLICATIONS IN PHARMACY (Theory)

1. Design a questionnaire using a word processing package to gather information about a particular disea
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

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Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal
Choice Based Credit System (CBCS)
Scheme of Examination

For Students admitted in Academic Session 2015-16

(With effect from academic year 2016-2017)

Bachelor of Pharmacy (B.Pharm.) Semester-IV

S.No.	Subject Code	Subject Name	Maximum Marks Allotted						Hrs/Week			Total Credits	Total Marks
			Theory			Practical							
			End Sem	Mid Sem. test	Quiz/ Assignment	End Sem	Lab Work	Quiz/ Assignment	L	T	P		
1	PY-401	Pharm. Chem.-IV (Organic Chem.-III)	75	15	10	35	10	05	03	0	04	5	
2	PY-402	Medicinal Chemistry-I	75	15	10	35	10	05	03	0	04	5	
3	PY-403	Pharmaceutical Analysis-I	75	15	10	35	10	05	03	0	04	5	
4	PY-404	Pharmacology-I	75	15	10	35	10	05	03	0	04	5	
5	PY-405	Pharmaceutical Engineering	75	15	10	35	10	05	03	0	04	5	
6	PY-406	Pathophysiology	75	15	10	00	00	00	03	0	00	3	850
			450	90	60	175	50	25	18	0	20	28	

PY-401 :PHARMACEUTICAL CHEMISTRY-IV (ORGANIC CHEMISTRY-III)

Course objectives:

- To provide fundamental knowledge of scientific nomenclature of heterocyclic compounds.
- To impart knowledge of structure, chemistry, synthesis, and reactions mechanism of some important heterocyclic compounds with one or two hetero atoms and fused hetrocyclic compounds.
- To understand stereoisomerism in organic compounds.
- To understand the role of reagents in organic synthesis.

Course outcomes:

Upon completion of this course the students are expected to be able to:

- Understand the structure, chemistry, synthesis and reactions of aryl halide, α-β unsaturated carbonyl compounds, some important heterocyclic compound with one or two hetero atoms and fused hetrocyclic compounds.
- Perform synthesis, purification, and characterization of heterocyclic compounds.
- Recognize isomers, like R/S isomers, Cis-Trans and E/Z.
- Predict the role of reagents like NaBH4 and LiAlH4 etc. in drug synthesis.

THEORY

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.

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.

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,

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

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

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PRACTICALS: Minimum 15 experiments based on following:

1. Laboratory Rules and Regulations
2. To Determine Melting Point, Molecular Weight & Thin layer chromatography of given sample.
3. Synthesis of Benzoyl Glycine (Hippuric Acid)
4. Synthesis of Dibenzylideneacetone
5. Synthesis of Chalcone (Benzylidene Acetophenone)
6. Preparation of Acetophenone Phenylhydrazone
7. Synthesis of Synthesis of 7-hydroxy-4-methyl Coumarin
8. Synthesis of Benzimidazole from O-Phenylenediamine.
9. Synthesis of 3-methyl-1-phenyl-5-pyrazolone
10. Synthesis of 4-arylidene-3-methyl-1-phenyl-5-pyrazolone
11. Synthesis of 2, 3-diphenyl quinoxaline
12. Synthesis of Isoxazole from Chalcone.
13. Synthesis of Pyrazole from Chalcone.
14. Synthesis of Pyrimidine derivative from Chalcone
15. Synthesis of 2-Phenyl Indole from Acetophenone Phenyl Hydrazone

BOOKS & REFERENCES RECOMMENDED

Textbooks:

1. Carey A. F., and Giuliano M. R., Organic Chemistry (2011): 8th Edition. McGraw-Hill Companies, Inc.
2. Finar I. L., Organic Chemistry (2011) vol. 1,: 6th Edition. Longman.
3. Finar I. L., Organic Chemistry (2011) vol.2, Organic Chemistry: 6th Edition. Longman.
4. Robert T. Morrison and Robert N. Boyd (2008) Organic Chemistry: 7th Edition. Printice Hall
5. Heterocyclic Chemistry, 2 nd Ed., T. L. Gilchrist
6. Heterocyclic Chemistry, 3 rd Ed., J. A. Joules, K. Mills and G. F. Smith (QD 400 J8)

Reference recommended:

1. Cleyden J., Greeves N., Warren S., and Wothers P., (2001) organic chemistry: 1st Edition. Oxford university press.
2. Mann, G. F., and Saunders, C. B., (1960) Practical Organic Chemistry: 4th Edition. Longman
3. Vogel, I. A., (1956) A Text Book of Practical Organic Chemistry Including Qualitative Organic Analysis: 3rd Edition. Longman

Internet references:

1. http://www.internetchemistry.com/chemistry/organic_chemistry.htm

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PY-402 :MEDICINAL CHEMISTRY – I

Course objectives:

- To impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs belonging to cholinergic, anticholinergic, adrenergic, antiadrenergic, antihistaminics, analgesics, antipyretics, anti-inflammatory, calcium channel blockers, potassium channel openers, renin-angiotensin receptor inhibitors, vasodilators, anticoagulants, diuretics and vitamins.
- To develop the knowledge of students abouteffect on biological activity with respect to changes in structure and use of this practice for drug development.
- To acquaint them about importance of physicochemical properties and metabolism of drugs.
- To clarify about synthetic routes of drugs.

Course outcomes:

After completion of the course the student will be able to define

- The chemistry of drugs with respect to their biological activity.
- The drug metabolism pathway and structure activity relationship of drugs.
- The chemical synthesis of drugs

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 (*)

THEORY

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.

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:

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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.

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, Isofluorphate, Echothiophate iodide, Parathione, 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*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride.

Drugs acting on Central Nervous System

A. Sedatives and Hypnotics:

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

Barbiturtes: SAR of barbiturates, Barbital*, Phenobarbital, Mephobarbital, Amobarbital, Butabarbital, Pentobarbital, Secobarbital

Miscelleneous:

Amides & imides: Glutethmide.

Alcohol & their carbamate derivatives: Meprobomate, Ethchlorvynol.

Aldehyde & their derivatives: Triclofos sodium, Paraldehyde.

B. Antipsychotics

Phenothiazeines: SAR of Phenothiazeines - Promazine hydrochloride, Chlorpromazine hydrochloride*, Trifluprомazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride.

Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine.

Fluro buterophenones: Haloperidol, Droperidol, Risperidone.

Beta amino ketones: Molindone hydrochloride.

Benzamides: Sulpieride.

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

Barbiturates: Phenobarbitone, Methabarbital.

Hydantoins: Phenytoin*, Mephenytoin, Ethotoin

Oxazolidine diones: Trimethadione, Paramethadione

Succinimides: Phensuximide, Methsuximide, Ethosuximide*

Urea and monoacylureas: Phenacemide, Carbamazepine*

Benzodiazepines: Clonazepam
Miscellaneous: Primidone, Valproic acid , Gabapentin, Felbamate
Drugs acting on Central Nervous System
General anesthetics:
Inhalation anesthetics: Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane.
Ultra short acting barbitutrates: 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, Anilerdine 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, Zomepriac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone.

PRACTICALS: Minimum 15 experiments based on following:

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

BOOKS & REFERENCES RECOMMENDED:

Text Books:

1. Block J. H., Beale J. M., "Wilson and Gisvold's Textbook of organic medicinal and pharmaceutical chemistry", 11th edition, 2004, Lippincott Williams and Wilkins-A Wolters Kluwer Company.
2. Lemke T. L., Williams D. A., "Foye's principles of medicinal chemistry", 6th edition, 2008, Lippincott Williams and Wilkins-A Wolters Kluwer Company.

Reference Recommended:

1. Wolff M. E., "Burger's medicinal chemistry and drug discovery" 5th edition, 1995, Wiley-

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Interscience, New York.

PY -403 : PHARMACEUTICAL ANALYSIS -I

Course objectives:

- To provide advanced technical skills and knowledge base required in the field of qualitative and quantitative chemical analysis.
- To provide basic knowledge of electroanalytical techniques used in drug quality control with reference to Pharmacopoeial standards.
- To impart hands-on experience in executing elementary analytical assays.

Course outcomes:

After completion of course, student should be able to:

- Understand the principles of volumetric and electro chemical analysis.
- Carryout various volumetric and electrochemical titrations and develop analytical skills.
- Use Pharmacopoeial standards for quality control of drug products.
- Perform elementary analytical assay procedures.

THEORY

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

Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures

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

Gravimetry: Principle and steps involved in gravimetric analysis. Purity of the precipitate: co-precipitation and post precipitation, Estimation of barium sulphate.

Precipitation titrations: Mohrs 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.

Redox titrations: Concepts of oxidation and reduction, Types of redox titrations (Principles and applications), Cerimetry, Iodimetry, Iodometry, Bromatometry, Dichrometry, Titration with potassium iodate

Electrochemical methods of analysis

a) **Conductometry**- Introduction, Conductivity cell, Conductometric titrations, applications.
b) **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.
c) **Polarography** - Principle, Ilkovic equation, construction and working of dropping mercury

electrode and rotating platinum electrode, applications.

PRACTICALS: Minimum 15 experiments based on the following:
Preparation and standardization of

1. Sodium hydroxide
2. Sulphuric acid
3. Sodium thiosulfate
4. Potassium permanganate
5. Ceric ammonium sulphate

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

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

BOOKS & REFERENCES RECOMMENDED

Text books:

1. Vogel's, Text book of Quantitative chemical Analysis, fifth edition, 1989, Longman Scientific & Technical UK.
2. David Harvey, Modern Analytical Chemistry, first edition, 2000, McGraw Hill Companies, New York.
3. Bentley and Driver's Textbook of Pharmaceutical Chemistry
4. John H. Kennedy, Analytical chemistry principles
5. Daniel C. Harris, Quantitative Chemical Analysis, Eighth edition, W. H. Freeman and Company, New York.

Reference recommended:

1. Pharmacopoeia of India, Govt. of India, Ministry of Health and Family Welfare, New Delhi.
2. Beckett, A.H. and Stenlake, J.B., Practical Pharmaceutical Chemistry, fourth edition, Vol. I and II, CBS Publishers and Distributors, New Delhi, India.

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PY-404- PHARMACOLOGY-I

Course Objectives:

- To understand pharmacology of drugs with basics of drug action and effect (desirable and undesirable) consequences in the course of disease treatment.
- To experimentally understand basic principles of pharmacology at laboratory level with consideration of ethical and legal issues.

Course outcomes:

After completion of course, student should be able to:

- Understand scientific principles of drug action and the various mechanisms by which drugs can mediate their pharmacological and other effects.
- Understand principles of pharmacokinetics that underlay the absorption, distribution, metabolism and elimination of drugs in the body and thereby affect drug effectiveness.
- Understand the biochemical reactions that result in the metabolism of drugs within the body.
- Understand the drug treatment of major diseases related to ANS, CNS.
- Understand legal requirements for animal house facility and ethical handling of animals.

THEORY

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

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.

Pharmacology of peripheral nervous system

a. Organization and function of ANS.
b. 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

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g. **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

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.

PRACTICALS: Minimum 15 experiments based on following:
1. Study the commonly used instruments in experimental pharmacology.
2. Study the common laboratory animals.
3. Study the CPCSEA guidelines for ethical manaement of laboratory animal facility.
4. Study of common laboratory techniques: blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
5. Study of different routes of drugs administration in mice/rats.
6. Study the effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
7. Study the effect of drugs on rabbit eye.
8. Study the effects of skeletal muscle relaxants using rota-rod apparatus.
9. Study the effect of drugs on locomotor activity using actophotometer.
10. Study the anticonvulsant activity of drugs by MES and PTZ method.
11. Study the stereotype and anti-catatonic activity of drugs on rats/mice.
12. Study of anxiolytic activity of drugs using rats/mice.
13. Study of local anesthetics by different methods

BOOKS & REFERENCES RECOMMENDED:
Textbooks
1 Tripathi, K. D. Essentials of Medicinal Pharmacology, 7th ed. 2013, Jaypee Brothers Medical Publishers (P) Ltd., New Delhi.
2 Satostkar, R.S., Rege, N.N., Bhandarkar, S.D. Pharmacology and Pharmacotherapeutics. Revised 23rd edition 2013, Popular Prakashan Pvt. LTD., Mumbai,
3 Rang, H.P., Dale, M.M., Ritter, J.M., Flower, R.J., Henderson, G. Rang and Dale's Pharmacology. 8th edition 2015, Elsevier India.
4 Ghosh, M. N. Fundamentals of Experimental Pharmacology. 2nd edition 1984, Scientific Book Agency, Calcutta.
5 Kulkarni, S.K., Hand Book of Experimental Pharmacology, 3rd Edition, 1999, Vallabh Prakashan.
6 Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews- Pharmacology

Reference recommended:

1. Brunton, L., Chabner, B.A., Knollman, B. Goodman and Gillman's the Pharmacological Basis of Therapeutics. 12th edition 2011, McGraw Hill Education.
2. Katzung B. G., Trevor A.J. Basic and Clinical Pharmacology.13th edition 2015, McGraw-Hill Medical
3. Vogel, H. G. Drug Discovery and Evaluation. 2nd edition 2002, Springer Publication, Berlin.

Website:
1. http://www.indphar.org

Software:
1 Ex-Pharm, Raveendran R. Department of pharmacology, JIPMER, Pandicherry, India, 2009.

Mobile application:
1 Pharmacology by Apple Medical Group 2014.

PY -405 : PHARMACEUTICAL ENGINEERING

Course objectives:

Upon completion of the course student shall be able:

- To enable the students to understand the engineering principles involved in the processing of drugs and pharmaceutical products.
- To create understanding about the basic principles of process engineering.
- To impart knowledge on operations of various equipments and machineries.
- To develop concept of unit operations.

Course Outcome:

On the completion of the course the student should be able to

- Develop strong background in basics of the pharmaceutical processing.
- Develop understanding the concepts of unit operations in pharmaceutical process.
- Create new process and can be able to modify the existing process.
- Impart knowledge on basic operations involved in material movement.
- Understand process of fluid flow and role of filtration for complex suspensions.
- Changes of micromeritic properties of pharmaceutical substances by crystallization technique.
- Understand the role of distillation in purification of multi component system.
- Understand the applications of particle size in pharmaceuticals.
- Effectively extract desired constituent from solid materials.
- Understand the application of automation in pharmaceutical process.
- Understand the material handling techniques.
- To know significance of plant lay out design for optimum use of resources.
- Understand the preventive methods used for corrosion control in pharmaceutical industries.

THEORY

- **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 & Silversion Emulsifier,

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- **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.
- **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, triple 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.
- **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
- **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
- **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.
- **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.

PRACTICALS: Minimum 15 experiments based on following:

1. Determination of radiation constant of brass, iron, unpainted and painted glass(4 experiments).
2. Steam distillation – To calculate the efficiency of steam distillation.
3. To determine the overall heat transfer coefficient.
4. Construction of drying curves (for calcium carbonate and starch).
5. Determination of moisture content and loss on drying.
6. Determination of humidity of air – i) From wet and dry bulb temperatures –use of humidity chart, II) Dew point method.

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7. Description of Construction working and application of Pharmaceutical Machinery such as
8. rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier.
9. Size analysis by sieving – To evaluate size distribution of tablet granulations –
10. Construction of various particle size frequency curves including arithmetic and logarithmic probability plots.
11. Size reduction: To verify the laws of size reduction using ball mill.
12. Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipments.

BOOKS & REFERENCES RECOMMENDED:

Textbooks:

1. Walter L. Badgre and T. Banchero, Introduction to chemical Engineering, McGraw-Hill, 1955.
2. Kaning J. K. (Editor), S. J. Carter, Tutorial Pharmacy, CBS Publishers & distributers, 1986, Indian Edition. 6th Ed.
3. Hickey A. J., and Ganderton D., Pharmaceutical Process Engineering, Marcel Dekker, 2001.

Reference recommended:

1. Parry H. (Editor), Chemical Engineering Hand Book, McGraw-Hill,1997, 7th Ed.
2. Leon Lachman and H. R. Libberman, The Theory and Practice of Industrial Pharmacy, CBS Publishers & Distributors, Special Indian Edition, 2009.
3. Max S. Peters, Elementary Chemical Engineering, Tata McGraw-Hill, 2009 2nd Ed.
4. Ganderton C., Unit Processes Pharmacy, William Heinemann medical book ltd, 1968.
5. Browns G., Unit Operations, Wiley and Sons, 1955.
6. Warren L. Maccabe, Juliano C. Smith. Unit Operations of Chemical Engineering. Biohazardous Waste Management., http://biosafety.uk.edu/waste/

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PY-406:PATHOPHYSIOLOGY

Course objectives:

- To understand the pathological changes and their basic mechanisms that leads to disease.
- To understand mechanism of resistance and adaptation towards pathological changes.
- To understand pathological presentation of common diseases of CNS, CVS, Hormones, respiratory system, GIT, bones, cancer, liver and kidney.

Course outcomes:

After completion of course, student should be able to:

- Develop understanding of modulation in normal anatomy and physiology during initiation and progression of diseases.
- Understand the mechanism of tissue repair process.
- Understand causes, symptoms and contributing factor in occurrence and progression of various diseases.
- Connect the mechanism of pathological modulations while studying pharmacology of drug molecule.
- Sort the pathways that require modulating in disease treatment.
- Understand pathological issues during designing and testing of drug molecules and dosage forms.

THEORY

(a) **Basic principles of Cell injury and Adaptation:** Introduction, definitions, Homeostasis, Components and Types of Feed back 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

(b) **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

(a) **Cardiovascular System:** Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis)

(b) **Respiratory system:** Asthma, Chronic obstructive airways diseases.

(c)**Renal system:** Acute and chronic renal failure.

(a)**Haematological Diseases:** Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalasemia, hereditary acquired anemia, hemophilia

(b) **Endocrine system:** diabetes, thyroid diseases, disorders of sex hormones

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

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(d) Gastrointestinal system: Peptic Ulcer
Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease.
(a) Disease of bones and joints: Rheumatoid arthritis, osteoporosis and gout
(b) Principles of cancer: classification, etiology and pathogenesis of cancer
(c) Diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis,Gout
(d) Principles of Cancer: Classification, etiology and pathogenesis of Cancer

Infectious diseases: Meningitis,Typhoid, Leprosy, Tuberculosis, Urinary tract infections
Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea

BOOKS & REFERENCES RECOMMENDED:
Text books:

1. Mohan, H. Textbook of Pathology, 7th revised edition 2014, Jaypee Brothers Medical Publishers.
2. Mandal, A.K., Choudhary, S. Textbook of Pathology for MBBS - General Pathology and Haematology / Systemic Pathology (Volume 1 and 2) 1st Edition 2014 Avichal Publishing Company.
3. Sharma S.C., Pathophysiology of Common Disease 1st edition

Reference recommended:

1. Kumar, V., Abbas, A.K., Fausto, N., Aster, J.C., Robbins and Cotran Pathologic Basis of Disease, 8th Edition, Elsevier Publication.
2. DiPiro, J., Talbert, R.L., Yee, G., Wells, B., Posey, L.M. Pharmacotherapy A Pathophysiologic 9th edition 2014, McGraw-Hill Education.
3. Kirkhorn, L.E.C.C. & Banasik, J.L. Pathophysiology 2009, W B Saunders Co.
4. Huether, S. E. and McCance, Kathryn, L. Understanding Pathophysiology. 6th Edition, Mosby.
5. Hart, M.N., Loeffler, A.G. Introduction to Human Disease: Pathophysiology for Health Professionals 5th edition 2011, Jones & Bartlett Learning.

Website:

1. http://library.med.utah.edu/WebPath/GENERAL.html

Bachelor of Pharmacy (B.Pharm.) Semester- V (As per PCI course regulations 2014)

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3	1	4
BP502T	Industrial Pharmacy I –Theory	3	1	4
BP503T	Pharmacology II-Theory	3	1	4
BP504T	Pharmacognosy and Phytochemistry II-Theory	3	1	4
BP505T	Pharmaceutical Jurisprudence –Theory	3	1	4
BP506P	Industrial Pharmacy I-Practical	4	-	2
BP507P	Pharmacology II- Practical	4	-	2
BP508P	Pharmacognosy and Phytochemisty II-Practical	4	-	2
	Total	**27**	**5**	**26**

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Schemes for internal assessments and end semester examinations V semester

Semester V

Course Code	Name of The Course	Internal Assessment				End Semester Exams		Total Marks
		Continuous Mode	Sessional Exams		Total	Marks	Duration	
			Marks	Duration				
BP501T	Medicinal Chemistry II – Theory	10	15	1 Hr	25	75	3 Hrs	100
BP502T	Industrial Pharmacy I –Theory	10	15	1 Hr	25	75	3 Hrs	100
BP503T	Pharmacology II-Theory	10	15	1 Hr	25	75	3 Hrs	100
BP504T	Pharmacognosy II-Theory	10	15	1 Hr	25	75	3 Hrs	100
BP505T	Pharmaceutical Jurisprudence – Theory	10	15	1Hr	25	75	3Hrs	100
BP506P	Industrial Pharmacy I-Practical	5	10	4 Hr	15	35	4 Hrs	50
BP507P	Pharmacology II- Practical	5	10	4 Hr	15	35	4 Hrs	50
BP508P	Pharmacognosy II-Practical	5	10	4 Hrs	15	35	4 Hrs	50
Total		**65**	**105**	**17 Hrs**	**170**	**480**	**27Hrs**	**650**

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Rajiv Gandhi Proudyogiki Vishwavidyalaya, Bhopal

Scheme of Examination

For Students admitted in Academic Session 2015-16

(With effect from academic year 2017-2018)

Bachelor of Pharmacy (B.Pharm.) Semester-VI

S.No.	Subject Code	Subject Name	Maximum Marks Allotted						Hrs/Week			Total Credits	Total Marks
			Theory			Practical							
			End Sem	Mid Sem. test	Quiz/ Assignment	End Sem	Lab Work	Quiz/ Assignment	L	T	P		
1	PY-601	Medicinal Chemistry-III	75	15	10	35	10	05	03	01	04	6	
2	PY-602	Pharmacology-III	75	15	10	35	10	05	03	01	04	6	
3	PY-603	Herbal Drug Technology	75	15	10	35	10	05	03	01	04	6	
4	PY-604	Biopharmaceutics and Pharmacokinetics	75	15	10	-	-	-	03	01	00	4	
5	PY-605	Pharmaceutical Biotechnology	75	15	10	-	-	-	03	01	00	4	
6	PY-606	Quality Assurance	75	15	10	-	-	-	03	01	00	4	
7	PY-607	Educational Study Tour	-	-	-	-	-	50	Educational Tour Report			2	
			450	90	60	105	30	65	18	06	12	32	800

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PY-601 . MEDICINAL CHEMISTRY – III (Theory)

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

Antibiotics
Historical background, Nomenclature, Stereochemistry, Structure activity relationship, Chemical degradation classification and important products of the following classes :
β-Lactam antibiotics: Penicillin, Cepholosporins, β- Lactamase inhibitors, Monobactams
Aminoglycosides: Streptomycin, Neomycin, Kanamycin
Tetracyclines: Tetracycline,Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline

UNIT – II

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, Artesunete, Artemether, Atovoquone.

UNIT – III

Anti-tubercular Agents
Synthetic anti tubercular agents: Isoniozid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.*
Anti tubercular antibiotics: Rifampicin, Rifabutin, Cycloserine Streptomycine, 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, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir.

UNIT – IV

Antifungal agents:
Antifungal antibiotics: Amphotericin-B, Nystatin, Natamycin, Griseofulvin.
Synthetic Antifungal agents: Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconozole, 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, Sulfamethoxaole*, Sulphadiazine, Mefenide acetate, Sulfasalazine.
Folate reductase inhibitors: Trimethoprim*, Cotrimoxazole.
Sulfones: Dapsone*.

UNIT – V

Introduction to Drug Design
Various approaches used in drug design.
Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammet's electronic parameter, Tafts steric parameter and Hansch analysis.
Pharmacophore modeling and docking techniques.
Combinatorial Chemistry: Concept and applications of combinatorial chemistry: solid phase and solution phase synthesis.

Recommended Books (Latest Editions)

Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
Foye's Principles of Medicinal Chemistry.
Burger's Medicinal Chemistry, Vol I to IV.
Introduction to principles of drug design- Smith and Williams.
Remington's Pharmaceutical Sciences.
Martindale's extra pharmacopoeia.
Organic Chemistry by I.L. Finar, Vol. II.
The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1-5.
Indian Pharmacopoeia.
Text book of practical organic chemistry- A.I.Vogel.

PY 601: MEDICINAL CHEMISTRY- III (Practical)

I Preparation of drugs and intermediates
Sulphanilamide
7-Hydroxy, 4-methyl coumarin
Chlorobutanol
Triphenyl imidazole
Tolbutamide
Hexamine

II Assay of drugs
Isonicotinic acid hydrazide
Chloroquine
Metronidazole
Dapsone
Chlorpheniramine maleate
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)

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PY -602 PHARMACOLOGY-III (Theory)

UNIT-I

Pharmacology of drugs acting on Respiratory system
Anti -asthmatic drugs
Drugs used in the management of COPD
Expectorants and antitussives
Nasal decongestants
Respiratory stimulants
Pharmacology of drugs acting on the Gastrointestinal Tract
Antiulcer agents.
Drugs for constipation and diarrhoea.
Appetite stimulants and suppressants.
Digestants and carminatives.
Emetics and anti-emetics.

UNIT-II

Chemotherapy
General principles of chemotherapy.
Sulfonamides and cotrimoxazole.
Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides

UNIT-III

Chemotherapy
Antitubercular agents
Antileprotic agents
Antifungal agents
Antiviral drugs
Anthelmintics
Antimalarial drugs
Antiamoebic agents

UNIT-IV

Chemotherapy
Urinary tract infections and sexually transmitted diseases.
Chemotherapy of malignancy.
Immunopharmacology
Immunostimulants
Immunosuppressant
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

UNIT-V

Principles of toxicology
Definition and basic knowledge of acute, subacute and chronic toxicity.
Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

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General principles of treatment of poisoning

Clinical symptoms and management of barbiturates, morphine, organophosphosphorus compound and lead, mercury and arsenic poisoning.

Chronopharmacology

Definition of rhythm and cycles.

Biological clock and their significance leading to chronotherapy.

Recommended Books (Latest Editions)

Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchil Livingstone Elsevier

Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill

Goodman and Gilman's, The Pharmacological Basis of Therapeutics

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

Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology

K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.

Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig& Robert,

Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,

Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,

N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

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PY 602 PHARMACOLOGY-III (Practical)

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*

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PY 603 HERBAL DRUG TECHNOLOGY (Theory)

UNIT-I

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.
Indian Systems of Medicine
Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy
Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

UNIT-II

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, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra.

UNIT-III

Herbal Cosmetics
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- IV

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs
Stability testing of herbal drugs.
Patenting and Regulatory requirements of natural products:
Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
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.

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UNIT - V

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.

Recommended Books: (Latest Editions)

Textbook of Pharmacognosy by Trease & Evans.

Textbook of Pharmacognosy by Tyler, Brady & Robber.

Pharmacognosy by Kokate, Purohit and Gokhale

Essential of Pharmacognosy by Dr.S.H.Ansari

Pharmacognosy & Phytochemistry by V.D.Rangari

Pharmacopoeal standards for Ayurvedic Formulation (Council of Research in Indian Medicine & Homeopathy)

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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PY 603 HERBAL DRUG TECHNOLOGY (Practical)

1. To perform preliminary phytochemical screening of crude drugs.
2. Determination of the alcohol content of Asava and Arista
3. Evaluation of excipients of natural origin
4. Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation.
5. Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements.
6. Monograph analysis of herbal drugs from recent Pharmacopoeias
7. Determination of Aldehyde content
8. Determination of Phenol content
9. Determination of total alkaloids

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PY 604 BIOPHARMACEUTICS AND PHARMACOKINETICS (Theory)

UNIT - I

Introduction to Biopharmaceutics

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

UNIT- II

Elimination: Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs

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

UNIT- III

Pharmacokinetics: Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations.

Pharmacokinetics parameters - K_E ,t1/2,Vd,AUC,Ka, Clt and CL_R- definitions methods of eliminations, understanding of their significance and application

UNIT- IV

Multicompartment models: Two compartment open model. IV bolus

Kinetics of multiple dosing, steady state drug levels, calculation of loading and mainetnance doses and their significance in clinical settins.

UNIT- V

Nonlinear Pharmacokinetics: a. Introduction, b. Factors causing Non-linearity.

Michaelis-menton method of estimating parameters, Explanation with example of drugs.

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Recommended Books: (Latest Editions)

Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
Biopharmaceutics and Pharmacokinetics; By Robert F Notari

Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA

Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal,Vallabh Prakashan Pitampura, Delhi

Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc.

Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.

Biopharmaceutics; By Swarbrick

Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and

Thomas, N. Tozen, Lea and Febrger, Philadelphia, 1995.

Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company,Pennsylvania 1989.

Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia

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PY 605 PHARMACEUTICAL BIOTECHNOLOGY (Theory)

UNIT- I

Brief introduction to Biotechnology with reference to Pharmaceutical Sciences.

Enzyme Biotechnology- Methods of enzyme immobilization and applications.

Biosensors- Working and applications of biosensors in Pharmaceutical Industries.

Brief introduction to Protein Engineering.

Use of microbes in industry. Production of Enzymes- General consideration - Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase.

Basic principles of genetic engineering.

UNIT- II

Study of cloning vectors, restriction endonucleases and DNA ligase.
Recombinant DNA technology. Application of genetic engineering in medicine.
Application of r DNA technology and genetic engineering in the production of:
Interferon ii) Vaccines- hepatitis- B iii) Hormones-Insulin.
Brief introduction to PCR

UNIT- III

Types of immunity- humoral immunity, cellular immunity

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

UNIT-IV

Immuno blotting techniques- ELISA, Western blotting, Southern blotting.
Genetic organization of Eukaryotes and Prokaryotes
Microbial genetics including transformation, transduction, conjugation, plasmids and transposons.
Introduction to Microbial biotransformation and applications.
Mutation: Types of mutation/mutants.

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UNIT-V

Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.
Large scale production fermenter design and its various controls.
Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Recommended Books (Latest edition):

B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.

RA Goldshy et. al., : Kuby Immunology.
J.W. Goding: Monoclonal Antibodies.
J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.

Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.

S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.

Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

PY 606 PHARMACEUTICAL QUALITY ASSURANCE (Theory)

UNIT – I

Quality Assurance and Quality Management concepts: Definition and concept of Qualitycontrol, 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 procedures

UNIT -II

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

UNIT – III

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

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

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

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Recommended Books: (Latest Edition)

Quality Assurance Guide by organization of Pharmaceutical Products of India.
Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
How to Practice GMP's – P P Sharma.

ISO 9000 and Total Quality Management – Sadhank G Ghosh
The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
Good laboratory Practices – Marcel Deckker Series
ICH guidelines, ISO 9000 and 14000 guidelines

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Reference books

1. Eliel, E. L.; Wilen, S. H Eliel, (1993) Steriochemistry of Organic Compounds: John Wiley & Sons, New York.
2. Mann, G. F., and Saunders, C. B., (1960) Practical Organic Chemistry: 4th ed. Longman
3. Vogel, I. A., (1956) A Text Book of Practical Organic Chemistry Including Qualitative Organic Analysis:3rded Longman.

Internet references

1. http://www.mhhe.com/physsci/chemistry/carey/student/olc/ch02summary.html

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