Bachelor of Pharmacy

Syllabus - First Semester

PHARMACEUTICAL ANALYSIS

Course Code : PHA2102 **Credit Units: 04**

Course Objective : This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs. Upon completion of the course student shall be able to understand the principles of volumetric and electro chemical analysis, carryout various volumetric and electrochemical titrations & develop analytical skills.

Course Contents :

Module-I
(a) Pharmaceutical analysis- Definition and scope
i) Different techniques of analysis
ii) Methods of expressing concentration
iii) Primary and secondary standards.
iv) Preparation and standardization of various molar and normal solutions-
Oxalic acid, sodium hydroxide, hydrochloric acid, sodium thiosulphate,
sulphuric acid, potassium permanganate and ceric ammonium sulphate
(b) Errors: Sources of errors, types of errors, methods of minimizing errors, accuracy, precision and significant figures
(c) Pharmacopoeia, Sources of impurities in medicinal agents,limit tests.

Module-II

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

Module-III

Precipitation titrations: Mohr's method, Volhard's, Modified Volhard's, Fajans method, estimation of sodium chloride.

Complexometric titration: Classification, metal ion indicators, masking and demasking reagents, estimation of Magnesium sulphate, and calcium gluconate.

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

Basic Principles,methods and application of diazotisation titration.

Module-IV

Redox titrations

(a) Concepts of oxidation and reduction

(b) Types of redox titrations (Principles and applications)

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

Module-V

Electrochemical methods of analysis

Conductometry: Introduction, Conductivity cell, Conductometric titrations, applications.

Potentiometry - Electrochemical cell, construction and working of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode), methods to determine end point of potentiometric titration and applications.

Polarography: Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions)

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

COMMUNICATION SKILLS

Course Code : PHA2105 **Credit Units: 02**

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

Course Contents:

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

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

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

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

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

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	10	2	1	2	35

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance
EE: End Semester Examination

Recommended Books: (Latest Edition)

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

PHARMACEUTICAL ANALYSIS PRACTICAL

Course Code : PHA2107 **Credit Units: 02**

List of experiments:

Limit Test of the following

(1) Chloride
(2) Sulphate
(3) Iron
(4) Arsenic

II **Preparation and standardization of**

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

III **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

IV **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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACEUTICS PRACTICAL

Course Code : PHA2108 **Credit Units: 02**

List of experiments :

1 . Syrups

a) Syrup IP'66

b) Compound syrup of Ferrous Phosphate BPC'68

3 Hours / week

2. Elixirs a) Piperazine citrate elixir

b) Paracetamol pediatric elixir

3.Linctus a) Terpin Hydrate Linctus IP'66

4. Solutions

b) Iodine Throat Paint (Mandles Paint)

a) Strong solution of ammonium acetate

b) Cresol with soap solution

c) Lugol's solution

5. Suspensions

a) Calamine lotion

b) Magnesium Hydroxide mixture

c) Aluminimum Hydroxide gel

6. Emulsions a) Turpentine Liniment

b) Liquid paraffin emulsion

7. Powders and Granules

a) ORS powder (WHO)

b) Effervescent granules

c)Dusting powder

d)Divded powders

8. Suppositories

a) Glycero gelatin suppository

b) Coca butter suppository

c) Zinc Oxide suppository

8. Semisolids

a) Sulphur ointment

b) Non staining-iodine ointment with methyl salicylate

c) Carbopal gel

9. Gargles and Mouthwashes

a) Iodine gargle

b) Chlorhexidine mouthwash

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

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COMMUNICATION SKILLS PRACTICAL

Course code : PHA2110 **Credit Units: 01**

The following learning modules are to be conducted using words worth® English language lab software

Basic communication covering the following topics
Meeting People
Asking Questions
Making Friends
What did you do?
Do's and Dont's

Pronunciations covering the following topics
Pronunciation (Consonant Sounds)
Pronunciation and Nouns
Pronunciation (Vowel Sounds)

Advanced Learning
Listening Comprehension / Direct and Indirect Speech
Figures of Speech
Effective Communication
Writing Skills
Effective Writing
Interview Handling Skills
E-Mail etiquette
Presentation Skills

Examination Scheme:

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**03**	**02**	**03**	**5**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

Syllabus - Second Semester

COMPUTER APPLICATIONS IN PHARMACY

Course Code : PHA2205 **Credit Units: 03**

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

Course Contents:

Module-I

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 : **I**nformation gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

Module-II

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

Module-III: 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

Module-IV

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

Module-V

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

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	50

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance
EE: End Semester Examination

Recommended books (Latest edition):

- Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
- Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
- Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
- 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

ENVIRONMENTAL SCIENCES

Course Code : PHA2206 **Credit Units: 03**

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

Course Contents:
Module-I: The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources:
Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources.

Module-II
Ecosystems Concept of an ecosystem.Structure and function of an ecosystem. Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

Module-III
Environmental Pollution: Air pollution; Water pollution; Soil pollution

Examination Scheme:

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	50

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance
EE: End Semester Examination

Recommended Books (Latest edition):
- Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
- Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
- Bharucha Erach, The Biodiversity of India, Mapin Pu blishing Pvt. Ltd., Ahmedabad – 380 013, India,
- Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
- Clark R.S., Marine Pollution, Clanderson Press Oxford
- Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001,
- Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
- De A.K., Environmental Chemistry, Wiley Eastern Ltd.

- Down of Earth, Centre for Science and Environment

COMPUTER APPLICATIONS IN PHARMACY PRACTICAL

Course Code : PHA2210 **Credit Units: 01**

List of experiments

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

Examination Scheme:

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**03**	**02**	**03**	**5**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance,
LR – Lab Record, V – Viva.

Syllabus - Third Semester

PHARMACEUTICAL ENGINEERING

Course Code : PHA2304 **Credit Units: 04**

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

Course Content:

Module-I

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.

Module-II

Heat Transfer: Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers.

Evaporation: Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator, climbing film evaporator, forced circulation evaporator, multiple effect evaporator& Economy of multiple effect evaporator.

Distillation: Basic Principles and methodology of simple distillation,flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

Module-III

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.

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, planetarymixers, Propellers, Turbines, Paddles & Silverson Emulsifier,

Module-IV

Filtration: Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter & Cartridge filter, membrane filters and Seidtz filter.

Centrifugation: Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & super centrifuge.

Module-V

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, basic of material handling systems.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions)

- Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
- Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson Latest edition.
- Module operation of chemical engineering – Mcabe Smith, Latest edition.
- Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
- Remington practice of pharmacy- Martin, Latest edition.
- Theory and practice of industrial pharmacy by Lachmann., Latest edition.
- Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
- Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

PHYSICAL PHARMACEUTICS PRACTICAL-I

Course Code : PHA2306 **Credit Units: 02**

List of Experiments

1. Determination the solubility of drug at room temperature
2. Determination of pKa value by Half Neutralization/ Henderson Hasselbalch equation.
3. Determination of Partition co- efficient of benzoic acid in benzene and water
4. Determination of Partition co- efficient of Iodine in CCl4 and water
5. Determination of % composition of NaCl in a solution using phenol-water system by CST method
6. Determination of surface tension of given liquids by drop count and drop weight method
7. Determination of HLB number of a surfactant by saponification method
8. Determination of Freundlich and Langmuir constants using activated char coal
9. Determination of critical micellar concentration of surfactants
10. Determination of stability constant and donor acceptor ratio of PABA-Caffeine complex by solubilitymethod
11. Determination of stability constant and donor acceptor ratio of Cupric-Glycine complex by pH titration method

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACEUTICAL MICROBIOLOGY PRACTICAL

Course Code : PHA2307 **Credit Units: 02**

List of experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACEUTICAL ENGINEERING PRACTICAL

Course Code : PHA2308 **Credit Units: 02**

List of Experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

Syllabus - Fourth Semester

PHARMACOLOGY-I

Course Code : PHA2404 **Credit Units: 04**

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

Course Content:

Module-I

1. General Pharmacology

a. Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy.

b. Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination

Module-II

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.

Module-III

2. Pharmacology of drugs acting on peripheral nervous system

a. Organization and function of ANS.

b.Neurohumoral transmission,co-transmission and classification of neurotransmitters.

c. Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics.

d. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral).

e. Local anesthetic agents.

f. Drugs used in myasthenia gravis and glaucoma

Module-IV

3. Pharmacology of drugs acting on 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

Module-V

3. Pharmacology of drugs acting on 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.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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

PHARMACOLOGY PRACTICAL-I

Course Code : PHA2408 **Credit Units: 02**

List of experiments

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

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACOGNOSY AND PHYTOCHEMISTRY PRACTICAL-I

Course Code : PHA2409 **Credit Units: 02**

List of experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

Syllabus - Fifth Semester

MEDICINAL CHEMISTRY-II

Course Code : PHA2501 **Credit Units: 04**

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

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

Module-I
Antihistaminic agents: Histamine, receptors and their distribution in the humanbody
H1–antagonists: Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines cuccinate, Clemastine fumarate, Diphenylphyraline hydrochloride, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium
H2-antagonists: Cimetidine*, Famotidine, Ranitidin.
Gastric Proton pump inhibitors: Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole
Anti-neoplastic agents:
Alkylating agents: Meclorethamine*, Cyclophosphamide, Melphalan, Chlorambucil, Busulfan, Thiotepa
Antimetabolites: Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine
Antibiotics: Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin
Plant products: Etoposide, Vinblastin sulphate, Vincristin sulphate
Miscellaneous: Cisplatin, Mitotane.

Module-II
Anti-anginal:
Vasodilators: Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole.
Calcium channel blockers: Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.
Diuretics:
Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorphenamide. Thiazides: Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, Loop diuretics: Furosemide*, Bumetanide, Ethacrynic acid. Potassium sparing Diuretics: Spironolactone, Triamterene, Amiloride.
Osmotic Diuretics: Mannitol
Anti-hypertensive Agents: Timolol, Captopril, Lisinopril, Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide,Minoxidil, Reserpine, Hydralazine hydrochloride.

Module-III

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

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

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

Drugs used in Congestive Heart Failure: Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan.

Module-IV

Drugs acting on Endocrine system

Nomenclature, Stereochemistry and metabolism of steroids

Sex hormones: Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.

Drugs for erectile dysfunction: Sildenafil, Tadalafil.

Oral contraceptives: Mifepristone, Norgestril, Levonorgestrol

Corticosteroids: Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone

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

Module-V

Antidiabetic agents:

Insulin and its preparations

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

Biguanides: Metformin.

Thiazolidinediones: Pioglitazone, Rosiglitazone.

Meglitinides: Repaglinide, Nateglinide.

Glucosidase inhibitors: Acrabose, Voglibose.

Local Anesthetics: SAR of Local anesthetics

Benzoic Acid derivatives; Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine.

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

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

Miscellaneous: Phenacaine, Diperodon, Dibucaine.*

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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. 1to 5.
- Indian Pharmacopoeia.
- Text book of practical organic chemistry- A.I.Vogel.

INDUSTRIAL PHARMACY-I

Course Code : PHA2502 **Credit Units: 04**

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

Course content:

Module-I

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

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

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization BCS classification of drugs & its significant. Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on stability of dosage forms.

Module-II

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, Formulation of tablets, granulation methods, compression and processing problems. Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

Module-III

Capsules:

a. ***Hard gelatin capsules:*** Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

b. ***Soft gelatin capsules:*** Nature of shell and capsule content, size of capsules,importance of base adsorption and minim/gram factors, production, in process and final product quality control tests. Packing, storage and stability testing of soft gelatin capsules and their applications.

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

Module-IV

Parenteral Products:

a. Definition, types, advantages and limitations. Preformulation factors and essential requirements, vehicles, additives, importance of isotonicity

b. Production procedure, production facilities and controls, aseptic processing

c. Formulation of injections, sterile powders, large volume parenterals and lyophilized products.

d. Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. Quality control tests of parenteral products.

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

Module-V

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

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

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

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions)

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

PHARMACOLOGY-II

Course Code : PHA2503 **Credit Units: 04**

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

Course Content:

Module-I

1. Pharmacology of drugs acting on cardio vascular system

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

Module-II

1. Pharmacology of drugs acting on cardio vascular system

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

2. Pharmacology of drugs acting on urinary system

a. Diuretics
b. Anti-diuretics.

Module-III

3. Autocoids and related drugs

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

Module-IV

5. Pharmacology of drugs acting on endocrine system

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

Module -V

5. Pharmacology of drugs acting on endocrine system

a. Androgens and Anabolic steroids.

b. Estrogens, progesterone and oral contraceptives.

c. Drugs acting on the uterus.

6. Bioassay

a. Principles and applications of bioassay.

b.Types of bioassay

c. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine,digitalis, histamine and 5-HT

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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. Vallabh Prakashan.

PHARMACOGNOSY AND PHYTOCHEMISTRY-II

Course Code : PHA2504 **Credit Units: 04**

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

Module-I

Metabolic pathways in higher plants and their determination

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

Module-II

General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites:
Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,
Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta
Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis
Volatile oils: Mentha, Clove, Cinnamon, Fennel, Coriander,
Tannins: Catechu, Pterocarpus
Resins: Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony
Glycosides: Senna, Aloes, Bitter Almond
Iridoids, Other terpenoids & Naphthaquinones: Gentian, Artemisia, taxus, carotenoids

Module-III

Isolation, Identification and Analysis of Phytoconstituents
a) Terpenoids: Menthol, Citral, Artemisin
b) Glycosides: Glycyrhetinic acid & Rutin
c) Alkaloids: Atropine,Quinine,Reserpine,Caffeine
d) Resins: Podophyllotoxin, Curcumin

Module-IV

Industrial production, estimation and utilization of the following phytoconstituents: Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

Module-V

Basics of Phytochemistry

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

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions)

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

PHARMACEUTICAL JURISPRUDENCE

Course Code : PHA2505 **Credit Units: 04**

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

Course Content:

Module-I

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

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

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

Conditions for grant of license and conditions of license for manufacture of drugs,

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

Module-II

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

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

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

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs

Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

Module-III

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

Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing,

Manufacture In bond and Outside bond, Export of alcoholic preparations,

Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.

Offences and Penalties.

Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

Module -IV

Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

Module-V

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

Code of Pharmaceutical ethics D efinition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended books: (Latest Edition)

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

INDUSTRIAL PHARMACY PRACTICAL-I

Course Code : PHA2506 **Credit Units: 02**

List of experiments

1. Preformulation studies on paracetamol/asparin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tables/granules
5. Preparation and evaluation of Tetracycline capsules
6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Qulaity control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACOLOGY PRACTICAL-II

Course Code : PHA2507 **Credit Units: 02**

List of experiments

1. Introduction to *in-vitro* pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively.
7. Bioassay of histamine using guinea pig ileum by matching method.
8. Bioassay of oxytocin using rat uterine horn by interpolation method.
9. Bioassay of serotonin using rat fundus strip by three point bioassay.
10. Bioassay of acetylcholine using rat ileum/colon by four point bioassay.
11. Determination of PA2 value of prazosin using rat anococcygeus muscle (by Schilds plot method).
12. Determination of PD2 value using guinea pig ileum.
13. Effect of spasmogens and spasmolytics using rabbit jejunum.
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model.
15. Analgesic activity of drug using central and peripheral methods

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACOGNOSY AND PHYTOCHEMISTRY PRACTICAL-II

Course Code : PHA2508 **Credit Units: 02**

List of Experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

Syllabus - Sixth Semester

MEDICINAL CHEMISTRY-III

Course Code : PHA2601 **Credit Units: 04**

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

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

Module-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

Module-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.

Module-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.

Module-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*.

Module-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 chemistry: solid phase and solution phase synthesis of combinatorial

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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

PHARMACOLOGY-III

Course Code : PHA2602 **Credit Units: 04**

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

Course Content:

Module-I

1. Pharmacology of drugs acting on Respiratory system

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

2. Pharmacology of drugs acting on the Gastrointestinal Tract

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

Module-II

3. Chemotherapy

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

Module-III

3. Chemotherapy

a. Antitubercular agents
b. Antileprotic agents
c. Antifungal agents
d. Antiviral drugs
e.Anthelmintics
f. Antimalarial drugs
g. Antiamoebic agents

Module-IV

3. Chemotherapy

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

4. Immunopharmacology

a. Immunostimulants
b. Immunosuppressant

Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

Module-V

5. Principles of toxicology

a. Definition and basic knowledge of acute, subacute and chronic toxicity.

b. Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity

c. General principles of treatment of poisoning

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

6. Chronopharmacology

a. Definition of rhythm and cycles.

b. Biological clock and their significance leading to chronotherapy.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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.

HERBAL DRUG TECHNOLOGY

Course Code : PHA2603 **Credit Units: 04**

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

Course Content:

Module-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

a) Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy

b) Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika,Churna, Lehya and Bhasma.

Module-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.

Module-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

Module-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:

a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy

b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

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

Module-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.

S**chedule T – GoodManufacturing 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.

Examination Scheme :

Components	**CT**	**HA**	**S/V/Q**	**ATTD**	**EE**
Weightage(%)	**15**	**3**	**3**	**4**	**75**

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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

PHARMACEUTICAL BIOTECHNOLOGY

Course Code : PHA2605 **Credit Units: 04**

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

Course Contents :

Module-I

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

Module-II

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

Module-III

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

Module-IV

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

Module-V

a) Fermentation methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring.

b) Large scale production fermenter design and its various controls.
c) Study of the production of - penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin,
d) Blood Products: Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substituties.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

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

PHARMACEUTICAL QUALITY ASSURANCE

Course Code : PHA2606 **Credit Units: 04**

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

Course Content:

Module-I
Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP
Total Quality Management (TQM): Definition, elements, philosophies
ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines
Quality by design (QbD): Definition, overview, elements of QbD program, tools
ISO 9000 & ISO14000: Overview, Benefits, Elements, steps for registration
NABL accreditation : Principles and procedures

Module-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.

Module-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

Module-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.

Module-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

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Edition)

- Quality Assurance Guide by organization of Pharmaceutical Products of India.
- Good Laboratory Practice Regulations, 2nd Edition, SandyWeinberg Vol. 69.
- Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol IWHO Publications.
- A guide to Total QualityManagement- Kushik Maitra and Sedhan K Ghosh
- How to Practice GMP's – P P Sharma.
- ISO 9000 and Total QualityManagement – 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

MEDICINAL CHEMISTRY PRACTICAL-III

Course Code : PHA2607 **Credit Units: 02**

List of experiments

I Preparation of drugs and intermediates
1 Sulphanilamide
2 7-Hydroxy, 4-methyl coumarin
3 Chlorobutanol
4 Triphenyl imidazole
5 Tolbutamide
6 Hexamine

II Assay of drugs
1 Isonicotinic acid hydrazide
2 Chloroquine
3 Metronidazole
4 Dapsone
5 Chlorpheniramine maleate
6 Benzyl penicillin

III Preparation of medicinally important compounds or intermediates byMicrowave 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)

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PHARMACOLOGY PRACTICAL-III

Course Code : PHA2608 **Credit Units: 02**

List of experiments

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*

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

HERBAL DRUG TECHNOLOGY PRACTICAL

Course Code : PHA2609 **Credit Units: 02**

List of experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

Syllabus - Seventh Semester

INSTRUMENTAL METHODS OF ANALYSIS

Course Code : PHA2701 **Credit Units: 04**

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

Course Content:

Module-I

UV Visible spectroscopy: Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. Applications - Spectrophotometric titrations, Single component and multi component analysis

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

Module-II

IR spectroscopy: Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications

Flame Photometry-Principle, interferences, instrumentation and applications

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications

Nepheloturbidometry- Principle, instrumentation and applications

Module-III

Introduction to chromatography

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

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

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

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

Module-IV

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

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

Module-V

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

Gel chromatography- Introduction, theory, instrumentation and applications

Affinity chromatography- Introduction, theory, instrumentation and applications

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K Sharma
- Organic spectroscopy by Y.R Sharma
- Text book of Pharmaceutical Analysis by Kenneth A. Connors
- Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- Organic Chemistry by I. L. Finar
- Organic spectroscopy byWilliam Kemp
- Quantitative Analysis of Drugs by D. C. Garrett
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- Spectrophotometric identification of Organic Compounds by Silverstein

INDUSTRIAL PHARMACY-II

Course Code : PHA2702 **Credit Units: 04**

Course Objectives: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

Course Content:

Module-I

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

Module-II

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

Module-III

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

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

Module-IV

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

Module-V

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

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions)

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

PHARMACY PRACTICE

Course Code : PHA2703 **Credit Units: 04**

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

Course Contents:

Module-I

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

b) Hospital pharmacy and its organization: Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

c) Adverse drug reaction: Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management.

d) **CommModuley Pharmacy:** Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

Module-II

a) Drug distribution system in a hospital: Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs.

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

c) Therapeutic drug monitoring: Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic DrugMonitoring, and Indian scenario for Therapeutic Drug Monitoring.

d) Medication adherence: Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence.

e) Patient medication history interview: Need for the patient medication history interview, medication interview forms.

f) CommModuley pharmacy management: Financial, materials, staff, and infrastructure requirements.

Module-III

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

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

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

d) Education and training program in the hospital: Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for commModuley pharmacy, and Role of pharmacist in the interdepartmental communication and commModuley health education.

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

Module-IV

a) Budget preparation and implementation: Budget preparation and implementation

b) Clinical Pharmacy: Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring - medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

c) Over the counter (OTC) sales: Introduction and sale of over the counter, and Rational use of common over the counter medications.

Module-V

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

b) Investigational use of drugs: Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

c) Interpretation of Clinical Laboratory Tests: Blood chemistry, hematology, and urinalysis

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest Edition):

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

INSTRUMENTAL METHODS OF ANALYSIS PRACTICAL

Course Code : PHA2705 **Credit Units: 02**

List of experiments

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

Examination Scheme :

IA				EE	
A	**PR**	**LR**	**V**	**PR**	**V**
02	**05**	**03**	**05**	**25**	**10**

Note: A-Attendance, IA –Internal Assessment, EE- External Exam, PR- Performance, LR – Lab Record, V – Viva.

PRACTICE SCHOOL

Course Code: PHA2706 **Credit Units: 06**

Objectives: Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time. At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of Semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

Examination Scheme:
Total: 150 marks

Internal Marks : 25
Continuous Mode :

Assignment	Periodic report
10	15

External Marks : 125

Objective(s) of the work done	15 Marks
Learning Outcomes	30 Marks
Presentation of Work	30 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
	Total = 125 Marks

Syllabus - Eighth Semester

BIOSTATISITCS AND RESEARCH METHODOLOGY

Course Code : PHA2801 **Credit Units: 04**

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

Course Content:

Module-I
Introduction: Statistics, Biostatistics, Frequency distribution
Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples
Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems
Correlation: Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples

Module-II
Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x
= a + by, Multiple regression, standard error of regression– Pharmaceutical Examples
Probability: Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems
Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples
Parametric test: t-test (Sample, Pooled or Unpaired and Paired) , ANOVA, (One way and Two way), Least Significance difference

Module-III
Non Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test
Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, plagiarism
Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph
Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Module-IV
Blocking and confounding system for Two-level factorials

Regression modeling: Hypothesis testing in Simple and Multiple regressionmodels
Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

Module-V

Design and Analysis of experiments:

Factorial Design: Definition, 22, 23design. Advantage of factorial design
Response Surface methodology: Central composite design, Historical design, Optimization Techniques

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest edition):

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

PHARMACEUTICAL REGULATORY SCIENCE

Course Code : PHA2804 **Credit Units: 04**

Course Objectives: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Content:

Module-I

New Drug Discovery and development: Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Module-II

Regulatory Approval Process: Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies: Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)

Module-III

Registration of Indian drug product in overseas market: Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.

Module-IV

Clinical trials: Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safetymonitoring in clinical trials

Module-V

Regulatory Concepts: Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended books (Latest edition):

- Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
- The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and
- Robert P. Martin, Drugs and the Pharmaceutical Sciences,Vol.185. Informa Health care Publishers.
- New Drug Approval Process: Accelerating Global Registrations By Richard A
- Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.
- Guidebook for drug regulatory submissions / SandyWeinberg. By John Wiley & Sons. Inc.
- FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
- Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
- Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
- Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
- Drugs: From Discovery to Approval, Second Edition By Rick Ng

PHARMACOVIGILANCE

Course Code : PHA2805 **Credit Units: 04**

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

Course Content:

Module-I

Introduction to Pharmacovigilance

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

Introduction to adverse drug reactions

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

Basic terminologies used in pharmacovigilance

Terminologies of adverse medication related events
Regulatory terminologies

Module-II

Drug and disease classification

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

Drug dictionaries and coding in pharmacovigilance

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

Information resources in pharmacovigilance

Basic drug information resources
Specialised resources for ADRs

Establishing pharmacovigilance programme

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

Module-III

Vaccine safety surveillance

Vaccine Pharmacovigilance

Vaccination failure

Adverse events following immunization

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series

Stimulated reporting

Active surveillance – Sentinel sites, drug event monitoring and registries

Comparative observational studies – Cross sectional study, case control study and cohort study

Targeted clinical investigations

Communication in pharmacovigilance

Effective communication in Pharmacovigilance

Communication in Drug Safety Crisis management

Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media

Module-IV

Safety data generation

Pre clinical phase

Clinical phase

Post approval phase (PMS)

ICH Guidelines for Pharmacovigilance

Organization and objectives of ICH

Expedited reporting

Individual case safety reports

Periodic safety update reports

Post approval expedited reporting

Pharmacovigilance planning

Good clinical practice in pharmacovigilance studies

Module-V

Pharmacogenomics of adverse drug reactions

Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population

Paediatrics

Pregnancy and lactation

Geriatrics

CIOMS

CIOMS Working Groups

CIOMS Form

CDSCO (India) and Pharmacovigilance

D&C Act and Schedule Y

Differences in Indian and global pharmacovigilance requirements

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest edition):

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

QUALITY CONTROL AND STANDARDIZATION OF HERBALS

Course Code : PHA2806 **Credit Units: 04**

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

Course Contents:

Module-I
Basic tests for drugs – Pharmaceutical substances, Medicinal plants materials and dosage
Forms WHO guidelines for quality control of herbal drugs.
Evaluation of commercial crude drugs intended for use

Module-II
Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine.
WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines
WHO Guidelines on GACP for Medicinal Plants.

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

Module-IV
Stability testing of herbal medicines.Application of various chromatographic techniques in standardization of herbal products.
Preparation of documents for new drug application and export registration
GMP requirements and Drugs & Cosmetics Act provisions.

Module-V
Regulatory requirements for herbal medicines.
WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems
Comparison of various Herbal Pharmacopoeias.
Role of chemical and biological markers in standardization of herbal products

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books: (Latest Editions

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

COMPUTER AIDED DRUG DESIGN

Course Code : PHA2807 **Credit Units: 04**

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

Course Content:

Module-I
Introduction to Drug Discovery and Development
Stages of drug discovery and development
Lead discovery and Analog Based Drug Design
Rational approaches to lead discovery based on traditional medicine,
Random screening, Non-random screening, serendipitous drug discovery, lead discovery based on drug metabolism, lead discovery based on clinical observation.
Analog Based Drug Design: Bioisosterism, Classification, Bioisosteric replacement. Any three case studies

Module-II
Quantitative Structure Activity Relationship (QSAR): SAR versus QSAR, History and development of QSAR, Types of physicochemical parameters, experimental and theoretical approaches for the determination of physicochemical parameters such as Partition coefficient, Hammet's substituent constant and Tafts steric constant. Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like
COMFA and COMSIA.

Module-III
Molecular Modeling and virtual screening techniques
Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening,
Molecular docking: Rigid docking, flexible docking, manual docking, Docking based screening. *De novo* drug design.

Module-IV
Informatics & Methods in drug design: Introduction to Bioinformatics, chemoinformatics. ADME databases, chemical, biochemical and pharmaceutical databases.

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

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest Editions)

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

COSMETIC SCIENCE

Course Code : PHA2809 **Credit Units: 04**

Course Contents :

Module-I

Classification of cosmetic and cosmeceutical products

Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs

Cosmetic excipients: Surfactants, rheologymodifiers, humectants, emollients, preservatives. Classification and application

Skin: Basic structure and function of skin.

Hair: Basic structure of hair. Hair growth cycle.

Oral Cavity: Common problem associated with teeth and gums**.**

Module-II

Principles of formulation and building blocks of skin care products: Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages.Application of these products in formulation of cosmecuticals.

Antiperspants & deodorants- Actives & mechanism of action.

Principles of formulation and building blocks of Hair care products: Conditioning shampoo, Hair conditioner,anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phylene diamine based hair dye. Principles of formulation and building blocks of oral care products: Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash.

Module-III

Sun protection, Classification of Sunscreens and SPF.

Role of herbs in cosmetics:

Skin Care: Aloe and turmeric

Hair care: Henna and amla.

Oral care: Neem and clove

Analytical cosmetics: BIS specification and analytical methods for shampoo, skincream and toothpaste**.**

Module-IV

Principles of Cosmetic Evaluation:Principles of sebumeter, corneometer. Measurement of TEWL, Skin Color, Hair tensile strength, Hair combing properties. Soaps,and syndet bars. Evolution and skin benfits.

Module-V

Oily and dry skin, causes leading to dry skin, skin moisturisation. Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes

Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. Antiperspirants and Deodorants- Actives and mechanism of action

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

References

- Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
- Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
- Text book of cosmelicology by Sanju Nanda & Roop K. Khar, Tata Publishers.

EXPERIMENTAL PHARMACOLOGY

Course Code : PHA2810 **Credit Units: 04**

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

Course Contents:

Module-I
Laboratory Animals:
Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia.

Module-II
Preclinical screening models
a. Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.
b. **Study of screening animal models for:** Diuretics, nootropics, anti-Parkinson's,antiasthmatics,
Preclinical screening models: for CNS activity- analgesic, antipyretic,anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease

Module-III
Preclinical Screening Models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, skeletal muscle relaxants, drugs acting on eye, local anaethetics

Module-IV
Preclinical screening models: for CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslepidemic, anti aggregatory, coagulants, and anticoagulants. Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics.
Research methodology and Bio-statistics: Selection of research topic, review of literature, research hypothesis and study design Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA. Graphical representation of data

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (latest edition):

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

ADVANCED INSTRUMENTATION TECHNIQUES

Course Code : PHA2811 **Credit Units : 04**

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

Course Content:

Module-I

Nuclear Magnetic Resonance spectroscopy: Principles of H-NMR and C-NMR, chemical shift, factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications

Mass Spectrometry- Principles, Fragmentation, Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications

Module-II

Thermal Methods of Analysis: Principles, instrumentation and applications of ThermogravimetricAnalysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC)

X-Ray Diffraction Methods: Origin of X-rays, basic aspects of crystals, Xray Crystallography, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

Module-III

Calibration and validation-as per ICH and USFDA guidelines

Calibration of following Instruments: Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, Fluorimeter, Flame Photometer, HPLC and GC

Module-IV

Radio immune assay: Importance, various components, Principle, different methods, Limitation and Applications of Radio immuno assay

Extraction techniques:General principle and procedure involved in the solid phase extraction and liquid-liquid extraction

Module-V

Hyphenated techniques-LC-MS/MS, GC-MS/MS, HPTLC-MS.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended Books (Latest Editions)

- Instrumental Methods of Chemical Analysis by B.K Sharma
- Organic spectroscopy by Y.R Sharma
- Text book of Pharmaceutical Analysis by Kenneth A. Connors
- Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
- Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
- Organic Chemistry by I. L. Finar
- Organic spectroscopy byWilliam Kemp
- Quantitative Analysis of Drugs by D. C. Garrett
- Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
- Spectrophotometric identification of Organic Compounds by Silverstein

DIETARY SUPPLEMENTS AND NUTRACEUTICALS

Course Code: PHA2812 **Credit Units: 04**

Course Objective: This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population.

Course Contents:

Module-I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, hypertension etc.

b. Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community.

c. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods: Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

Module-II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, leutin

b) Sulfides: Diallyl sulfides, Allyl trisulfide.

c) Polyphenolics: Reservetrol

d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones

e) Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum

f) Phyto estrogens : Isoflavones, daidzein, Geebustin, lignans

g) Tocopherols

h) Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like.

Module-III

a) Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.

b) Dietary fibres and complex carbohydrates as functional food ingredients..

Module-IV

a) Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.

b) Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin Synthetic antioxidants: Butylated hydroxy Toluene, Butylated hydroxy Anisole.

c) Functional foods for chronic disease prevention

Module-V

a) Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals.

b) Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.
c) Pharmacopoeial Specifications for dietary supplements and nutraceuticals.

Examination Scheme :

Components	CT	HA	S/V/Q	ATTD	EE
Weightage(%)	15	3	3	4	75

CT: Class Test, HA: Home Assignment, S/V/Q: Seminar/Viva/Quiz, ATTD: Attendance EE: End Semester Examination

Recommended books :

- Dietetics by Sri Lakshmi
- Role of dietary fibres and neutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
- Advanced Nutritional Therapies by Cooper. K.A., (1996).
- The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
- Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
- G. Gibson and C.williams Editors *2000 Functional foods* Woodhead Publ.Co.London.
- Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
- Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good
- Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
- Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
- Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

PROJECT WORK

Course Code: PHA2837 **Credit Units: 06**

Objectives:
The aim of the project work is to provide student with an opportunity to further intellectual and personal development in chosen field by undertaking a significant practical unit of activity, having an educational value at a level commensurate with the award of the degree. The project work can be defined as a scholarly inquiry into a problem or issues, involving a systematic approach to gathering and analysis of information / data, leading to production of a structured report.

The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages).

THE COMPONENTS OF A PROJECT REPORT
The outcome of Project Work is the Project Report. A project report should have the following components:
1) Cover Page: This should contain the title of the project proposal, to whom it is submitted, for which degree, the name of the author, name of the supervisor, year of submission of the project work, name of the University.
2) Acknowledgement: Various organizations and individuals who might have provided assistance /co-operation during the process of carrying out the study.
3) Table of Content: Page-wise listing of the main contents in the report, i.e., different Chapters and its main Sections along with their page numbers.
4) Body of the Report: The body of the report should have these four logical divisions

a. *Introduction:* This will cover the background, rationale/ need / justification, brief review of literature, objectives, methodology (the area of the study, sample, type of study, tools for data collection, and method of analysis), Limitations of the Study, and Chapter Planning.
b. *Conceptual Framework / National and International Scenario*: (relating to the topic of the Project).
c. *Presentation of Data, Analysis and Findings*: (using the tools and techniques mentioned in the methodology).
d. *Conclusion and Recommendations:* In this section, the concluding observations based on the main findings and suggestions are to be provided.

5) Bibliography or References: This section will include the list of books and articles which have been used in the project work, and in writing a project report.
6) Annexures: Questionnaires (if any), relevant reports, etc.
(The main text of the Project should normally be in the range of 5000 words. However, there may be annexure in addition to the main text)

THE STEPS OF PROJECT WORK
STEP I : Selection of the topic for the project by taking following points into consideration:

- Suitability of the topic.
- Relevance of the topic
- Time available at the disposal.
- Feasibility of data collection within the given time limit.
- Challenges involved in the data collection (time & cost involved in the data collection, possibility of getting responses, etc.)

STEP II : Finalisation of the Topic and preparation of Project Proposal in consultation with the Supervisor.
STEP III : Collection of information and data relating to the topic and analysis of the same.
STEP IV : Writing the report dividing it into suitable chapters, viz.,
Chapter 1: Introduction,
Chapter 2: Conceptual Framework / National & International Scenario,
Chapter 3: Analysis & Findings
Chapter 4: Conclusion and Recommendations.
STEP V : The following documents are to be attached with the Final Project Report.
1) Approval letter from the supervisor (Annexure-IA)
2) Student's declaration (Annexure-IB)
3) Certificate from the Competent Authority of the Organisation / Institution, if the student undertakes the Project Work in any Organisation / Institution.
Annexures, References / Bibliography

Guidelines for Evaluation:

- Each of the students has to undertake a Project individually under the supervision of a teacher and to submit the same following the guidelines stated below.
- Language of Project Report and Viva-Voce Examination may be English. The Project Report must be typed and hard bound.
- Failure to submit the Project Report or failure to appear at the Viva-voce Examination will be treated as "Absent" in the Examination. He /she has to submit the Project Report and appear at the Viva-Voce Examination in the subsequent years (within the time period as per University Rules).
- No marks will be allotted on the Project Report unless a candidate appears at the Viva-Voce Examination. Similarly, no marks will be allotted on Viva-Voce Examination unless a candidate submits his/her Project Report.
- Evaluation of the Project Work to be done jointly by one internal expert and one external expert with equal weightage, i.e., average marks of the internal and external experts will be allotted to the candidate.
- A candidate has to qualify in the Project Work separately, obtaining minimum marks of 80 (Dissertation Book and Presentation taken together).

Examination Scheme: Total-150 marks

Evaluation of Dissertation Book:

Objective(s) of the work done	15 Marks
Methodology adopted	20 Marks
Results and Discussions	20 Marks
Conclusions and Outcomes	20 Marks
	Total-75 Marks

Evaluation of Presentation:

Presentation of work	25 Marks
Communication skills	20 Marks
Question and answer skills	30 Marks
	Total-75 Marks