JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
B. PHARMACY IV YEAR COURSE STRUCTURE AND SYLLABUS

Effective from Academic Year 2017-18 Admitted Batch

IV Year I Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS701	Instrumental Methods of Analysis	3	1	0	4
2	PS702	Industrial Pharmacy-II	3	1	0	4
3	PS703	Pharmacy Practice	3	1	0	4
4	PS704	Novel Drug Delivery Systems	3	1	0	4
5	 PS705 PS706 PS707 PS708	**Open Elective - III** i. Pharmaceutical Marketing ii. Pharmaceutical Regulatory Science iii. Pharmacovigilance iv. Quality Control and Standardization of Herbals	3	1	0	4
6	PS709	Instrumental Methods of Analysis Lab	0	0	4	2
7	PS710	Practice School	0	0	4	2
8	PS711	Industrial Training	0	0	2	1
		Total	**15**	**5**	**10**	**25**

IV Year II Semester

S.No	Course Code	Course Title	L	T	P	Credits
1	PS801	Biostatistics and Research Methodology	3	1	0	4
2	PS802	Social and Preventive Pharmacy	3	1	0	4
3	PS803	Pharmaceutical Jurisprudence	3	0	0	3
4	 PS804 PS805 PS806 PS807	**Open Elective - IV** i. Computer Aided Drug Design ii. Nano Technology iii. Experimental Pharmacology iv. Advanced Instrumentation Techniques	3	1	0	4
5	PS808	Project Work	0	0	6	3
		Total	**12**	**3**	**6**	**18**

PS701: INSTRUMENTAL METHODS OF ANALYSIS

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

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

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

UNIT – I **10 Hours**

1. **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

2. **Fluorimetry**

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

UNIT – II **10 Hours**

1. **IR spectroscopy**
   Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations
   Instrumentation - Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermistor, Pyroelectric detector and applications
2. **Flame Photometry** - Principle, interferences, instrumentation and applications
3. **Atomic absorption spectroscopy** - Principle, interferences, instrumentation and applications
4. **Nepheloturbidometry** - Principle, instrumentation and applications

UNIT – III **10 Hours**

Introduction to chromatography

1. **Adsorption and partition column chromatography**- Methodology, advantages, disadvantages and applications.
2. **Thin layer chromatography**- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.
3. **Paper chromatography**- Introduction, methodology, development techniques, advantages, disadvantages and applications
4. **Electrophoresis**– Introduction, factors affecting electrophoretic mobility, Techniques of paper, gel, capillary electrophoresis, applications

UNIT – IV **08 Hours**

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

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

UNIT – V **07 Hours**

1. **Ion exchange chromatography** - Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications
2. **Gel chromatography** - Introduction, theory, instrumentation and applications
3. **Affinity chromatography** - Introduction, theory, instrumentation and applications

Recommended Books (Latest Editions):

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

PS702: INDUSTRIAL PHARMACY - II

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

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

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

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

UNIT – I **10 Hours**

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

UNIT – II **10 Hours**

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

UNIT – III **10 Hours**

1. **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
2. **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT – IV **08 Hours**

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

UNIT – V **07 Hours**

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

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php

3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' 2nd Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.
5. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition

PS703: PHARMACY PRACTICE

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

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 community pharmacy, students will be learning various skills such as dispensing safe medication and patient counseling.

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

- Know various drug distribution methods in a hospital
- Appreciate the pharmacy stores management and inventory control
- Monitor drug therapy of patient through medication chart review and clinical review
- Know pharmaceutical care services
- do patient counseling in community pharmacy

UNIT – I **10 Hours**

1. **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.
2. **Hospital pharmacy and its organization**
   Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.
3. **Community Pharmacy**
   Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

UNIT – II **10 Hours**

1. **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.
2. **Therapeutic drug monitoring**
   Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.
3. **Community pharmacy management**
   Financial, materials, staff, and infrastructure requirements.

UNIT – III **10 Hours**

1. **Drug information services**
   Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.
2. **Patient counseling**
   Definition of patient counseling; steps involved in patient counseling, and Special cases that require the pharmacist
3. **Education and training program in the hospital**
   Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

UNIT – IV **08 Hours**

1. **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.
2. **Over the counter (OTC) sales**
   Introduction and sale of over the counter, and Rational use of common over the counter medications.

UNIT – V **07 Hours**

Drug store management and inventory control

Organization 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

Recommended Books (Latest Edition):

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

PS704: NOVEL DRUG DELIVERY SYSTEMS

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

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

Course Outcomes: Upon completion of the course student shall be able:

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

UNIT – I **10 Hours**

1. **Controlled drug delivery systems:** Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations
2. **Polymers:** Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

UNIT – II **10 Hours**

1. **Microencapsulation:** Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications
2. **Mucosal Drug Delivery system:** Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems
3. **Implantable Drug Delivery Systems:** Introduction, advantages and disadvantages, concept of implantsand osmotic pump

UNIT – III **10 Hours**

1. **Transdermal Drug Delivery Systems:** Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches
2. **Gastroretentive drug delivery systems:** Introduction, advantages, disadvantages, approaches for GRDDS – Floating, high density systems, inflatable and gastroadhesive systems and their applications
3. **Nasopulmonary drug delivery system:** Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers

UNIT – IV **08 Hours**

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

UNIT – V **07 Hours**

1. **Ocular Drug Delivery Systems:** Introduction, intra ocular barriers and methods to overcome – Preliminary study, ocular formulations and ocuserts
2. **Intrauterine Drug Delivery Systems**: Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications

Recommended Books: (Latest Editions)

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

PS705: PHARMACEUTICAL MARKETING (Open Elective - III)

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

Course Objectives: The pharmaceutical industry not only needs highly qualified researchers, chemist, technical people but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. Sales & Marketing which grooms the people for taking a challenging role in Sales and Product management.

Course Outcome: Provide an understanding of marketing concepts and techniques and the application of the same in the pharmaceutical industry.

UNIT – I **10 Hours**

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

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

UNIT – II **10 Hours**

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

UNIT – III **10 Hours**

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

UNIT – IV **10 Hours**

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

Professional sales representative (PSR): Duties of PSR, purpose of detailing, selection and training, supervising, norms for customer calls, motivating, evaluating, compensation and future prospects of the PSR.

UNIT – V **10 Hours**

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

Emerging concepts in marketing: Vertical & Horizontal Marketing; Rural Marketing; Consumerism; Industrial Marketing; Global Marketing.

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche: Marketing Strategy- Planning and Implementation, Tata McGraw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata McGraw Hill

4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Management: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications.

PS706: PHARMACEUTICAL REGULATORY SCIENCE (Open Elective - III)

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

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

Course Outcomes: Upon completion of the subject student shall be able to:

- Know about the process of drug discovery and development
- Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- Know the regulatory approval process and their registration in Indian and international markets

UNIT – I **10 Hours**

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.

UNIT – II **10 Hours**

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

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

UNIT – III **10 Hours**

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.

UNIT – IV **08 Hours**

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 - safety monitoring in clinical trials

UNIT – V **07 Hours**

Regulatory Concepts: Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book

Recommended books (Latest edition):

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N. S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, 2nd Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.

5. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
6. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
8. Principles and Practices of Clinical Research, 2nd Edition Edited by John I. Gallin and Frederick P. Ognibene
9. Drugs: From Discovery to Approval, 2nd Edition by Rick N

PS707: PHARMACOVIGILANCE (Open Elective - III)

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

Course Objective: 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.

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

- Why drug safety monitoring is important?
- History and development of pharmacovigilance
- National and international scenario of pharmacovigilance
- International standards for classification of diseases and drugs
- Adverse drug reaction reporting systems and communication in pharmacovigilance
- Data during pre-clinical, clinical and post approval.
- Pharmacovigilance Program of India (PvPI)
- ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning

UNIT - I **10 Hours**

Introduction to Pharmacovigilance:

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

Introduction to adverse drug reactions:

a) Definitions and classification of ADRs
b) Detection and reporting
c) Methods in Causality assessment
d) Severity and seriousness assessment
e) Predictability and preventability assessment

Basic terminologies used in pharmacovigilance:

a) Terminologies of adverse medication related events
b) Regulatory terminologies

UNIT – II **10 hours**

Drug and disease classification:

a) Anatomical, therapeutic and chemical classification of drugs
b) International classification of diseases
c) Daily defined doses

Drug dictionaries and coding in pharmacovigilance:

a) WHO adverse reaction terminologies
b) MedDRA and Standardized MedDRA queries
c) WHO drug dictionary

Information resources in pharmacovigilance:

a) Basic drug information resources

Establishing pharmacovigilance programme:

a) Establishing in a hospital
b) Establishment & operation of drug safety department in industry
c) Contract Research Organizations (CROs)

UNIT – III **10 Hours**

Vaccine safety surveillance:

a) Vaccine Pharmacovigilance
b) Vaccination failure
c) Adverse events following immunization

Pharmacovigilance methods:

a) Passive surveillance – Spontaneous reports and case series
b) Stimulated reporting
c) Active surveillance – Sentinel sites, drug event monitoring and registries
d) Comparative observational studies – Cross sectional study, case control study and cohort study
e) Targeted clinical investigations

UNIT – IV **08 Hours**

Statistical methods for evaluating medication safety data

Safety data generation:

a) Pre-clinical phase
b) Clinical phase
c) Post approval phase

ICH Guidelines for Pharmacovigilance:

a) Organization and objectives of ICH
b) Expedited reporting
c) Individual case safety reports
d) Periodic safety update reports
e) Post approval expedited reporting
f) Pharmacovigilance planning
g) Good clinical practice in pharmacovigilance studies

UNIT – V **07 hours**

Pharmacogenomics of adverse drug reactions:

Drug safety evaluation in special population

a) Pediatrics
b) Pregnancy and lactation
c) Geriatrics

Recommended Books (Latest edition):

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.

6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones& Bartlett Publishers.

7. Textbook of Pharmacoepidemiolog edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. http://www.whoumc.org/DynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297
13. http://www.ich.org/
14. http://www.cioms.ch/
15. http://cdsco.nic.in/
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

PS708: QUALITY CONTROL AND STANDARDIZATION OF HERBALS (Open Elective - III)

B.Pharm. IV Year I Sem. L/T/P/C 3/1/0/ 4

Course Objective: 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 Outcomes: Upon completion of the subject student shall be able to:

- Know WHO guidelines for quality control of herbal drugs
- Know Quality assurance in herbal drug industry
- Know the regulatory approval process and their registration in Indian and international markets
- Appreciate EU and ICH guidelines for quality control of herbal drugs

UNIT – I **10 hours**

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

UNIT – II **10 hours**

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

UNIT – III **10 hours**

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

UNIT – IV **08 hours**

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

UNIT – V **07 hours**

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

Recommended Books: (Latest Editions)

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-.

8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
10. 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.
11. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

PS709: INSTRUMENTAL METHODS OF ANALYSIS LAB

B.Pharm. IV Year I Sem. L/T/P/C 0/0/4/ 2

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

Recommended Books (Latest Editions):

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

PS710: PRACTICE SCHOOL

B.Pharm. IV Year I Sem. L/T/P/ C
0 /0/4/ 2

Course Objectives: Practice school is an educational innovation seeking to link industry/hospital/ pharmacy experience with university instruction. The student will:

- Meet the rapidly changing needs and challenges of a professional work place.
- Acquire knowledge and skills.
- Bear an economic relevance to the society.

Course Outcome: Institutionalized linkage between university/college and industry. Student's involvement in real life projects continues internal evaluation and monitoring the faculty help by student to understand the practical issues. After successful completion of 150 hrs, the students will submit the detailed report in the following field.

Note: Any domains relevant to pharmacy can be given to students. Following domains for for reference

Industry oriented PS:
It comprises industry visits and interactions with executives to facilitate the process of learning by observations and discussions duly aided by the check list. It promotes learning by doing in various departments like production quality control and assurance, R&D etc. Taking one issue and working on it for prescribed hours and submit the report.

Hospital oriented PS:
The student is asked to visit the hospitals and work on some case studies like cardiovascular, diabetics, gastrointestinal, gynecological, pulmonary pediatric etc. related cases of some 5 to 6 to be studied and detailed data to be submitted.

Retail pharmacy-oriented PS:
The students have to visit different pharmacy shops and collect the data related to the most prescribed medicines in that area, prescription patterns, medical audit etc and submit the report.

Election of medicinal plants orientated PS:
The students have to visit medicinal plant gardens and collect some medicinal plants those are useful to various disorders and submit the report in detail about the plants they come across during their study period

Regulatory affairs: collect and analyse the regulatory affairs. Some important cases filed by drug control officers to be analysed and reported.

National poison centre: visit the local poison centre and write the relevant matter

Formulation aspects: Formulations using any equipments which otherwise are not usually used for regular practicals

PS801: BIOSTATISTICS AND RESEARCH METHODOLOGY

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

Course Objectives: To understand the applications of Biostatics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies.

Course Outcomes: Upon completion of the course the student shall be able to

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

UNIT – I **10 Hours**

Introduction: Statistics, Biostatistics, Frequency distribution

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

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

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

UNIT – II **10 Hours**

Regression: Curve fitting by the method of least squares, fitting the lines y= a + bx and x = a + by, Multiple regression, standard error of regression– Pharmaceutical Examples.

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

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

UNIT – III **10 Hours**

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

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

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

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

UNIT – IV **8 Hours**

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R - Online Statistical Software's to Industrial and Clinical trial approach

UNIT – V **7 Hours**

Design and Analysis of experiments:

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

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

Recommended Books (Latest edition):

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

PS802: SOCIAL AND PREVENTIVE PHARMACY

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

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

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

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

UNIT – I **10 Hours**

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

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

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

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

UNIT – II **10 Hours**

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

UNIT – III **10 Hours**

National health programs, its objectives, functioning and outcome of the following: HIV and AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National
programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

UNIT – IV **08 Hours**

National health intervention programme for mother and child, national family welfare programme, national tobacco control programme, national malaria prevention program, national programme for the health care for the elderly, social health programme; role of *who in indian national program

UNIT – V **07 Hours**

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

Recommended Books (Latest edition):

1. Short Textbook of Preventive and Social Medicine, Prabhakara G N, 2nd Edition, 2010, ISBN: 9789380704104, JAYPEE Publications
2. Textbook of Preventive and Social Medicine (Mahajan and Gupta), Edited by Roy Rabindra Nath, Saha Indranil, 4th Edition, 2013, ISBN: 9789350901878, JAYPEE Publications

3. Review of Preventive and Social Medicine (Including Biostatistics), Jain Vivek, 6th Edition, 2014, ISBN: 9789351522331, JAYPEE Publications
4. Essentials of Community Medicine - A Practical Approach, Hiremath Lalita D, Hiremath Dhananjaya A, 2nd Edition, 2012, ISBN: 9789350250440, JAYPEE Publications
5. Park Textbook of Preventive and Social Medicine, K Park, 21st Edition, 2011, ISBN-14: 9788190128285, Banarsidas Bhanot Publishers.
6. Community Pharmacy Practice, Ramesh Adepu, BSP publishers, Hyderabad

PS803: PHARMACEUTICAL JURISPRUDENCE

B.Pharm. IV Year II Sem. L/T/P/ C
3/0/0/ 3

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

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

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

UNIT – I **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945:

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

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

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

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

UNIT – II **10 Hours**

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

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

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

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

UNIT – III **10 Hours**

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

Medicinal and Toilet Preparation Act -1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

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

UNIT – IV **08 Hours**

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

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

UNIT – V **07 Hours**

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

Recommended books: (Latest Edition)

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

PS804: COMPUTER AIDED DRUG DESIGN (Open Elective - IV)

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

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

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

UNIT – I **10 Hours**

Introduction to Drug Discovery and Development: Stages of drug discovery and development

Lead discovery and Analog Based Drug Design

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

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

UNIT – II **10 Hours**

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

UNIT – III **10 Hours**

Molecular Modeling and virtual screening techniques

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

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

UNIT – IV **08 Hours**

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

UNIT – V **07 Hours**

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

Recommended Books (Latest Editions):

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Prak Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.

5. Koro Ikovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.

PS805: NANO TECHNOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

Course Objectives: To develop expertise regarding suitability and evaluation of nanomaterials, able to apply the properties to the fabrication of nanopharmaceutical, evaluate the intensity of dosage forms and availability for targeting and controlled delivery.

Course Outcomes: The students should be able to select the right kind of materials, able to develop nano formulations with appropriate technologies, evaluate the product related test and for identified diseases

UNIT - I

Introduction to Nanotechnology

a. Definition of nanotechnology
b. History of nanotechnology
c. Unique properties of nanomaterials
d. Classification of nanomaterials

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UNIT - II

Synthesis of Nanomaterials

Methods for synthesis of:

a. Gold nanoparticles
b. Magnetic nanoparticles
c. Polymeric nanoparticles
d. Self – assembly structures such as liposomes, Niosomes, micelles, aquasomes and nanoemulsions

UNIT - III

Biomedical applications of Nanotechnology

a. Nanotechnology products used for in vitro diagnostics
b. Applications in imaging and targeting.

UNIT - IV

Design of nanomaterials for drug delivery, pulmonary, nasal drug delivery, cardiovascular diseases and localized drug delivery systems.

UNIT - V

Characterization, drug release and stability studies of nanomaterials

Recommended Books (Latest Editions):

1. Nanomedicine and Nanoproducts: Applications, Disposition and Toxicology in the Human body, Eiki Igarashi, CRC press. 2015
2. Nanotechnology and Drug Delivery Volume one and two: Nanoplatforms in Drug Delivery, Jose L. Arias, CRC press
3. Nano: The Essentials: Understanding Nanosicence and Nanotechnology, T. Pradeep, Tata McGraw-Hill Publishing Company Limited, New Delhi, 2008.
4. Nanocrystals: Synthesis, Properties and Applications, C. N. R. Rao, P.J. Thomas and G.U. Kulakarni, Springer (2007)
5. Nanostructures and Nanomaterials: Synthesis, Properties and Application, Guozhong Gao, Imperial College Press (2004)

6. Nano chemistry: A Classical Approach to Nanomaterials – Royal Society for Chemistry, Cambridge, UK (2005)
7. Nanocomposite science and technology, pulickel M. Ajayan, Linda S. Schadler, paul V. Braun, Wiley-VCH Verlag, Weiheim (2003)
8. Nanoscale materials in chemistry, Edited by Kenneth J. Klabunde, John Wiley & Sons, 2009
9. Nanoparticles as Drug carriers, Vladimir P Torchiling, Imperial College Press, USA, 2006
10. Introduction to Nano Science and Technologies, Ankaneyulu Yerramilli, BS Publications. 2016

PS806: EXPERIMENTAL PHARMACOLOGY (Open Elective - IV)

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

Course Objectives: This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines.

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

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals and newer screening methods used in the drug discovery
- Understand the Research methodology to be followed Bio-statistical data interpretation of the assays

UNIT - I

Laboratory Animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia

UNIT - II

Preclinical screening models: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups

UNIT - III

Preclinical screening models: for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics and skeletal muscle relaxants.

UNIT - IV

Preclinical screening models for diuretics, anticoagulants and anticancer activities

UNIT - V

Research methodology and Bio-statistics, Selection of research topic, review of literature, research hypothesis and study design, Interpretation using Student't' test and One-way ANOVA. Graphical representation of data.

Recommended Books (Latest Editions):

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin.
2. Screening methods in Pharmacology by Robert Turner. A.
3. Methods in Pharmacology by Arnold Schwartz.
4. Pharmacological screening methods and Toxicology by A Srinivasa Rao and N. Bhagya Lakshmi
5. Fundamentals of experimental Pharmacology by M. N. Ghosh.
6. Experimental Pharmacology for undergraduates by M C Prabhakara.
7. Drug discovery and Evaluation by Vogel H. G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S.K. Gupta.
10. Handbook of Experimental Pharmacology, S K. Kulkarni.
11. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
12. Screening Methods in Pharmacology, Robert A. Turner.

PS807: ADVANCED INSTRUMENTATION TECHNIQUES (Open Elective - IV)

B.Pharm. IV Year II Sem. L/T/P/ C
3/1/0/ 4

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

- Understand the advanced instruments used and its applications in drug analysis
- Understand the chromatographic separation and analysis of drugs.
- Understand the calibration of various analytical instruments
- Know analysis of drugs using various analytical instruments.

UNIT – I **10 Hours**

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, instrumentation and applications.

UNIT - II **10 Hours**

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

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

UNIT - III **10 Hours**

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

UNIT – IV **08 Hours**

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

UNIT – V **07 Hours**

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

Recommended Books (Latest Editions):

1. Instrumental Methods of Chemical Analysis by B. K Sharma
2. Organic spectroscopy by Y. R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar

7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein