

PHYSICAL PHARMACY – II

Subject Code : PY.07.881.6.2.T

Periods / Week: 4credits:4

Nature of Exam: Theory

Sessional : 30

Examination : 70

Exam Duration: 3 Hrs

Unit – I

Solubility and Distribution Phenomena

Definitions, Expressions, Phase rule, Solvent - Solute interactions - polar solvents and semipolar solvents, Solubility of gases in liquids - effect of pressure and temperature, Salting out, Effect of chemical reactions, Solubility calculations. Solubility of liquids in liquids ideal and real solutions, Complete and partial miscibility, Influence of foreign substances, Three component systems, Dielectric constant and solubility. Solubility of solids in liquids Ideal and non ideal solutions solvation and association in solutions. Solubility of salts in water, Solubility of slightly soluble and weak electrolytes, Calculating solubility of weak electrolytes as influenced by pH, Influence of solvents on the solubility of drugs, Combined effect of solvents. Distribution of solutes between immiscible solvents - Effect of ionic dissociation and molecular association on partition & extraction, Solubility and partition coefficients, Preservative action of weak acids in emulsions, Drug action and partition coefficients.

Unit – II

Chemical Kinetics

Rates and orders of reactions - Rate, order of reaction, Molecularly, Specific rate constant, Units of basic rate constants, Mathematical treatment of rates.

Apparent zero order kinetics. First order reactions. Second order reactions. Determination of order of a reaction. Elementary and complex reactions. Specific and general acid base catalysis. Influence of temperature and other factors on reaction rates - Effect of solvents, Ionic strength, Dielectric constant, Catalysts and light. Decomposition and destabilization of medicinal agents against hydrolysis, Oxidation. Kinetics in the solid state. Accelerated stability analysis.

Unit – III

Interfacial Phenomena

Introduction, liquid interphases - Surface and interfacial tensions, Surface free energy, measurement of surface and interfacial tensions, Spreading coefficient. Adsorption at liquid interfaces - Surface active agents, Systems of hydrophilic - Lipophilic classification, Solubilization and detergency. Types of monolayer at liquid surfaces, applications of amphiphiles. Adsorption at solid interfaces - Solid/Gas interface - Solid/Liquid interface. Electric properties of interfaces - Electric double layer, Nernst and zeta potentials.

Unit – IV

Colloids and Micromeritics

Dispersed systems, Size and shape of colloidal particles - pharmaceutical application, Types - Lipophilic, Lipophobic and Association colloids, Comparison of properties of colloidal sols; Optical, Kinetic and Electric properties of colloids, Solubilization gels - Structure, Properties and Applications.

Particle size and size distribution - average particle size, particle size distribution, number and weight distributions, Particle number; Methods for determining particle size - optical microscopy, sieving, Sedimentation, Particle volume measurement, Particle shape and surface area, Methods for determining surface area - Absorption methods, Air permeability methods; Derived properties of powders - Porosity, Packing arrangements, Densities, bulkiness, Flow properties.

Unit – V

Rheology and Polymers

Rheology of Pharmaceutical Fluids: Newtonian and Non-Newtonian Systems;

Newtonian systems - Laws of flow, Kinematic viscosity, Effect of temperature.

Non newtonian systems - Plastic and Pseudoplastic dilatant flow.

Thixotropy - Measurement of thixotropy, Thixotropy in formulation.

Determination of rheologic properties - choice of viscometer, Capillary, falling sphere, Cup and bob, and cone and plate viscometers. Psychorheology. Applications to pharmacy.

Polymers: Definition, Types of Polymers, Water Soluble and Water Insoluble Polymers;

Polymers as Thickening Agents; Pharmaceutical Application of Polymers;

Examination: One question from each unit with internal choice.

Text Books

- 1. A.N. Martin, Arthur Cammarata and J. Swarbrick, Physical Pharmacy by 3rd ed, K.M. Varghese & Co, Bombay.**
- 2. C.V.S. Subrahmanyam, Textbook of Physical Pharmaceutics, 2nd Edition, Vallabh Prakashan, Delhi, 2004.**

Reference books

- 1. Tutorial Pharmacy by Cooper & Gunn, ed S.J. Carter, CBS Publishers, Delhi.**
- 2. Physical Pharmaceutics by Shotton & Ridgway, Oxford University press, London.**
- 3. Remington's Pharmaceutical Sciences, ed A.R. Gennaro, Mack publishing Co, PA.**

PHARMACOLOGY – II

Subject Code: PY.07.881.6.2.T

Periods/week: 04 credits:4

Nature of Exam: Theory

Hrs

Sessional : 30

Examination : 70

Exam Duration: 3

Unit – I

Chemotherapy of Infections and Cancer

Basic Principles of Chemotherapy; Systemic Pharmacological study of Anti-bacterial, Antiviral, Anti-fungal, Anti-protozoal and Anti-helmenthic drugs; Cancer Chemotherapy

Unit – II

Pharmacology of Autocoids: Local Hormones

Anti-histamines: Histamine, Serotonin and ergot alkaloids; Vasoactive principles; Eicosanoids; Prostagladins, Thromboxanes, Leukotrines and related compounds. Nitric oxide, Donors and inhibitors. Para Drugs acting on blood and blood forming agents - Coagulants, Anti-coagulants, Haematinics (iron, vitamin-B12, Folic acid) and Thrombolytic Agents.

Unit – III

Pharmacology of Endocrine System

Systemic Pharmacological study of Pituitary Hormones, Sex Hormones, Oral Contraceptives, Oxytocics and Uterine relaxants; Pharmacology of thyroid and Anti-thyroid drugs, Insulin, Oral hypoglycemics, Glucagon and Adrenocortico steroids;

Unit – IV

Bioethics and Bioassay Of Some Selective Drugs

Principles of Bioethics, Bioethics of Animals used in Bioassay studies; Principles of Bioassays; Official Bioassays; Biological assay of anti-haemophilic fraction, Heparin sodium, Chorionic gonadotropin, Corticotropin, Insulin, Oxytocin, Vasopressin and Adrenaline; Biological assay of diptheria anti-toxin, anti-rabies vaccine, tetanus anti-toxin and old tuberculin vaccine;

Unit – V

Toxicology of Drugs and Clinical Pharmacology

Principles of Toxicology; Definition of Poison; General principles of treatment of poisoning with special reference to barbutirates, Opium and Organophosphorus toxicity;

Treatment of Poisoning for the following toxins: Methyl Alcohol, Heavy metals, Paracetamol and Digitalis

Introduction to Clinical pharmacology and Phases of clinical trials;

Examination: One question from each unit with internal choice.

Text Books

- 1. Essentials of Medical Pharmacology, K.D. Tripathi., Jaypee Brothers Medical Publishers**
- 2. Pharmacology and Pharmacotherapeutics., R.S.Saathoskar and S.D. Bandarkar., Popular Prakashan, Mumbai.,**
- 3. Text Book of Pharmacology by Rang and Dale**

Reference Books

- 1. Goodman and Gilman's: "The Pharmacological basis of Therapeutics" by Joel G. Hardman and Lee E. Limbard., Pergamon Press**
- 2. Lewis's Pharmacology by J. Crossland., Churchill Livingstone Publications**
- 3. Basic and Clinical Pharmacology by Katzung B.G., Prentice-Hall**
- 4. Clinical pharmacology by Lanzence**

PHARMACOGNOSY-II

Subject Code : PY.07.881.6.3.T

Periods / Week: 4 credits:4

Nature of Exam: Theory

Hrs

Sessional : 30

Examination : 70

Exam Duration: 3

Systematic Pharmacognostic study, which includes sources (Biological and Geographical) diagnostic characters, chemical constituents, chemical tests, uses, substituents and adulterants of the crude drugs mentioned in the following units. **MICROSCOPICAL CHARACTERS OF ONLY THE DRUGS UNDERLINED SHALL BE STUDIED.**

Unit – I

Alkaloids

Introduction, definition, classification, isolation, tests, chemical nature and uses of Rauwolfia, Vinca, Nuxvomica, opium, ipecac, belladonna, datura, lobelia, vasaka, kurchi, ephedra, cinchona, colchicum, aconite, punemava, shankhpushpi, tobacco.

Unit – II

Glycosides

Introduction, Definition, Classification, Isolation, tests, chemical nature and uses of Senna, aloes, rhubarb, digitalis, squill, dioscoreia, liquorice, momordica, black mustard, ammi, psoralea, gentian, picrorrhiza, ashwagandha, gokhru, kalmegh, stropanthus, shatavari, brahmi, quassia, gymnema.

Unit – III

Phytopharmaceuticals

Chemistry, Tests, Isolation, Characterization and Estimation of Following Constituents 1. Sennosides from Senna 2. Caffeine from tea 3. Cineole from eucalyptus oil 4. Quinine from cinchona 5. Carvone from dill 6. Tannic acid from myrobalan 7. Rutin, hesperidin from citrus fruits.

Introduction, definition, classification, isolation, tests, chemical nature and uses of Volatile Oils and Resins from following Plant Sources: Fennel, Clove, Cinamon, Gaultheria oil, Artemisia, Taxus, Capsicum, Turmeric, Podophyllum, Guggul Asafoetida and Pyrethrum.

Unit – IV

Tissue Culture

History, introduction, callus culture, suspension culture, Immobilization of culture, single cell culture, organogenesis and embryo culture.

Production of secondary metabolites, biotransformation and clonal propagation, Significance and application of plant tissue culture.

Unit – V

Herbal Medicines

Herbal medicines in India, practice, regulations, Quality Control and Standardization of Raw Materials. Types of herbal formulations and products.

Some Traditional Plant Medicines as a source of New Drugs

Introduction to dosage form of Ayurveda - Aristavas, Asawas, Chumas, Bhasma, Leyhas, Ghrityams, Rasayanam and Kashayams.

Examination: One question from each unit with internal choice.

Text Books

- 1. Trease and Evans, Pharmacognosy by W.C. Evans, Elsevier Ltd., London, UK/ Vailliers Tindal Easbourn UK.**
- 2. Pharmacognosy by C.K. Kokate, Nirali Publication, Pune.**
- 3. Pharmacognosy by T.E. Wallis CBS publishers and Distributors, Delhi.**

Reference Books

- 1. The Ayurvedic pharmacopoeia of India I-III Govt. of India, Ministry of Health and Family Welfare Dept. of Indian system of medicine and Homeopathy, New Delhi.**
- 2. Herbal Drug Industry, Eastern publishers, New Delhi.**
- 3. Natural Products by O.P. Agarwal Vol.I & II Goel publications, Meerut.**
- 4. Text Book of Pharmacognosy by Brady & Taylor.**
- 5. Tissue culture and plant science by street**
- 6. An Introduction to plant Tissue culture by M.K. Razdan, Oxford & IBH publishing Co. Pvt. Ltd. – New Delhi & Calcutta.**

**FORENSIC PHARMACY
(PHARMACEUTICAL JURISPRUDENCE)**

Subject Code : PY.07.881.6.4.T
Periods/week : 04 credits:4
Nature of Exam: Theory
Hrs

Sessional : 30
Examination : 70
Exam Duration: 3

Unit – I

- 1. Evolution of Pharmaceutical and Drug Legislation in India.**
- 2. The Pharmacy Act 1948.**
- 3. Code of Pharmaceutical Ethics.**
- 4. Consumer protection Act 1986.**
- 5. Narcotic and Psychotropic substances Act 1985.**

Unit – II

Drugs and Cosmetics Act 1940 and Drugs & Cosmetic Rules 1945 (also amendments).

- 1. Administration of the Act – The controlling and licensing regulation at state level and central level (the organisation, function and duties of state and central drug control authorities).**
- 2. Drugs & Cosmetic Act Rules – the provisions related to**
 - a. The manufacture of drugs (other than homeopathic) including schedule C, C(1), F, F(1) and X drugs and cosmetics.**
 - b. The sale and distribution of drugs (other than homeopathic) including schedule C, C(1), F, F(1) and X drugs and cosmetics.**

Unit – III

Drugs & Cosmetics Act Rules

- 1. (i.) The import and export of drugs & cosmetics.**
(ii) Labelling and packing requirements for all categories of drugs & cosmetics.
- 2. (i.) List of schedules to the Drugs & Cosmetics Rules.**
(ii.) Detailed study of schedule M (new), U and Y.
- 3. Medicinal & Toilet preparations (Excise Duties) Act 1955.**

Unit – IV

- 1. Drugs and magic Remedies (Objectionable Advertisements) Act 1954.**
- 2. Prevention of Food Adulteration Act 1954 (salient features)**
- 3. The Factories Act 1948 and the Amendment (salient features.).**

Unit – V

IPR's and Patent Laws

- 1. Intellectual Property Rights – a brief introduction to various IPR's.**
- 2. Indian Patent Act 1970 and the Amendments to the Act (upto date with reference to WTO Agreement)**

a. Introduction & Objectives

b. Inventions and Not inventions according to the Act.

c. Procedure of obtaining patent for drugs and pharmaceuticals.

3. Drug Price Control Order (Latest).

4. Pharmaceutical Policy 2002.

Examination: One question from each unit with internal choice.

Text Books

1. Forensic Pharmacy by B.M. Mithal, Vallabh Prakashan.

2. Forensic Pharmacy by Dr. B.S. Kuchekar, A.M. Khadatare and Sachin C. Itkar, Nirali Prakashan, Pune.

3. Drugs and Cosmetics Act 1940 by Vijay Malik, Eastern Book Company, Lucknow.

Reference Books

1. Bare Acts, published by Govt. of India.

2. Patent Act 1970 with patent Rules , published by Taxman Allied services (P) Ltd., 59132, New Rohtak Road, New Delhi – 110005.

3. ISO, International Organisation for Standardisation, Switzerland, 1994.

PHARMACOTHERAPEUTICS

Scheme of Instruction

Total Duration	: 45 hrs
Periods / Week	: 3
Credits	: 3
Instruction Mode	: Lecture
Subject Code	: FY.07.881.6.5.T

Scheme of Examination

Maximum Marks	: 100
Internal Exam	: 30
End Semester	: 70
Exam Duration	: 3 Hrs

Course Objectives

To train the students in the drug therapy management of different diseases. To develop the skills in students to identify and resolve any drug related problems. To appreciate the quality of medicines.

Course Outcomes

Describe and explain the rationale for drug therapy. Summarize the therapeutic approach for management of these diseases including reference to latest available evidence. Discuss the preparation of individualized therapeutic plans based on diagnosis. Describe the etiology, incidence, and prognosis associated with all disease states discussed.

Unit-I

- **Introduction:** Etiopathogenesis and pharmacotherapy of diseases associated with the following systems.
- **Cardiovascular system:** hypertension, congestive heart failure, angina pectoris, myocardial infarction, hyperlipidaemias, electrophysiology of heart and arrhythmias.
- **Respiratory system:** Introduction to pulmonary function test, asthma, chronic obstructive airway disease, drug induced pulmonary diseases.

Unit-II

- **Endocrine system:** diabetes, thyroid diseases, oral contraceptives, hormone replacement therapy, osteoporosis.
- **Ophthalmology:** glaucoma, conjunctivitis—viral and bacterial.

Unit-III

General prescribing guidelines for

- a. Paediatric patients.
- b. Geriatric patients,
- c. Pregnancy and lactation.

Unit-IV

Infectious diseases: guidelines for the rational use of antibiotics and surgical prophylaxis, tuberculosis, meningitis, respiratory tract infections, gastroenteritis, endocarditis, septicaemia, urinary tract infections, protozoal infection, HIV & opportunistic infections, fungal infections, viral infections, gonorrhoea and syphilis.

Unit-V

- **Musculoskeletal Etiopathogenesis and pharmacotherapy :** rheumatoid arthritis, osteoarthritis, gout, spondylitis, systemic lupus.
- **Oncology:** basic principles of cancer therapy, introduction to cancer chemotherapeutic agents, chemotherapy of breast cancer, leukemia, management of chemotherapy nausea and emesis.
- **Dermatology:** psoriasis, scabies, eczema, impetigo.

TEXT BOOKS

1. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Pathophysiologic approach-Joseph T. Dipiro et .al Appleton & Lange.

REFERENCE BOOKS

1. Pathologic basis of disease –Robins SL, W.B. Saunders publication
2. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice- Green and Harris, Chapman and Hall publication
3. Clinical pharmacy and Therapeutics- Eric. T. Herfindal, Williams and Wilkns publication
4. Applied therapeutics: The clinical use of Drugs.Lloyd and Koda- Kimble MA
5. Avery's Drug treatment, 4th edi, 1997, Adis International Limited

QUALITY ASSURANCE

Scheme of Instruction

Total Duration	: 60 Hrs.
Hours/Week	: 3 Hrs.
Credits	: 3
Instruction Mode	: Lecture
Course Code	: PY.09.885.15.T

Scheme of Examination

Max. Marks	: 100
Mid Semester	: 20
Quiz	: 05
End Semester	: 75
Exam Duration	: 3 Hrs.

Course Objectives:

Achieve comprehensive understanding and acquiring professional competency in global quality standards systems and regulatory requirements in the pharmaceutical industry.

Develop and implement a robust quality assurance system in an organization towards quality excellence

Course Outcomes:

This subject is aimed at giving knowledge about concepts of quality assurance,

- Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
- Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
- Understand the importance of effective documentation and formula for various operating procedures in Pharmaceutical industry.

Unit - I :

Basic Quality Assurance Systems: Basic concept of quality control & quality assurance, functions, sources of variation, quality assurance for raw materials, APIs, packing materials & finished products (specifications, receipt, testing, sampling and certificate of analysis), production (change control, aseptic process control, temperature, pressure & humidity control tests, tests for air flow pattern, microbiological monitoring) buildings & facilities (design and construction features, construction materials, lighting, air handling systems, sanitation & maintenance) equipments (construction, cleaning and maintenance, calibration & handling).

Unit - II :

In-Process Quality Control: Importance, inspection, IPQC tests for tablets (weight variation, hardness, thickness, friability, disintegration tests and content uniformity), suspensions and emulsions (appearance and feel, volume check, viscosity, particle size distribution, electrical conductivity and content uniformity) and parenterals (pH, volume check, clarity, content uniformity, integrity of seals and particulate matter). Problems encountered and trouble shooting.

Unit - III

Quality Systems: ISO- Quality Concepts, Quality Management – Vocabulary, ISO 9000 series- Standards, Guidelines and Selection, Requirements, ISO - Certification Procedure, ISO 14000.

Audits: GMP compliance audit, Definition summary, Audit policy, Internal and External Audits, Second Party Audits, External third party audits.

Unit - IV :

Quality Control Laboratory: Scope, Organization, Personnel – Desirable Qualities of Analyst, Responsibilities of Key Personnel in the Quality Control Lab. Operation Systems and Procedures in QC Lab, Analytical Worksheet, Test Methods, Evaluation of Test Results. Safety Guidelines in QC Lab.

Documentation: Good Documentation Practices, Root Cause Analysis, Corrective Action Preventive Action (CAPA), Out of Specifications (OOS) and Out of Trend (OOT);

Unit - V :

Impurity Profile: Sources of Impurities, their Effect on Drug Stability and Therapeutic Action. Determination of Impurities in Bulk Drugs and Formulation - Isolation, Characterization, Analytical Methods and Guidelines as per ICH and WHO for Impurity and Related Substances, Concept of Purity Angle, Threshold and Flag;

Study of Compendia: Evolution, Study of Parts of Compendia like: Policies, General Notices, Monographs, Comparative Picture of IP, USP, BP.

Books and References:

1. Gupta SC. Fundamentals of Statistics. 6th Ed., Himalaya publishing house, Hyderabad, 2004.
2. Sharma PP. How to Practice GMPs, 4th ed., Vandana Publications Pvt. Ltd., Delhi, 2004.
3. Sharma PP. How to Practice GLP, Vandana Publications Pvt. Ltd., Delhi, 2000.
4. Quality Assurance of Pharmaceutical (A Compendium of Guidelines and Selected Materials) Vol. I & II, WHO, Geneva, Pharma Book Syndicate, Hyderabad, 2002.
5. Basic Tests for Pharmaceutical Substances, WHO, Geneva, All India traveler book seller, India, 1990.
6. The International Pharmacopoeia, Vol. I-II, 3rd ed., WHO, Geneva, 1981.
7. Mehra ML. Good Manufacturing Practices (GMP), University Book Agency.
8. Subrahmanyam.CVS, Pharmaceutical Production and Management 2005, Vallabh Prakashan, New Delhi.
9. D.A. Berry, Statistical Methodology in Pharmaceutical Science, Marcel Dekker, NY.
10. DH Shah, Quality Assurance Manual: Business Horizons, New Delhi.
11. Y. Anjaneyulu, R. Marayya. Quality Assurance and Quality Management in Pharmaceutical Industry, Pharma Book Syndicate, Hyderabad

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PHYSICAL PHARMACY PRACTICALS

Subject Code : PY.07.881.6.6.P

Periods / Week: 6

Nature of Exam: Practical

Sessional : 25

Examination : 50

Exam Duration: 4 Hrs

List of Experiments

Minimum 12 experiments of the following shall be conducted

1. Determination of bulk density and flow properties of powders/ granules.
2. Determination of viscosity of liquids using Ostwald viscometer/ Redwood viscometer.
3. Determination of surface tension by stalagmometer method.
4. Determination of HLB of surfactant- Saponification method.
5. Determination of CMC of a surfactant-Drop count method using stalagmometer.
6. Ternary phase diagram for a three component system comprising of alcohol, water and benzene.
7. Determination of adsorption behavior of acetic acid on charcoal.
8. Determination of CST of Phenol-water system
9. Effect of sodium chloride on CST of phenol water system.
10. Determination of solubility- Heat of solution method.
11. Determination of first order reaction rate constant - Acid hydrolysis of ester.
12. Preparation of pharmaceutical buffer and determination of its buffer capacity.
13. Determination of second order reaction rate constant- Alkali hydrolysis of ester.
14. Determination of ionization constant by conductivity method/ distribution method.
15. Determination of distribution coefficient of benzoic acid in benzene and water.
16. Determination of particle size distribution - Microscopy.

Reference Books

1. C.V.S Subrahmanyam and S.G. Vasantharaju, Laboratory Manual of Physical Pharmacy, Vallabh Prakashan, New Delhi, 2005.
2. C.V.S Subrahmanyam and J. Thimma Setty, Laboratory Manual of Physical Pharmaceutics, Vallabh Prakashan, New Delhi, 2002.
3. Manavalan. Ramasamy, Physical Pharmaceutics, Vignesh Publishers, Chennai, 2004.

PHARMACOLOGY PRACTICALS

Subject Code : PY.07.881.6.7.P

Periods / Week: 4 credits:2

Nature of Exam: Practicals

Hrs

Sessional : 25

Examination : 50

Exam Duration: 6

List of Experiments

1. An introduction to different equipments used in Pharmacology laboratory
2. Effect of routes of administration on the action of drugs.
3. Dose response curves of Acetyl cholins.
4. Demonstration of different types of antagonism on isolated tissue preparations.
5. Effect of different electrolytes or drugs on isolated frog's heart.
6. Effect of drugs on isolated frog rectus abdominus (any four drugs).
7. Bioassay of drugs by matching method
8. Bioassay of drugs by graphical (interpolation) method
9. Bioassay of drugs by three point and four point methods.
10. Effect of various drugs on isolated rabbit intestine / guinea pig ileum
11. Hypoglycemic activity of insulin in rabbit.
12. Effect of drugs on ciliary movement of frog's esophagus
13. Local anesthetic activity on Rabbit eye / Guinea pig! Frog's hind limb withdrawal (Demo).
14. Anti-psychotic effect by pole climbing apparatus (Demo)
15. To study the analgesic effect of narcotic analgesic by using tail-flic/hot-plate/acetie acid induced writhing method. (demo)
16. Effect of drug on blood vessels
17. Antipyretic effect in rabbits.

Reference Books

1. S.K Kulkarni, Hand Book of Experimental Pharmacology, 3rd Edition, Vallabh Prakashan, Hilton and Company, Kolkata, 2005.
2. M.N Gash, Fundamentals of Experimental Pharmacology, 3rd Edition, Vallabh Prakashan, Hilton and Company, Kolkata, 2005.
3. K.K Pillai, Experimental Pharmacology, 1st Edition, CBS Publications & Distributors, Delhi, 2008.
4. R.K Goyal, Elements of Pharmacology, 13th Edition, B.S. Shah Prakashan, Ahmadabad, 2003.

