OSMANIA UNIVERSITY

Faculty of Pharmacy

SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

(Effective for Batches Admitted from 2016 – 17 Academic Year Onwards)

Program Code: 881 B. Pharmacy (Fourth year)

SEMESTER - VII

Course Code	Description	Course Title	Hours/Week			Credits	Marks		Duration of Exam
			L	T	P		Internal	End Exam	
PY.08.881.7.1.T	PS, CORE	Medicinal Chemistry-II	4	0	-	4	30	70	3
PY.08.881.7.2.T	PS, CORE	Pharmaceutical Analysis-II (Instrumental Analysis)	4	0	-	4	30	70	3
PY.08.881.7.3.T	PS, CORE	Dosage Formulation Design	4	0	0	4	30	70	3
PY.08.881.7.4.T	PS, FC	Biopharmaceutics & Pharmacokinetics	3	2	0	3	30	70	3
PY.08.881.7.5.T	HS, FC	Pharmaceutical Business Management	3	0	0	3	30	70	3
PY.08.881.7.6.P	PS, CORE	Medicinal Chemistry-II Practical	0	0	4	2	30	70	4
PY.08.881.7.7.P	PS, CORE	Pharmaceutical Analysis-II (Instrumental Analysis) Practical	0	0	4	2	30	70	4
PY.08.881.7.8.P	PS, CORE	Dosage Formulation Design Practical	0	0	4	2	30	70	4
			18	2	12	24	240	560	

MEDICINAL CHEMISTRY-II

Subject Code : PY.08.881.7.1.T **Sessional : 30**
Periods / Week : 4 credits:4 **Examination : 70**
Nature of Exam: Theory **Exam Duration: 3 Hrs**

Note: Introduction, definition, classification, structures, synthesis, general mechanisms, mode of action (wherever known), SAR including physicochemical, steric aspects, metabolism and uses of various categories of drugs mentioned in brackets against each category of the following units.

Unit – I

Local Anesthetics - (Lidocaine and Bupivacaine).
Narcotic analgesics - (Pethidine and Fentenyl), Narcotic antagonists - (Nalaxone),
Peripheral analgesics, Antipyretics & Anti-inflammatory agents - (Aspirin, Paracetamol, Piroxicam, Ibuprofen and Diclofenac Sodium).

Unit – II

Anti-neoplastic agents - (Chlorambucil, Busulfan, Fluorouracil, Methotrexate and Tamoxifen),
Chemotherapeutic agents, Sulfonamides - (Sulphamethoxazole and Sulphadioxine) Antibiotics - General Classification of Antibiotics; Beta-Iactam antibiotics - (Penethicillin, Ampicillin, Cloxacillin); Cephalosporins - (Cephalexin); Tetracyclines - (Chlortetracycline, Oxytetracycline), Quinolones - (Norfloxacin and Ciprofloxacin); Aminoglycosides, Macrolides, Polypeptides; Miscellaneous - (Chloromphenicol and Novobiocin).

Unit – III

Antituberular drugs - (INH, PAS, Ethambutol); Antileprotic drugs - (Dapsone); Antifungal drugs - (Ketoconazole and Fluconazole); Antiviral drugs - (Zidovodine); Antimalarial drugs - (Chloroquine, Pyrimethamine, Primaquine); Anthelmentic drugs - (Diethyl carbamazine citrate, Albendazole, Niclosamide, Pyrantel formate and Piperazine citrate); Antiprotozoal drugs - (Metronidazole, Tinidazole).

Unit – IV

Drugs acting on CNS: CNS stimulants and psychotropic agents - (Imipramine and Amiryptiline),
General Anesthetics - (Halothane, Ketamine, Enflurane),
Sedative & Hyponotics - (Phenobarbitone, Glutethimide, Zolpiclone), Anxiolytics - (Diazepam, Medazolam, Buspirone).
Antipsychotic (Tranquilizing) agents: (Chlorpromazine, Thiothixene, Haloperidol and Pimozide)
Anticonvulsants - (Phenytoin, Carbamazepine, Ethosuximide),
Antiparkinsonism drugs - (Benztropine and Carbidopa).

Unit – V

Vitamins: Structure, Preparation, Storage, Uses and their biochemical role in health promotion (Fat Soluble – A, D, E & K and Water Soluble – B_1 $_2$ $_3$ $_5$ $_6$ $_{12}$,B ,B ,B ,B & C)
Structure and Functional Role of Essential Amino Acids; Development of Protein Drugs.

Examination: One question from each unit with internal choice.

Text Books

1. J.H. Block &J.M. Beale (Eds) Wilson and Giswold's Text Book of Organic Medicinal & Pharmaceutical Chemistry, 11th edition, Lippincott, Raven, Philadelphia, 2004.

2. W.O. Foye, Text Book of Medicinal Chemistry, 5th edn, Lea & Febiger, Philadelphia, 2002.

3. S.N. Pandeya, Text Book of Medicinal Chemistry, 2nd edn, S. G. Pubs, Varanasi, 2003.

Reference books

1. D. Abraham (Ed), Burger Medicinal Chemistry and Drug Discovery, Vol.I , 6th edition, John Wiley & Sons, New York, 2003.

2. B.N. Lads, M.G. Mandel and F.I.Way, Fundamentals of drug Metabolism & Disposition, William & Welking Co, Baltimore U.S.A.,

3. C. Hansch, Comprehensive Medicinal Chemistry, Vol I-VI Elsevier Pergamon Press, Oxford, 1991.

4. Daniel Lednicer, Strategies for organic Drug Synthesis and Design, John Wiley N.Y., 1998.

5. D. Lednicer , Organic Drug Synthesis, Vol. I-VI, John Wiley N.Y

PHARMACEUTICAL ANALYSIS – II
(INSTRUMENTAL METHODS OF ANALYSIS)

Subject Code: PY.08.881.7.2.T **Sessional :30**
Periods/week: 4 credits:4 **Examination :70**
Nature of Exam: Theory **Exam Duration: 3 Hrs**

Unit – I

UV /Visible Spectroscopy

Regions of Electromagnetic spectrum, properties of EMR, atomic and molecular spectra, Beer - Lambert's law and deviations from Beer's law Principles and theoretical aspects of UVN/Visible Spectroscopy, electronic transition, effect of conjugation, concept of chromophore and auxochrome, bathochromic, hypsochromic, hyperchromic and hypochromic shifts Instrumentation - components of spectrophotometer, types of spectrophotometers, Solvents and sample handling, Applications - Qualitative and quantitative analysis - single component

Unit – II

IR spectroscopy

Principles and theoretical aspects - Molecular vibrations, Hook's Law, Intensity and position of IR bands, Measurement of IR spectrum, finger print region and characteristic absorption of various functional groups.

Instrumentation - Spectrophotometer components, Sample preparation and handling Application - Interpretation of IR spectra of simple organic compounds, quantitative applications.

Unit – III

i)NMR - A brief introduction to the principle and instrumentation, chemical shift, spin-spin interaction, shielding and de shielding.

ii)MS - A brief introduction to the principle and instrumentation, various methods of ion production and fragmentation rules.

iii)Fluorescence spectroscopy - Fundamentals, radiative and non radiative process, mirror image relation ship, fluorescence and molecular structure, properties of fluorescence. Instrumentation - components of spectrofluorimeter and applications

Unit – IV

Electrochemical methods

i) Amperometric titrations

ii) Potentiometry - principles and theoretical aspects - electrodes, measurement of cell potential, end point evaluation methods, potentiometric titrations, Null point potentiometry and application.

iii) Conductometry - principles and theoretical aspects, conductance, equivalent and molar conductance, effect of dilution on conductance, conductivity water, cell constant, conductivity cell, measurement of conductivity, conductimetric titrations and applications. Other analytical techniques - Principle, Instrumentation and application of following instrumental methods of analysis nephelometry, turbidometry, flame photometryand differential thermal analysis

Unit – V

Chromatography: Principle, instrumentation and experimental details and applications of paper chromatography, TLC, column chromatography, gas chromatography, HPLC and HPTLC.

Electrophoresis : Principle, instrumentation, experimental details and applications of paper and gel electrophoresis .

Examination: One question from each unit with internal choice.

Text Books

1. Practical Pharmaceutical Chemistry Vol. I & II by A.G.Beckett and J.B. Stresnlake, The Athlone press of the University of London.

2. Instrumental methods of Chemical Analysis by B.K. Sharma, 23rd edn, GOEL Pub. House,

References Books

1. Indian Pharmacopoeia Published by Controller of Publications.
2. B.P. / U.S.P./Extra Pharmacopoeia.
3. A Text Book of Pharmaceutical Analysis by K.A. Connors, Wiley Interscience, New York.
4. Jenkin's Quantitative Pharmaceuticals Chemistry by A.M.Knevel & F.E. Digengl, McGraw Hill Book Co., New York.
5. Pharm.Analysis by Higuchi.T and Hansen E.B.
6. Vogels textbook of Quantitative chemical analysis,sixth Edition J. Mendham, R.C.
7. Denny, J.D. Bannes M J K Thomas, Pearson education ,Delhi, India.
8. Principles of Instrumental Analysis, fifth edition D.A. Skoog, F. James Holler, Timothy A. Nieman, Harcourt Brace college publishers, Florida, US.
9. J.A. Howell, Hand Book of Instrumental techniques for Analytical Chemistry, prentice hall, upper saddle river (1197).

DOSAGE FORMULATION DESIGN

(PHARMACEUTICS – III)

Subject Code : PY.08.881.7.3.T **Sessional : 30**
Periods/week : 4 credits:4 **Examination : 70**
Nature of Exam: Theory **Exam Duration: 3 Hrs**

Unit – I

Pre Formulation Studies

Study of Physical Properties of Drug: Particle size, Shape, pKa, Solubility, Partition Coefficient, Crystallinity, Polymorphism and Hygroscopicity,

Powder Characteristics: Bulk density, Flow Properties, Solid State stability, Solution stability, and Stability Protocol, Dissolution and Organoleptic property and their effect on formulation.

Study of Chemical Properties of Drug: Hydrolysis, Oxidation, Polymerization etc., and their influence on formulation and stability of the Products.

Unit – II

Sustained Action Pharmaceuticals

Concept, Benefits, Limitations, Advantages & Disadvantages, Definition of various types of prolonged action pharmaceuticals.

Sustained Action Oral Products: Theory-Zero order release approximation, First order release approximation, Approaches based on drug modification and dosage form modification, *in vitro* & *in vivo* evaluation of the sustained release products. Formulation - Drug complexes, Encapsulated slow release granules, Tabletted slow release granulations and matrix tablets.

Microencapsulation: Applications, Core and Coat materials, Techniques- Air suspension, Coacervation-Phase separation, Pan Coating, Spray Drying & Spray congealing, Solvent Evaporation,. Polymerisation.

Unit – III

New Drug Delivery Systems

Importance, Formulation and Applications.

Transdermal Drug Delivery Systems: Concept, Advantages and disadvantages, Approaches used in developing Transdermal drug delivery systems (4 types), *in vitro* evaluation of Transdermal drug delivery systems.

Liposomes: Formulation, Preparation of liposomes-physical dispersion and solvent dispersion, Characterisation of Liposomes, Applications in Pharmacy.

Occular Drug Delivery Systems: Concept, Advantages and disadvantages, Mucoadhesives, design of Occuserts (Pilo 40 and Pilo 20), Erodable inserts.

Nanoparticles: A brief introduction to Nanoparticle technology and Nanoparticles as drug carriers in controlled & targeted drug delivery systems.

Unit – IV

Performance Evaluation Methods

Bioavailability: Definitions, Objectives, Considerations, Assessments, Enhancement Methods, Dissolution Studies for solid dosage forms and methods of interpretation of dissolution data.

***In vitro* and *In vivo* methods of evaluation**

Bioequivalence: Definition, Objectives, Testing Protocols and Procedures, Experimental Design of single dose bioequivalence study and Statistical Interpretation of data.

Concepts of Process Validation: Definition, Importance, types of validation in Pharmaceutical Operations and Introduction to different process validation methods.

Concepts of Good Manufacturing Practices in Production of Pharmaceutical Products

Unit – V

Quality Control and Assurance

Introduction, Quality Assurance, Sources of Quality variation,

Control of Quality variation: Raw Materials Control - Raw Material Quality Assurance Monograph, Active or Therapeutic Materials Control,

Quality Assurance at startup - Raw Materials Processing, Compounding, Packing materials.

Quality Assurance during packing operation - Auditing, Concept of statistical Quality Control and Quality Control Charts.

Control & Assurance of Manufacturing practices: Personal, Equipment & Buildings.

Control of records - Master formula record, Batch production record.

Control of production procedures - Manufacturing control, Packing Control and Labels control. Stabilization and stability testing protocols for various pharmaceutical products.

Examination: One question from each unit with internal choice.

Text Books

1. L. Lachman, H.A. Lieberman and J.L. Kanig, Theory and Practice of Industrial Pharmacy, Lea & Febiger, Philadelphia, 3rd Edition, 1997.

2. S.P. Vyas and Roop K. Khar, Targetted and Controlled Drug delivery Novel carrier systems, 1st edition, 2002, C.B.S. New Delhi.

Reference Books

1. A.R. Gennaro, Remington: The Science and Practice of Pharmacy, 20th Edition, Vol. 1, Lippincott Williams & Wilins, Philadelphia, 2004.

2. E.A. Rawlins, Bentely's Textbook of Pharmaceutics, 8th Edition, Baillere Tindill, London, 1992.

3. S.H. Willing, M.M. Tucherrman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, 2nd Edition, Marcel Dekker, Inc., New York, 1988.

4. Gilbert S. Banker and Christopher T Rhodes , Modern Pharmaceutics, IV Edition, Marcel – Dekker, USA, 2005.

5. Yiew Chien, Novel Drug delivery systems, 2nd edition, Marcel Dekker, USA, 1992.

6. Robert .A. Nash, Pharmaceutical Process Validation, 3rd edition, Marcel Dekker, 2003.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code: PY.08.881.7.4.T **Sessional : 30**
Periods/week:3 credits:3 **Examination : 70**
Nature of Exam: Theory **Exam Duration: 3 Hrs**

Unit – I

Biopharmaceutics
Introduction & their role in formulation development & clinical settings, fate of drugs after administration.
Drug absorption: drug absorption mechanisms, factors affecting drug absorption (physiochemical, biological, metabolic, formulations and dosage form considerations).

Unit – II

Drug distribution & protein binding of drugs
Distribution of drug through organ /tissue - factors affecting distribution
(Physicochemical properties of drugs, organ/tissue size, blood flow to the organ, physiological barriers to the distribution of drugs, drug binding blood / tissue / macromolecules).
Protein /tissue binding of drugs- factors affecting protein binding of drugs, significance and kinetics, tissue binding of drugs.

Unit – III

Drug metabolism & excretion of drugs
Biotransformation of drugs- drug metabolizing enzymes & organs, phase I & phase II reactions, factors affecting biotransformation, drug metabolism significance, extrahepatic metabolism, pharmacological activity of metabolite, deposition of metabolite.
Excretion of drugs - renal excretion of drug, factors affecting renal excretion of drugs, nonrenal routes of excretion of drug & factors affecting them, enterohepatic circulation.

Unit – IV

Pharmacokinetics
Introduction, basic concepts- rate processes in biological systems, pharmacokinetics parmneters- Cmax, tmax, AUC, biological half life, apparent volume of distribution, clearance (hepatic, renal, organ, metabolite).
Pharmacokinetics drug interaction and their significance in combination therapy.
Clinical pharmacokinetics: dosage adjustment in patient with and without renal and hepatic failure.

Unit – V

Compartment models
Basic concepts, one & two compartment models- pharmacokinetics of drug absorption, distribution and elimination under following conditions:
i) Intravenous bolus injection
ii) Intravenous infusion
iii) Oral single dose
Application of pharmacokinetic principles & computation of parameters by graphical

approach.

Examination: One question from each unit with internal choice.

Text Books

1. Biopharmaceutics and Pharmacokinetics – An Introduction by Robert E. Notary, 2nd edn. 1975, Marcel Dekkar Inc., New York.

2. D.M. Brahmankar and S.B.Jaiswal, Biopharmaceutics and Pharmcokinetics - A Treatise, Vallabh Prakasham, Delhi, 1995.

3. L. Shargel and A.B.C. Yu, Textbook of Applied Biopharmaceutics & Pharmacokinetics, 4th Edn, Appleton-Century-Crofts, Connecticut, 2004.

4. Venkateswarlu, Fundamentals of Biopharmaceutics & Pharmacokinetics, Paras Pubs, Hyd.

Reference Books

1. Remingtons Pharmaceutical sciences 17th edn. 1985 Mac Pub. Co., Easton, Pennsylvania.

2. Modern Pharmaceutics by Banker, 1979, Marcel Dekker Inc., New York.

3. L. Lachman, H.A. Lieberman, J.L. Kanig, The Theory and Practice of Industrial Pharmacy, 3rd Edition, Varghese Publishing House, Mumbai, 1991.

4. A.R. Gennario, Remington: The Science and Practice of Pharmacy, 20th Edition, Volume II, Lippincott Williams & Wilkins, Philadelphia, 2004.

PHARMACEUTICAL BUSINESS MANAGEMENT

Subject Code: PY.08.881.7.5.T **Sessional : 30**
Periods/week: 3 credits:3 **Examination : 70**
Nature of Exam: Theory **Exam Duration: 3 Hrs**

Unit – I

General Management (Production and Control)
Management concepts: Policies, goals and objectives, principles of management, functions of management, levels of management, management information systems (MIS);
Production Planning and Quality Control - Production Forecasting, Process production, Batch Production, Process planning, Economic Batch quantity. Problems of Productivity; Integration of modem management practices and principles of Total Quality Management (TQM) with requirements specified in GMP, GSP, ISO 19000, GB/T 19000 and ES 29000.

Unit – II

Industrial Management (Pharmaceutical Industry)
Pharmaceutical manufacture, Development, Location-Factors influencing, Special provisions.
Plant Layout: Types of plant layout, Factors influencing plant layout, Methods of factory layout, Special provisions, Storage space requirements, Layouts-Sterile or aseptic area, tablets production area.
Building: Compartmentalized facilities-Rooms, floors, walls and ceilings.
Pharmaceutical Process Flow and Work Study: General Flow Patterns, Work Station Design, Process Flow Diagrams - Production of Tablets, Work Study and Work Measurement.
Utilities and Services: Power, Water, Air conditioning systems, Dust collection systems, Compressed air systems, Vacuum and special gases.
Good Manufacturing Practices: Equipment and documentation (Records).

Unit – III

Materials and Stores Management
Materials Purchasing Procedure, Stores Organization - location and layout of stores, receiving, inspection of materials, Issue, Control of store and store stocks, Stock accounting and records. Selection of site for drug store, Layout design for drug store and compliance with control measures; Inventory control - Objectives, Economic order Quantity, ABC analysis.

Unit – IV

Personnel Management
Selection, Appointment, Training, Transfer, Promotion and demotion policies, Remuneration, Job Evaluation and merit rating.
Industrial Psychology - Concept, Individual and group behaviour, X and Y theory, Hawthrone experiments, morale, motivation and fatigue.

Unit – V

Marketing Management

Meaning and Scope, Types of Target Market, size, composition, demographic description and socio-psychological characteristics of the consumer, marketing mix.

Market consideration in product development - product classification, product planning, product differentiation, Branded V s Generic, new Product Development. Distribution Channels - Selection of Channels, Wholesaler and retailers, role and distribution.

Pricing policies - factors affecting price, selective and exclusive pricing, discount policies, Credit policies, Patent policies,

Sales Promotion policies - Objectives, detailing to physician, professional personnels sampling, window and interior display, media planning and publicity.

Examination: One question from each unit with internal choice.

Text Books

1. **Industrial Engineering and Management – O.P. Khanna.**
2. **C.V.S Subrahmanyam, Pharmaceutical Production and Management, Vallabh Prakashan, New Delhi, 2005.**

Reference Books

1. **Pharmaceutical Marketing in India by S.V. Subba Rao, Asian Institute of Pharmaceutical Marketing, Hyderabad**
2. **"Principles of Marketing" by Philip Kotler, Eastern Edn.,**

MEDICINAL CHEMISTRY – II

Subject Code : PY.08.881.7.6.P **Sessional : 25**
Periods / Week:4 credits:2 **Examination : 50**
Nature of Exam: Practicals **Exam Duration: 4 Hrs**

List of Experiments

1. **Synthesis of Phenytoin**
2. **Synthesis of Phenacetin**
3. **Synthesis of antipyrine**
4. **Synthesis of 6-methyl uracil**
5. **Synthesis of Sulphanilamide**
6. **Synthesis of 7-Hydroxy - 4-Methyl Coumarin.**
7. **IR spectral study of drugs (Acetazolamide, Clonidine HCl, Ibuprofen, INH, Metronidazole).**
8. **Estimation of drugs in formulations (Phenytoin, Phenacetin, Sulphanilamide and Codeine Phosphate).**

Reference Books

1. B.S Furniss, AJ Hannaford, PWG Smith and AR Tatchell, Vogel's Text book of Practical Organic Chemistry, 5th Edition, Longman Singapore Publishers, Singapore, 1996.

2. R K Bansal, laboratory Manual of Organic Chemistry, 4th Edition, New Age International Publishers, New Delhi, 2005.

3. AI Vogel, Elementary Practical Organic Chemistry, Part - I, Small Scale Preparations, 2nd Edition, CBS Publishers & Distributors, New Delhi, 2004.

4. FG Mann and BC Saunders, Practical Organic Chemistry, 4th Edition, Orient Longman, Hyderabad, 2004.

5. Indian Pharmacopoeia , Volume - I & II, Controller of Publications, Delhi,1996

6. British Pharamacopea, 2008.

PHARMACEUTICAL ANALYSIS – II PRACTICALS
(INSTRUMENTAL METHODS OF ANALYSIS)

Subject code : PY.08.881.7.7.P **Sessional : 25**
Periods/Week : 4 credits:2 **Examination : 50**
Nature of Exam: Practical **Exam Duration: 4 Hrs**

List of Experiments

1. **Experiments based on paper chromatography / TLC / Column chromatography.**
2. **Determination of Lamda max.**
3. **Determination of Isosbestic point.**
4. **Determination of Molar absorptivity.**
5. **Estimation of drugs by using colorimeter / UV -Spectrophotometer / Fluorimeter.**
6. **Determination of sulphate or chloride ions by turbidimetry and Nephelometry.**
7. **Potentiometric determination of equivalence point.**
8. **Conductimetric titration.**
9. **Determination of concentration of Ions by Polarography.**
10. **Determination of concentration oflons by Specific - Ion Electrode.**
11. **Experiments based on Eelectrophoresis.**
12. **Determination of Na and K Ions using Flame photometer.**
13. **Determination of moisture content of a drug by using Karl Fischer titrator.**

Reference Books

1. **A.H Beckett and J.B Stenlake, Practical Pharmaceutical Chemistry, Part – II, 4th Edition, CBS Publications, New Delhi, 2004.**
2. **Indian Pharmacopoeia, Controller of Publications, Delhi,1996.**
3. **B.G Nagavi, Laboratory Hand book for Instrumental Drugs Analysis, 3rd Edition, Vallabh Prakashan, New Delhi, 2000.**

DOSAGE FORMULATION DESIGN PRACTICALS

(PHARMACEUTICS – III)

Subject Code: PY.08.881.7.8.P **Sessional : 25**
Period/week: 04 credits:2 **Examination : 50**
Nature of Exam: Practical **Exam Duration: 6 Hrs**

List of Experiments

1. Preparation and evaluation of albumin microspheres by heat stabilization technique and their particle size characteristics.
2. Preparation of matrix tablets using various polymers like PVP etc and studying their release pattern.
3. Preparation and evaluation of drug (ibuprofen, salicylic acid) loaded alginate microspheres.
4. Evaluation of marketed sustained release tablets for in vitro dissolution behaviour.
5. Preparation and evaluation of matrix tablets containing drugs.
6. Preparation and evaluation of solid dispersion of drugs using PEG polymers.
7. Preparation and evaluation of reservoir type devices using PEG-ethyl cellulose in chloroform-dichloromethane).
8. *In vitro* transport of marketed transdermal preparation using suitable diffusion cell.
9. Preparation of drug loaded liposomes using solvent evaporation method and evaluation of extent of entrapment (demonstration).

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