SCHEME OF INSTRUCTION AND EXAMINATION FOR
B. PHARMACY - IV YEAR IST SEMESTER

COURSE NO.	SUBJECTS	PERIODS/WEEK (50 Mts.)	MARKS		DURATION OF EXAM.
		Theory/Practicals	Sessionals	Exams.	Hrs.
PYT.4.101	BioPharmaceutics & Pharmacokinetics	4	30	70	3
PYT.4.102	Pharmaceutical Analysis – II (Instrumental Analysis)	4	30	70	3
PYT.4.103	Medicinal Chemistry – II	4	30	70	3
PYT.4.104	Dosage formulation Design (Pharmaceutics – III)	4	30	70	3
PYT.4.105	Ph.Business Management	4	30	70	3
PYP.4.106	Pharmaceutical Analysis – II (Instrumental Analysis) Lab	4	25	50	4
PYP.4.107	Medicinal Chemistry Lab	6	25	50	4
PYP.4.108	Dosage formulation Design (Pharmaceutics – III) Lab	4	25	50	4
		34	225	500	

SCHEME OF INSTRUCTION AND EXAMINATION FOR
B. PHARMACY - IV YEAR IIND SEMESTER

COURSE NO.	SUBJECTS	PERIODS / WEEK (50 Mts.)	MARKS		DURATION OF EXAM.
		Th/Pr	Sessionals	Exams	Hrs.
PYT.4.201	Pharmaceutical Biotechnology	4	30	70	3
PYT.4.202	Hospital and Clinical Pharmacy	4	30	70	3
PYT.4.203	Cosmetic Technology	4	30	70	3
PYT.4.204	Pharmacoinformatics	4	30	70	3

PYP.4.205	Pharmaceutical Biotechnology Lab	4	25	50	4
PYP.4.206	Cosmetic Technology Lab	4	25	50	4
PYP.4.207	Pharmacoinformatics Lab	4	25	50	4
PYP.4.208	Seminar	2	A˜B˜C˜D		
		30	195	430	

BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code: PYT. 4 .101 Sessional : 30
Periods/week4 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 ANALYSIS – II
(INSTRUMENTAL METHODS OF ANALYSIS)

Subject Code: PYT.4.102 Sessional :30
Periods/week: 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).

MEDICINAL CHEMISTRY-II

Subject Code : PYT. 4.103 Sessional : 30
Periods / Week : 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

DOSAGE FORMULATION DESIGN

(PHARMACEUTICS – III)

Subject Code : PYT 4.104 Sessional : 30
Periods/week : 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.

PHARMACEUTICAL BUSINESS MANAGEMENT

Subject Code: PYT 4.105 Sessional : 30
Periods/week: 4 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.,

PHARMACEUTICAL ANALYSIS – II PRACTICALS
(INSTRUMENTAL METHODS OF ANALYSIS)

Subject code : PYP. 4.106 Sessional : 25
Periods/Week : 4 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.

MEDICINAL CHEMISTRY – II

Subject Code : PYP. 4.107 Sessional : 25
Periods / Week: 6 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.

DOSAGE FORMULATION DESIGN PRACTICALS

(PHARMACEUTICS – III)

Subject Code: PYP. 4.108 Sessional : 25
Period/week: 06 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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PHARMACEUTICAL BIO TECHNOLOGY

Subject Code : PYT. 4.201 Sessional : 30
Periods / Week: 4 Examination : 70
Nature of Exam: Theory Exam Duration: 3 Hrs

Unit – I

Genetic Engineering

Introduction, History, Development, Application and Scope Genetics, DNA/RNA replication, Restriction Endonucleases, DNA Ligases, Vectors, Hosts, Cloning strategies, Gene Expression in Recombinant DNA. Application of recombinant DNA in manufacture of biological products such as Insulin, Human growth hormones, Interferons and Interleukins.

Unit – II

Biochemical Engineering – Fermentation Technology

Introduction, development and maintenances of industrial micro-organisms, batch and continuous fermentations, process controls, oxygen supply and demand, single and multiple bubble aeration, sparger aeration, foam control equipment, scale-up of Fermentors.

Microbiological Assay of antibiotics and Vitamin B_{12}.

Study of culture, media, production conditions, extraction and purification of the following:

Antibiotics – Semi synthetic penicillin's, streptomycin and erythromycin as per IP.
Hormones - Insulin Production
Enzymes – Amylase and Diastase; Immobilization and their applications in drug manufacture.

Biomass – **Lactobacillus sporogenes**

Unit – III

Immunization Products

Manufacture, Standardization, Storage, Labeling and Specific Applications of the following vaccines: Bacterial vaccines, toxoids, viral vaccines, Rickettsial vaccines, Rabies, MMR, BCG, DPT, Cholera, Hepatitis B and Polio

Standardization and Storage of the following Passive immunization products – Anti toxins, Anti venom, Immune sera and other products related to immunity and Immuno Diagnostics;

Unit – IV

Blood and Glandular Products

Collection, processing and storage of whole human blood, Concentrated human R.B.C. dried human plasma, Human plasma protein fraction, dried human serum, Human fibrinogen, Human thrombin, human normal immunoglobulin, Human fibrin foam, Plasma substitutes – Ideal requirements, PVP, Dextran 40, Control of blood products, Transfusion products.

Preparation of extracts and isolation of pure substances and their dosage forms from Pituitary, Adrenal, Pancreas and Thyroid glands;.

Unit – V

Biotransformations and Animal Cell Biotechnology

Microbial transformation of steroids: Introduction, Types and methods of transformations mediated by microorganisms, design of biotransformation processes and selection of organisms.
Animal cell culture: Techniques, Media used and Applications.
Hybridoma culture: Production of monoclonal antibodies and their applications.

Examination: One question from each unit with internal choice.

Text Books

1. **Pharmaceutical Biotechnology** by S.S. Kori.
2. **Principles of Fermentation Technology** by P.F. Standury & A. Whitaker, Pergamon Press,
3. **Industrial Microbiology** by Cassida.

Reference books

1. **Monoclinical Antibody Technology** by A.M. Campbeli.
2. **Handbook of enzyme Biotechnology** by A. Wiseman.
3. **Recombinant DNA Technology** by J.D. Watson.
4. **Molecular Biology and Biotechnology** by Smith and Hood.
5. **General Pharmacy** by Copper and Gunn.
6. **A text book of Pharmaceutics**, A.O. Bentley, 8th Edition, 1982 Bailler Tindall & Co.,
7. **Microbial Biotechnology** Alexander N. Glazer & Hiroshi Nikaido, W.H. Freeman Co., 1995.
8. **Principles of Fermentation Technology** by P.F. Stanbury Whitaker.
9. **Bioitechnology** by Wulf Crueger and Anneliese Crueger, 2nd edition, Publisher – Panima Publication Corporation, New Delhi.

HOSPITAL & CLINICAL PHARMACY

Subject Code : PYT.4.202 Sessional : 30

Periods / Week: 4 Examination : 70
Nature of Exam: Theory Exam Duration: 3 Hrs

UNIT – I

Introduction to Hospital and Hospital Pharmacy

Hospital and its Organisation,

Hospital Pharmacy: Objectives, Functions, Organisation, Planning, Personnel and Administration of Hospital Pharmacy Services; Hospital Drug Policy – General Considerations;

Hospital Committees: Purpose, Organization and Functions of Pharmacy and Therapeutic Committee (PTC), Role of Hospital Pharmacist in Hospital Committees and Practice of Rational Drug Therapy and Drug Exchange Program;

UNIT – II

Hospital Formulary

Organization, Formulary Content, Preparation and Distribution; Pharmacy Procedural Manual Preparation; Drug distribution, Dispensing to Inpatient and Ambulatory Patient care, Dispensing of ancillary and controlled substance; Procurement and Distribution of alcohol; Manufacturing of Bulk and sterile supplies; Storage and Handling of Radio isotopic Pharmaceuticals; Budget Planning, Purchasing and Inventory Control; Use of Surgical Instruments & Hospital Equipment.

UNIT – III

Clinical Pharmacy

Introduction, Scope, History and Development of Clinical Pharmacy; Investigational use of Drugs and Drug Therapy Monitoring with examples, Adverse Drug Reaction Management; Drug and Poison Information, Medication history review and Patient Counseling; Patient Compliance, Patient Data Analysis and its Use in evaluation of Clinical Tests for Common Disease States and Organ Functional Tests (Liver, Pulmonary and Renal) for Drug Therapy; Definition and Differences of Generic and Prescription Drugs;

UNIT – IV

Basic Principles of Drug Therapy

Concepts of Essential Drugs and Rational Drug Use;

Drug Distribution: Out Patient and In Patient Services; Unit dose drug distribution systems, floor ward stock systems, satellite pharmacy services, central sterile services and bed side pharmacy;

Drug- Drug Interactions: Mechanism of Pharmacokinetic and Pharmacodynamic interactions with suitable examples; Food and Drug interactions. Incidence, Classification and Surveillance Methods of Adverse Reactions of Drugs; Therapeutic Aspects of Pharmaco Genetics;

Drug induced Disease – Dermatological, Hepatic, GI, Renal, Gout, Parkinsonism, Cancer, Depression, Psychosis, Ototoxicity, Ocular toxicity and Teratogenicity. Adverse drug reactions.

UNIT – V

Pharmaco Therapy of Diseases

Diseases: – Symptoms, Manifestation, Patho-Physiology and Etiology of - Gastrointestinal diseases: Peptic ulcer, Ulcerative colitis, Hepatitis & Cirrhosis (Liver). Cardio Vascular System diseases – Angina Pectoris, Acute Myocardial Infunction, Atherosclerosis, Essential Hypertension, Cardiac arrhythmia. Respirtory diseases – Asthma and T.B.; STD – HIV, Syphilis and Gonorrhea.;

Anemia, Parkinsonism, Diabetes, Gout and Rheumatiod arthritis.
Pharmaco Therapy and Critical Analysis of Rational Use of Drugs in the following Disorders: Cardio Vascular, Respiratory, Renal, Gastro-Intestinal, Nervous, Psychiatric, Rheumatic, Hematological, Endocrine and Infections.

Examination: One question from each unit with internal choice.

Text Books

1. **Hospital Pharmacy** by Hassan.
2. **Clinical Pharmacy and Therapeutics** by Herfindal, Herschnan.
3. **Essential Clinical Medicine** R.H. Salter.

Reference Books

1. **Remington Pharmaceutical Sciences.**
2. **Drug Interaction** by hamsten, Kven Stockley.
3. **Clinical Pharmacology and Drug therapy** Grahame Smith and Aronson.
4. **Drug Interactions** – J.K. Mehra, Basic Business Publishers, Bombay.

COSMETIC TECHNOLOGY

Subject Code : PYT.4.203 Sessional : 30
Periods / Week : 4 Examination : 70

Nature of Exam: Theory Exam Duration: 3 Hrs

Unit – I

Introduction, Definition of cosmetics. Basic knowledge of the skin classification of cosmetics.

General aspects of cosmetic preparations: Colouring agents in cosmetics, Preservatives and antioxidants and other additives used in cosmetics, Regulatory provisions related to cosmetics.

An approach to the formulation, ingredients, use, method of manufacturing, packing, labeling, and quality control of the following cosmetics.

Unit – II

Face Preparations - Vanishing creams, Cleansing creams, Face powders and lipsticks.
Eye Preparations - Mascaras, Eye liners, Eye shadows.
Baby Specialties - Baby powder, Baby oils, Baby lotions and Baby shampoos.

Unit – III

Preparations For Skin - Bleaching preparations, Body Lotions and Body Creams.
Preparations For Nails - Nail laquers and Nail polish removers

Body Cosmetic Preparations - Deodorants, Antiperspirants and Talcum powders.

Shaving Preparations: Pre-Shave and after-shave lotions, Shaving creams and Soaps.

Unit – IV

Preparations For The Hair - Shampoos, Hair Conditioners, Hair Straightners, Hair creams, Hair dyes, Depilatories and Epilatories.
Dental Preparations - Tooth powders and pastes, Mouth washes.

Unit – V

Herbal Cosmetics
Skin care products: Body oils and Moisturising lotions.
Hair care products - Shampoos, Hair Conditioners.
Cosmetics for face: Face packs.

Examination: One question from each unit with internal choice.

Text Books

1. Cosmetics formulation manufacturing & Quality control by P.P. Sharma, Vandana Pub, Delhi.
2. Poucher's Perfumes, Cosmetics and Soaps by H. Butler, Chapman & HALL, London.

Reference Books

1. **Martindale's Extra Pharmacopia**, 29th edn. 1989, Pharmaceutical Press, London.
2. **Cosmetic Science & Technology**, Volume I, II & III by Sagarin 2nd edn. John wiley & Co.

PHARMACOINFORMATICS

Subject Code : PYT 4.204 Sessional : 30
Periods/ Week : 04 Examination : 70

Nature of Exam: Theory Exam Duration: 3 Hrs

Unit – I

Database Design

Databases: Structure of databases, Sequence databases, Relational databases; Sequence analysis, Software resources; Sequence alignment and database searches and Phylogenetic analysis; Principles of database organization, Data mining and knowledge discovery in databases, Bibliographic databases and library catalogs and Drug information databases Database Concept, Database Architecture, Codd Rules, Normalization, Access 2000 Database and Accord 2000 Cheminformatics Database; Importance of Biological Databases

Unit – II

Information Management

Search algorithms: Search logic and complex queries and Search in non-text databases (images and chemical structures); Algorithms for alignment of sequences and structures of nucleic acids, proteins and protein families; Substitution of similarity matrices; Dynamic Programming methods; Structural superposition algorithms; Hidden Markov Models (Construction and Use in Alignment and Prediction); Domain detection and Identification of Genes;

Storage and retrieval of information: Database Querying, Key work searching, Search Machines, Complex searches, Homology searches, Pattern matching and Bio-PERL;

Unit – III

Drug information services

Drug Information: Introduction, Resources Available; Design of Literature Searches; Critical Evaluation of drug information and literature, Preparation of Written and Verbal reports, Development of Drug information, Database useful for emergency treatment of poisoning;

Pharmacy automation: Automated medication dosage, filling and packaging, Coding of information and bar-codes, Medication distribution, management and Inventory control.

Unit – IV

Introduction to Genomics and Proteomics

Structure and Functional Genomics; Genome Analysis; DNA databaks, GENEBANK;

Libraries: Preparation of ordered cosmid libraries, bacterial artificial chromosome libraries; shotgun libraries; Homology algorithims (BLAST) for Proteins and Nucleic Acids

Sequencing: Conventional (Sanger, Maxam and Gilbert Methods) and Automated Sequencing

Protein Analysis; Protein Sequence Databanks, (SWISSPORT, PIR and INTERPRO) Conserved Protein motifs related to structure/function (PROSITE, PFAM and profile Scan) and database for Protein Structure (PDB); SCOP/CATH and Introduction to EMBOSS;

Unit – V

Computational Concepts in Drug Design

Introduction to drug design; Molar Reactivity of Compounds for Structure Activity Relationship (SAR) and Quantitative Structure Activity Relationship (QSAR) analysis; Free-Wilson and Hansch Methods of Analysis; Detrmination of Partition Coefficient and Dissociation Constant; using computational methods; Application of Quantum Mechanics;

Factors Affecting Bioactivity of Drugs: Resonance, Inductive Effect, Isosterism, bioisosterism, Special Considerations: Conformational Space, Energy Calculations, Local and Global Minimization; Energy Minimization; Molecular dynamics simulations; Docking;

Theory of Drug Activity: Occupancy Theory; Rate Theory; Induced Fit Theory; Drug-Recptor

Interactions; Influence of Isomers on Drug Receptors; Biochemical approaches in drug design;

Examination: One question from each unit with internal choice.

Text and Reference Books

1. Bioinformatics 2000, Higgins and Taylor. OUP
2. Internet and the New Biology: Tools for genomic and Molecular research By Peruski, Jr
3. Functional genomics: A Practical Approach, Edited by Stephen P. Hunt and Rick Liveey
4. Chemical space navigation in lead discovery by Tudor I. Oprea
5. Database Management and Information Systems, by Henry Korth

PHARMACEUTICAL BIO TECHNOLOGY

Subject Code : PYP.4.205 Sessional : 25
Periods / Week: 4 Examination : 50
Nature of Exam: Practical Exam Duration: 4 Hrs

List of Experiments

1. Standardization of cultures
2. Microbiological assay of Antibiotics / Vitamins
3. Production of alcohol by fermentation techniques
4. Immobilization of cells / enzymes by different techniques
5. Comparison of efficacy of immobilized cells.
6. Sterility testing of Pharmaceutical products.
7. Isolation of mutants by gradient plate technique.
8. Preparation of bacterial vaccine.
9. Preparation of blood products / human normal immunoglobulin injection
10. Extraction of DNA.

Reference Books

1. F.C. Garg, **Experimental Microbiology**, CBS Publishers, New Delhi, 2003.

2. R.S Gaud and G.D Gupta, **Practical Microbiology**, 6th Edition, Nirali Prakashan, Pune, 2006.

3. R.S Gaud, G.D Gupta and S.B. Gokhale, **Practical Biotechnology**, 2nd Edition, Nirali Prakashan, Pune, 2004.

4. Vinita Kale and Kishore Bhusar, **Practical Microbiology Principles and Techniques**, Himalaya Publishing House, Hyderabad, 2005.

COSMETIC TECHNOLOGY

Subject Code : PYP.4.206 Sessional : 25
Periods/week : 4 Examination : 50

Nature of Exam : Practicals Exam Duration: 4 Hrs

List of Experiments

Preparation of the following products

1. Cleansing creams
2. Vanishing creams
3. Shaving creams
4. Tooth paste
5. After shave lotion
6. Hand lotion
7. Baby lotion
8. Face powder / talcum powder / tooth powder / baby powder
9. Nail paint / Lip stick
10. Nail paint remover
11. Deodorant formulation.

Reference Books

1. B.M. Mithal and R.N Saha, Hand Book of Cosmetics, Vallabh Prakashan, New Delhi. 2006.
2. P.P. Sharma, **Cosmetics: Formulation Manufacturing & Quality Control**, Vandana Publications, Delhi, 2005.
3. W.A Poucher**, Modern Cosmetics, Vol – I, II & III**, B I Publications, New Delhi.
4. Anne Moung, **Practical Cosmetic Science**, Milh & Boon Ltd, London,

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PHARMACOINFORMATICS PRACTICALS

Subject Code :PYP.4.207 Sessional : 25
Periods / Week : 4 Examination : 50
Nature of Exam: Practicals Exam Duration: 4 Hrs

List of Experiments

Minimum 8 experiments of Exercise and Problem Solving of the following shall be conducted.

1. Review of key internet sites for sequence analysis (Hypertext and World Wide Web)
   - Information search in WWW
   - Pharmaceutical resources in WWW
   - Retrieving and installing a program (Tree Tool)
   - Similarity Searching BLAST/FASTA
   - Multiple Sequence Alignment (CLUSTAL W and Bee)

- Basic Sequence Analysis and Multiple Sequence Analysis
- GCG sequence Analysis

2. Virtual Library
   - Searching MEDLINE on the PubMed System from the NCBI site
   - Searchingthe Science Citation Index and Current Contents Connect from the ISI
   - Accessing full text journals on the internet through INFLIBNET and other sources
3. Database and Search Tools
   - Types of indexing tools and search strategies
   - Literature evaluation Methods
4. Basic Programming in BioPERL
5. Problems related Gene Sequencing and Protein Sequencing
6. Basic Programming in SQL

Reference Books

1. S Misener and SA Krawets, **Bioinformatics: Methods & Protocols, Vol. 132**, Human Press Inc, New Jersey, 2003.
2. SC Rastogi, N Mediratta and P Rastogi, **Bioinformatics: Concepts, Skills & Applications**, CBS Publishers & Distributors, New Delhi, 2004.
3. D Higgins and W Taylors, (ed) **Bioinformatics – Sequence, Structure and Data-Banks – Practical Approaches**, Oxford University Press, New Delhi, 2006.
4. WD Mount, **Bioinformatics – Sequence and Genome Analysis**, 2nd Edition, CBS. Publishers & Distributors, New Delhi, 2005.
5. I Bayrogs, **SQL / PL/ SQL/ - The Programming Language of Oracle**, 3rd Edition, BPB Publication, New Delhi, 2006.
6. DC Jamison, **Perl Programming for Bioinformatics & Biologists**, John Wiley & Sons Inc, New Delhi, 2004.
7. http: // blast. Ncbi nlm. Nih. Gov / blast. Csi. http: // www. ebi.ac.uk/.