UTTARAKHAND TECHNICAL UNIVERSITY DEHRADUN  
STUDY AND EVALUATION SCHEME  
[Effective from the session: 2009-10]

Course: B.Pharm.  
Year – IV Semester - VII

T.A. – Teacher Assessment, ESE – End Semester Examination, CT – Cumulative Test

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<th>S.N.</th>
<th>Course Code</th>
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Practical Day to Day Evaluation

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Note: - Duration in Theory & Practical of ESE shall be 3 (three) hours and 4 (four) hours respectively

0.6 Credits – Sessional  
2.4 Credits - ESE
Course: B. Pharm.

Year – IV Semester – VIII
T.A. – Teacher Assessment, ESE – End Semester Examination, CT – Cumulative Test

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<td>Elective (A)- Standardization of Herbal Drugs and Cosmetics Or (B)- Drug Design Or (C)- Pharmaceutical Marketing Or (D)- Pharmaceutical Packaging Or (E)- Novel Drug Delivery Systems Or (F)-GMP, Quality Assurance &amp; Validation Or (G)- Hospital Pharmacy Or (H)- Advanced Pharmacology Or (I)- Pharmaceutical Entrepreneurship</td>
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0.6 Credits – Sessional
2.4 Credits – ESE
B.Pharm IV (VII Semester)

PHR- 701

PHARMACEUTICAL INDUSTRIAL MANAGEMENT

Unit-I
Concept of Management: Administrative Management (Planning, Organizing Staffing Directing and Controlling). Entrepreneurship development, Operative Management (Personnel, Materials, Production, Financial, Marketing, Time/space, Margin/ Morale)  [08]

Unit-II
Principles of Management (Coordination, Communication, Motivation, Decision making, leadership, Innovation Creativity, Delegation of Authority / Responsibility. Record Keeping), Identification of key points to give maximum thrust for development and perfection.  [08]

Unit-III
Economics: Principles of economics with special reference to the Laws of demand and supply, demand schedule, demand curves labor welfare, general principles of insurance and inland and foreign trade, procedure of exporting and importing goods.
DPCO Act: Cost Accounting, Formulation record rules  [10]

Unit-IV
Pharmaceutical Marketing: Functions, buying, selling, transportation, storage financed feedback information, channels of distribution, wholesale, retail, department store, multiple shop and mail order business.
Salesmanship: Principle of sales promotion, advertising, ethics of sales, merchandising, literature, detailing, Recruitment, training, evaluation, compensation to the pharmacist.  [08]

Unit-V
Supply Chain Management: Procurement, Receipt, Analysis, Approval, Issuance, Production, Quality control, Distribution & Marketing  [06]

BOOKS RECOMMENDED:
2. Massie L. Joseph Essentials of Management / PHI.
3. Vidya sagar Pharmaceutical Industrial Management, Pharma Book Syndicate
6. Datta A.K., Material Management / PHI.
7. Chadwick Leslie, The essence of management accounting / PHI.
PHARMACEUTICS -VIII
(BIOPHARMACEUTICS & PHARMACOKINETICS)

Unit-I:
Introduction to Biopharmaceutics and Pharmacokinetics, Biopharmaceutical Classification System
- Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion and pinocytosis).
- (B) Factors influencing absorption
- (C) Distribution, metabolism and excretion

Unit-II:
Pharmacokinetics:
- Significance of plasma drug concentration measurement.
- Compartment model and Non-compartment model. Definition and Scope
- (C) Pharmacokinetics of drug absorption – zero order and first order absorption rate constant using Wagner – Nelson, Loo-Reigelman method.

Unit-III:
- Volume of distribution and distribution coefficient.
- Compartment kinetics – One compartment and Preliminary information of multicompartment models. Determination of pharmacokinetic parameters from plasma and urine data after drug administration by intravascular and oral route.
- Clinical Pharmacokinetics: Definition and scope

Unit-IV:
(A) Dosage adjustment in patients with and without renal and hepatic failure.
(B) Pharmacokinetic drug interactions and their significance in combination therapy.

Unit-V: Bioavailability and Bioequivalence:
(A) Measures of bioavailability, C-max, and area under the curve (AUC).
(B) Review of regulatory requirements for conduction of bioequivalent studies.

PHR-702P

PHARMACEUTICS-VIII
(BIOPHARMACEUTICS & PHARMACOKINETICS)
PRACTICAL
1. Experiments designed for the estimation of various pharmacokinetic parameters with given data.
2. In vitro evaluation of different dosage forms for drug release.
4. Bioavailability and Bioequivalence studies
5. Permeability studies
6. Protein binding
7. Statistical treatment of pharmaceutical data.

BOOKS RECOMMENDED:
1. Notari, R.E, Biopharmaceutics and Pharmacokinetics – An introduction Marcel Dekker Inc. N.Y.
2. Rowland M, and Tozer T.N. Clinical Pharmacokinetics, Lea and Febriger, N.Y.
PHARMACEUTICAL CHEMISTRY –VIII
(MEDICINAL CHEMISTRY - III)

Unit-I:
Introduction, Classification, Mode of action, uses, structure-activity relationship of the following classes of drug (Synthetic procedures of individually mentioned drugs only).

Steroids and related drugs:
- Special emphasis on Nomenclature, Stereochemistry
  - Androgens and Anabolic steroids – Testosterone, Stanazolol.
  - Estrogens and Progestogens – Progesterone, Estradiol.
  - Adrenocorticoids – Prednisolone, Dexamethasone, Betamethasone.

(D) Anti-Fertility Drugs [08]

Unit-II:
Introduction, Classification, Mode of action, uses, structure-activity relationship of the following classes of drug (Synthetic procedures of individually mentioned drugs only).

Antibiotics:
- Penicillin, Amoxicillin, Methicillin, Streptomycin, Tetracyclines, Cephalosporins, Chloramphenicol, Gentamycin, Clavulanic acid

Antimycobacterial Agents:
- PAS, Ethambutol, Isoniazid, Dapsone

Quinolones:
- Nalidixic acid, Norfloxacin [08]

Unit-III:
Introduction, Classification, Mode of action, uses, structure-activity relationship of the following classes of drug (Synthetic procedures of individually mentioned drugs only).

Antimalarials:
- Choloroquine, Primaquine, Artemesinin

Antiamoebics:
- Metronidazole, Tinidazole, Diloxanide

Antiseptics & Disinfectants – Benzalkonium chloride

Antihelmintics:
- Mebendazole

Antifungals:
- Griseofulvin, Clotrimazole Amphoterincin B

Antibacterials – Sulphamethoxazole, Sulphadiazine, Sulphacetamide. [08]

Unit-IV:
Introduction, Classification, Mode of action, uses, structure-activity relationship of the following classes of drug (Synthetic procedures of individually mentioned drugs only).

Anti-HIV agents:
- Zidovudine, Zalcitabine, Saquinavir.

Antivirals:
- Amantadine, Acyclovir, Lamivudine.

Prostaglandins – Misoprostol, Carboprost.

Anti-cancer drugs
- Alkylating Agents - Chlorambucil, Carmustine
- Antimetabolites - Methotrexate
- 6-Mercaptopurine
- 5-Fluorouracil [08]

Unit-V:
Introduction, Classification, Mode of action, uses, structure-activity relationship of the following classes of drug (Synthetic procedures of individually mentioned drugs only).

Thyroid and Antithyroids:
- Carbimazole, Levothyroxine, Propylthiouracil, Methimazole.

Hypoglycaemics:
- Insulin Chlorpropamide, Metformin, Tolbutamide, Glibenclamide. [08]

BOOKS RECOMMENDED:
5. Patrick G L. Medicinal Chemistry, Oxford University Press NY
7. Pharmacopoeia of India, Ministry of Health, Govt. of India.
PHR– 704

PHARMAOCOLOGY –III

Unit-I: Pharmacology of Endocrine System
Hypothalamic & pituitary hormones, Thyroid hormones & Thyroid Drugs, Parathormone, Calcitonin & Vitamin D, Insulin, oral hypoglycemic agents & glucagon. [07]

Unit-II: ACTH & Corticosteroids, Androgens & anabolic steroids, Estrogens, Progesterone & Oral Contraceptives, Drugs acting on uterus. [08]

Unit-III: Chemotherapy
General Principles of Chemotherapy, Sulfonamides, Cotrimoxazole, Quinolones, Antibiotics – Penicillins, Cephalosporins, Chloramphenicol, Tetracyclines, Macrolides. [08]

Unit-IV: Chemotherapy of Parasitic infections, Tuberculosis, Leprosy, Malaria, Fungal infections, Viral diseases, Introduction to Immunomodulators and Chemotherapy of Cancer, Multi-drug resistance [10]

Unit-V:
A. Principles of Toxicology Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organophosphorous & atropine poisoning, Heavy metal Anagnostons.

B. Bioassays- Basic Principles, Bioassay of oxytocin and acetylcholine [07]

PHR-704P

PHARMAOCOLOGY- III

PRACTICAL

1. To calculate the pA2 value of Atropine & chlorpheniramine.
2. Bioassay of Ach, histamine & oxytocin on suitable isolated preparations using matching assay, bracketing assay, three point assay & four point assay.
3. Bioassay of histamine and acetylcholine using matching and interpolation method on rat guinea pig. All experiments will be conducted using software wherever possible.

BOOKS RECOMMENDED:

3. Laurene, DR & Bennet PN; Clinical Pharmacology, Churchill Livingstone.
PHR-705

PHARMACOGNOSY-IV

Unit-I: 1. Systematic study of source, cultivation, collection, processing, commercial varieties, chemical constituents, substitute’s adulterants, uses, diagnostic macroscopic & microscopic features & specific chemical tests of following alkaloid containing drugs included in Ayurvedic Pharmacopoeia
Tobacco, Areca & Lobelia.

Belladona, Hyoscyamus, Datura, Coca & Withania
Cinchona, Ipecac & Opium
Ergot, Rauwolfia, Catharanthus & Nux-vomica.

Unit-II:
Pilocarpus. Veratrum & Kurchi.
Ephedra & Colchicum.
Solanum. Coffee & Tea Vasaka
Biosynthesis, Utilization & production of phytoconstituents such as– Tropane, Quinoline Opium and Indole alkaloids. Techniques employed in elucidation of biosynthetic pathways

Unit-III
(A) World wide trade in Medicinal plants & derived product. Tropane alkaloids containing drugs, Cinchona, Ipecac, Rauwolfia, Taxol, Diosgenin, Digitalis, Liquorice, Papain, Ginseng, Aloe, Valerian, & plant laxatives.
(B) Role of Medicinal & aromatic plants in National Economy.

Unit-IV

Unit-V:
Historical development of plant tissue culture, type of culture, Nutritional requirement, growth & their maintenance. Application of plant tissue culture in pharmacognosy.

PHR-705P

PHARMACOGNOSY -IV

PRACTICAL
1. Identification of crude drugs listed above.
2. Microscopic study of characters of any 8 selected drugs given in theory in entire and powder form.
3. Chemical evaluation of powdered drugs & Enzymes.
4. Isolation of some phytoconstituents
5. Chromatographic studies of some herbal constituents.
6. Some preliminary experiments in plant tissue culture.

BOOKS RECOMMENDED:
11. Indian Pharmacopoeia.
B.Pharm IV (VIII Semester)

**PHR- 801:** ENVIRONMENT & ECOLOGY

**Unit I**

**Environment studies**
A- Definition, scope & importance
B- Natural Resources – renewable & non renewable
C- Use, utilization, exploitation and associated problems of forests, Water resources, Mineral resources, Food resources, Energy resources, Land resources.
D- Equitable use of resources for sustainable life style, role of an individual in conservation. [08]

**Unit II**

**Ecosystems**
A. Introduction, types features & functions of difference ecosystems- Forest Grassland, Desert and Aquatic.
B. Biodiversity & its conservation with special reference to India. [08]

**Unit III**

Environmental pollution- Air, Water, Soil, Marine, Noise, Thermal, Nuclear- Introduction causes and control measures. [08]

**Unit IV**

Law related to Environmental Protection
Air (Prevention and Control of pollution )Act 1987
Water prevention & Control of Pollution Act. 1974 [08]

**Unit V**

**Environmental Protection Act -1986**
Noise Pollution
Hazardous Wastes
Hazardous Chemical
Hazardous Microorganism
Biomedical Waste
Solid waste disposal
Provisions as applicable to drugs and cosmetics. [08]

**BOOKS RECOMMENDED:**
PHR- 802
CLINICAL PHARMACY AND DRUG INTERACTIONS

Unit-I
INTRODUCTION TO CLINICAL PHARMACY
Definition, development and scope

PATIENT DATA ANALYSIS
The patient’s case history, its structure and use in evaluation of drug therapy, Communication skills including patient medication history interview, patient counseling. Hematological, Liver function, renal function, Tests associated with cardiac disorders. Adverse drug reaction- Epidemiology, Classification, Risk factors, Monitoring a detecting adverse drug reactions, Assessing causality, Reporting adverse drug reactions. [10]

Unit-II
DAILY ACTIVITIES OF CLINICAL PHARMACISTS
Drug therapy monitoring (Medication chart view, clinical review, TDM pharmacist interventions. Drug utilization evaluation (DUE) and review (DRU). Quality assurance of clinical Pharmacy services, Prescription auditing and medication errors and monitoring [08]

Unit-III
CLINICAL PHARMACOKINETICS
Physiological determinants of drug clearance and volumes of distribution. Renal and non-renal clearance. Estimation and determinants of bioavailability. Calculation of loading and maintenance doses. Dose adjustment in renal failure, hepatic dysfunction, geriatric and paediatric patients. [08]

Unit- IV
CONCEPT OF ESSENTIAL DRUGS AND RATIONAL USE OF DRUGS
Definition, symptoms, classifications of the disease, treatment and parameters to monitor the therapy of following systems/diseases
  Cardiovascular systems- hypertension, congestive cardiac failure, ischemic heart disease
  Renal system- acute and chronic renal failure
  GI diseases

Unit-V
RESEARCH DESIGN AND CONDUCT OF CLINICAL TRIALS- Research support including planning and execution of clinical trials. Guidelines for good clinical research practice and ethical requirements. Various phases of clinical trials. Categories of Phase IV studies.[06]

BOKS RECOMMENDED:
1. Basic skills in interpreting laboratory data- Scott LT, American Society of Health System Pharmacists, Inc., USA.
3. Clinical Pharmacokinetics-Rowland and Tozer, Williams and Wilkins Publication.
5. Relevant review articles from recent medical and pharmaceutical literature.
7. Davisson’s Principles and Practice of Medicine, ELBS/Churchill Livingstone.
8. Herfindal E.T. and Hirashman J.L., Clinical Pharmacy and Therapeutics Williams and Wilkins
**PHR–803**

**PHARMACEUTICAL ANALYSIS -III**

**Unit-I:**
Colorimetric Method- Chemistry, Instrumentation and applications
Ultra violet and Visible- Electronic excitation, spectrophotometry, quantitative laws, deviation from Beer’s law, instrumentation, single and double beam spectrophotometry.
Applications in pharmacopoeial analysis [08]

**Unit-II:**
Fluorimetric Analysis- Theory, Instrumentation and applications.
Infra- Red spectrophotometry-Theory, instrumentations, Interpretation of IR , spectra of simple compounds, FTIR, applications in pharmaceutical analysis. [08]

**Unit-III**
NMR Spectroscopy- Theory of 1H.NMR, chemical shift, Shielding & Desheilding, spin-spin coupling, spin-spin splitting spectra of simple compounds.
Applications in pharmacopoeial analysis [10]

**Unit-IV**
Mass Spectroscopy –Theory, Instrumentation & Applications, mass spectra of some simple compounds. Applications in pharmacopoeial analysis [08]

**Unit-V**
Basic Principles, Instrumentation and Application of GLC & HPLC.
Applications in pharmacopoeial analysis [06]

**PHR-803P**

**PHARMACEUTICAL ANALYSIS -III**

**PRACTICAL**

1. Assay of official formulation containing more than one ingredients using instrumental techniques.
2. Interpretation of spectra.

**BOOKS RECOMMENDED:**
2. Skoog V, Principles of Instrumental Analysis, Holler-Neimen
7. Pharmacopoeia of India, Ministry of Health, Govt of India.
Unit I
General notices, test methods- biological and chemical [8]

Unit II
Test methods- Physiochemical and Pharmaceuticals methods [8]

Unit III
Tests on herbal products, Vaccines & Blood related products, General tests [8]

Unit IV
Containers, general notices, general monographs on dosage forms [8]

Unit V
General monographs of veterinary products, general requirements for herbs and herbal products, vaccines and antisera, General monographs of biotechnology products, blood and blood related products
Illustrative studies of 2 monographs each for API (paracetamol, dexamethasone), excipients (lactose, starch) and dosage forms (amoxicillin dry syrup, betamethasone eye drop) [8]

BOOKS RECOMMENDED:
1. Indian Pharmacopoeia 2010
PHR –805

ELECTIVE

Any one of the following:
(A) Standardization of herbal drugs and cosmetics
(B) Drug design.
(C) Pharmaceutical Marketing
(D) Pharmaceutical Packaging
(E) Novel Drug Delivery System
(F) GMP, Quality Assurance & Validation
(G) Hospital Pharmacy
(H) Advanced Pharmacology
(I) Pharmaceutical Entrepreneurship

(A) STANDARDISATION OF HERBAL DRUGS and COSMETICS
Unit I – Commerce and quality control of natural medicinal plants products, organoleptic, microscopical, physical & chemical evaluation of crude drugs. [08]
Unit-II - Standardization of plant material as per WHO guidelines. [08]
Unit-III – Herbal Cosmetics:
Brief study of Phytocosmetics, Industrial significance and current status. Herbs used for different cosmetic formulations like shampoos, conditioners, hair darkeners and skin care products. Study of following drugs used in different cosmetic formulations: Soapnut, Amla, Henna, Hibiscus, Tea, Aloe vera, Glycyrrhiza, turmeric, sandalwood etc. Basic evaluation parameters for skin care products and shampoos. [08]
Unit-IV - Analysis of official formulations derived from crude drugs including some ayurvedic preparations. [08]
Unit-V – Role of markers in the standardization of herbal products [08]

BOOK RECOMMENDED
1. Trease, G.E. Evans W.C., Pharmacognosy ELBS.
2. Tyler Varro. E., Brady Lynn. R. Robbers J.E. Pharmacognosy
4. Harborne Phytochemical methods of chemical analysis.
5. Pharmacoepial standards for Ayurvedic formulations CCRAS, Delhi.
7. Mottal.A.C. Clerk’s isolation & identifications of drugs
10. Peach K. & Tracey MV, Modern methods of plant analysis
12. Indian herbal pharmacopocia.
13. Chaudhary.R.R., Herbal drug industry
(B) DRUG DESIGN

Unit-I
Introduction to Drug Design, Lead Discovery, Interactions (Forces) involved in drug receptor complex, Physiochemical properties in relation to biological action, Stereochemical aspects in drug design, Bioisosters. [08]

Unit-II
Drug metabolism-Phase I & Phase II Metabolic Reactions, Prodrugs & Soft drug concepts [08]

Unit-III
a. Analogous based drug design concept with suitable examples
b. Structure Based drug design concept with examples [08]

Unit-IV
Combinatorial chemistry-Introduction, Parallel and Split & Mixed synthesis. [08]

Unit-V QSAR
Introduction, parameters, Quantitative models- Hansch method & Software’s in QSAR. [08]

BOOKS RECOMMENDED:

(C) PHARMACEUTICAL MARKETING

Unit-I Principles of marketing management, Introduction to pharmaceutical marketing, Identification of the marketing, Market behaviour, Prescribing habits of physician, Patient motivation, Market analysis. [08]


Unit-III Economic and competitive aspects of pharmaceutical industry- Advertising, Detailing, Retail competition, International marketing. [08]

Unit-IV Distribution channels in pharmaceutical marketing – Manufacturerc, Wholesaler, Retailer, Hospital & Government agencies, Selection of stockists and distributors. [08]

Unit-V Controls- Internal control and external control. [08]

BOOKS RECOMMENDED
(D) PHARMACEUTICAL PACKAGING

Unit-I
New concepts in pharmaceutical packaging.
Package systems, package design research, package design for international transit [08]

Unit-II
3. Packaging materials with special reference to polymers, metals, glass and plastics, control of packaging materials and their specifications
4. Blister and strip packaging materials, their testing and specifications including microbiology [08]

Unit-III
5. Testing of containers & closures, Pharmacopoeial tests and specifications, Defects in packages.
6. Stability of package and packaging material
7. Ancillary materials used in packaging, their design and specifications [08]

Unit-IV
8. Sterilization of packaging materials, post-sterilization testing
9. Packaging of Parenterals, Ophthalmics, aerosols and testing
   Corrugated fiber board materials, Printing requirements, label and leaflets preparation, Legal requirement as per D &C rules and rules of importing countries, testing of packaging materials and their transit worthiness [08]

Unit-V
Mechanization of packaging operation, use of bar codes and controls on inline packing, testing of finished packs as per ICH guidelines, packaging materials and product mix-up, their investigations and corrective & punitive action (CAPA) [08]

BOOKS RECOMMENDED:
1. Ross, Packaging of Pharmaceuticals.
3. Griffin, Drug and cosmetic Packaging.
7. USP
8. BIS specifications

(E) NOVEL DRUG DELIVERY SYSTEM

Unit-I
1. Theory of controlled release drug delivery systems.

Unit-II
3. Carriers for drug delivery systems, Prodrugs, Physical, chemical and biomedical engineering approach to achieve controlled drug delivery.
4. Microencapsulation: Methods, kinetics of drug release from microcapsules technology and applications. [08]

Unit-III
5. Transdermal drug delivery systems: Theory, formulation and evaluation, ionotophoresis.
6. Implants and inserts: Types, design and evaluation methods, Osmotic pumps. [08]

Unit-IV
7. Targeted Drug delivery systems: Concept of drug targeting, importance in therapeutics, methods in drug targeting, drug immobilization techniques, nanoparticles, liposomes, niosomes, pharmacosomes and resealed-erythrocytes. [08]

Unit-V
8. Advances in drug delivery systems. An Introduction to buccal, nose to brain, ocular, pulmonary colonic delivery, transmucosal and stemceuticals [08]
BOOKS RECOMMENDED
2. Robinson and Vincent, Controlled Drug Delivery.
4. Noxon, Microencapsulation.
6. Deasy, Microencapsulation and Related Processes.
8. Lisbeth, Illum & Davis, Polymers in Controlled Drug Delivery.
9. Ghosh, Premamoy “Polymer Science & Technology”.

(F) GMP, QUALITY ASSURANCE & VALIDATION

Unit-I
No GMP- GMP-cGMP-CGMP with reference to Indian scenario
1. Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 series. & ICH [08]

Unit-II
2. Documentation- Protocols, Forms and maintenance of records in Pharmaceutical industry.
3. Preparation of documents for new drug approval and export registration (schedule L1 & Y) [08]

Unit-III
4. Basic concept of quality assurance, Quality assurance systems, Sources and control of quality
variation- raw materials, containers, closures, personnel, environment etc [08]

Unit-IV
Facility design- Concepts in validation, validation master plan, validation of product, process,
equipment, machinery, systems. Cleaning, Building management systems [08]

Unit-V
6. In process quality control tests, IPQC problems in pharmaceutical industries.
7. Pharmacopoeial standards for dosage form and acceptance criteria, Sampling plan, Sampling
and operating characteristics curves -raw materials, IPC, finished products and packaging
materials
Internal audits, investigations of market complaints, out of specifications (OOS) [08]

BOOKS RECOMMENDED:
2. OPPI, Quality Assurance.
4. Florey, Analytical Profile of Drugs (All volumes).
5. Indian Pharmacopoeia.
10. Sharma P.P. How to practice GMP’s , Vandana Publication, New Delhi
11. Sharma P.P. Validation in pharmaceutical industry , Vandana Publication, New Delhi
12. TRS guidelines
13. Orange guide
14. D&C Act
15. 21CFR part 211
16. ICH guidelines
(G) HOSPITAL PHARMACY

Unit-I: Organization and Structure: Organization of a hospital and hospital pharmacy, Responsibilities of a hospital pharmacist. Pharmacy and therapeutic committee, Budget preparation and implementation.

Hospital Formulary: Contents, preparation and revision of hospital formulary. [08]

Unit-II: Drug Store Management and Inventory Control: Organization of drug., Types of materials stocked, storage conditions.

Purchase and Inventory control: Principles, various methods of inventory control, purchase procedures, purchase order, procurement and stocking. [08]

Unit-III: Central Sterile Supply Unit and their Management: Aseptic techniques and clean area classification, Types of materials for sterilization, packing of materials prior to sterilization, sterilization equipments, Supply of sterile materials.

Manufacture of Sterile and Non-sterile Products: Policy making of manufacturable items, demand and costing, personnel requirements, manufacturing practice, Master formula record, Production control, Manufacturing records. [08]

Unit-IV: Drug information service: Sources of information on drugs, treatment schedules, procurement of information, computerized services (e.g. MEDLINE), Retrieval of information, Medication error.

Records and Reports: Prescription filling drug profile, Patient medication profile, case on drug interaction & adverse reactions, idiosyncratic cases etc. [08]

Unit-V: Drug distribution systems in Hospitals: Out-patient dispensing, methods adopted, Dispensing of drugs to in-patients. Types of drug distribution systems Charging Policy, labeling, Dispensing of drugs to ambulatory patients, Dispensing of controlled drugs.

Nuclear Pharmacy: Introduction to Radiopharmaceutics- radio-active half life, Units of radioactivity. Production of radio pharmaceuticals, methods of isotonic tagging, preparation of radioisotopes in laboratory using radiation dosimetry, radio-isotope generators, permissible radiation dose level, Radiation hazards and their prevention, specifications for radio-active laboratory. [08]

BOOKS RECOMMENDED:
UNIT 1 Molecular Pharmacology
Receptor occupancy and cellular signaling systems including G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phospholipases.

Pharmacology of receptors: Classification, cellular signaling systems, and pharmacology of agonists of the following receptor types:
Excitatory Amino Acid receptors, Purinoreceptors, GABA & Benzodiazepine Receptors, Neurosteroid receptors, Cannabinoid receptors, Melatonin receptors

Ion Channels and Their Modulators: Classification and biology of potassium ionic channels, and pharmacology of their modulators

UNIT 2. Novel Target Sites: Physiological functions, pharmacological implications, and therapeutic potential of the following target sites: Rho kinase (ROCK)
Phosphoinositide 3-kinase (PI3K), Akt (Protein kinase B), Caspases, Poly (ADPribose) polymerase (PARP), Peroxisome proliferator activator receptors (PPAR)-a
and AMP activated protein kinases, Protein kinases, Phosphodiesterases

UNIT 3 Pharmacological Techniques to Evaluate the following Class of Drugs
Antiepileptics
Antianxiety agents and drugs used in mood and sleep disorders
Antipsychotics
Drugs affecting memory
Skeletal muscle relaxants and neuromuscular blockers
Antidiabetic agents
Analgesics and drugs used in arthritis and neuropathic pain.
Anti-inflammatory agents
Antihypertensive agents
Hepatoprotective agents

UNIT 4 Pharmacotherapeutics
Etiopathogenesis and pharmacotherapy of diseases associated with following systems/diseases:
Cardiovascular System: Hypertension, Congestive cardiac failure, Angina pectoris, Myocardial infarction, hyperlipidemia, Arrhythmias.
Endocrine System: Diabetes, Thyroid diseases, Oral contraception, HRT osteoporosis.
Infection Diseases: Tuberculosis, HIV and related opportunistic infections, malaria, amoebiasis, helminthiasis, leprosy.
Psychiatric Disorder: Anxiety, Alzheimer’s diseases, mood & sleep disorder, schizophrenia.
Neurological disorder: Epilepsy, Parkinson, myasthenia gravis, migraine.

UNIT 5 Stem cell therapeutics
Biology of stem cells.
Potentials of stem cell in various disorders.
Ethical Issues.

BOOKS RECOMMENDED
2. Edinburg University Pharmacology Staff (ed.) Pharmacological Experiments on Isolated Preparations, Livingstone, UK
7. E.T. Herfindal and D.R. Gourley, Text Book of Therapeutics: Drug and Disease Management, Lippincott Williams & Wilkins, USA.

**(I)- Pharmaceutical Entrepreneurship**

**Unit-I**
Entrepreneurship- history & concept, importance

**(8)**

**Unit-II**
Entrepreneurship in the pharmaceutical industry- needs, problems and issues
Importance of communication, decision making and problem solving skills. Business strategies, competition, marketing opportunities, supply chain management keeping in mind return on investments. Case studies -3 to 5  

**(8)**

**Unit-III**
Identification of market for product and services, SWOT analysis
Formulation of strategies, market leaders and success stories of their leading brands. 
Regulatory aspects- Drugs and Cosmetics Act and rules relevant to licensing requirements for retail, wholesale, (schedules H,G,L1,M,Miii,P,P1,U,V,X,Y); DPCO - price control and price fixation, Factory Act, Central and State Excise Act Including Vat, Environmental Protection Act covering air, water, solid waste disposal record keeping, income tax and sales tax, (include only relevant to working), quality system and its relevance.  

**(8)**

**Unit-IV**
Technology Transfer considerations
Funding of projects- Financial, Bootstrapping, External Financing
Project Management, Financial Management – understanding of balance sheet and profit and loss accounts, imports and exports. (need based for understanding for practical application). Case studies - 3  

**(8)**

**Unit-V**
Importance of hr recourses- team building and management
Concept of social entrepreneurship & sustainable entrepreneurship (Growth oriented). Case studies-3  

**(8)**

**Suggested Books:**
4. Handbook of Entrepreneurship Research: An Interdisciplinary Survey and Introduction
10. Bootstrapping Your Business: Start And Grow a Successful Company With Almost No Money by Greg Gianforte, Marcus Gibson, Publisher Adams Media 2005
11. Drugs and Cosmetics Act and Rules, and DPCO, Govt. of India.
12 Factory Act.
13 Shop and Establishment Act.
14 Environmental Protection Act.
15. Central Excise Tariff Act and Import Policy.

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