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

S.N.	Course Code	Subject Name	Period (Hours)		Sessional			Exam	Subject Total	Credits
		Theory	L	P	CT	TA	Total	ESE		
1	PHR- 701	Pharmaceutical Management	3	0	15	05	20	80	100	3
2	PHR- 702	Pharmaceutical Bio-pharmaceutics & Pharmacokinetics	3	0	15	05	20	80	100	3
3	PHR- 703	Medicinal Chemistry-III	3	0	15	05	20	80	100	3
4	PHR- 704	Pharmacology-III	3	0	15	05	20	80	100	3
5	PHR- 705	Pharmacognosy -IV	3	0	15	05	20	80	100	3
Practical Day to Day Evaluation										
6	PHR- 702P	Pharmaceutical Bio-pharmaceutics & Pharmacokinetics	0	4	--	--	20	80	100	2
7	PHR- 704P	Pharmacology-III	0	4	--	--	20	80	100	2
8	PHR- 705P	Pharmacognosy -IV	0	4	--	--	20	80	100	2
9	PHR- 706P	Report on Industrial Visit							100	
			15	12	--	--	160	640	900	

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

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

Course: B. Pharm.

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

S.N.	Course Code	Subject Name	Period (Hours)		Sessional			Exam	Subject Total	Credits
		Theory	L	P	CT	TA	Total	ESE		
1	PHR- 801	Environment and Ecology	3	0	15	05	20	80	100	**3**
2	PHR- 802	Clinical Pharmacy& Drug Interaction	3	0	15	05	20	80	100	**3**
3	PHR- 803	Pharmaceutical Analysis-III	3	0	15	05	20	80	100	**3**
4	PHR- 804	Pharmacopoeial Standards	3	0	15	05	20	80	100	**3**
5	PHR- 805	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 & Validation **Or** (G)- Hospital Pharmacy **Or** (H)- Advanced Pharmacology **Or** (I)- Pharmaceutical Entrepreneurship	4	0	15	05	20	80	100	**4**
Practical Day to Day Evaluation										
6	PHR-803P	Pharmaceutical Analysis	0	4	--	--	20	80	100	**2**
7	PHR- 805P	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 & Validation **Or** (G)- Hospital Pharmacy **Or** (H)- Advanced Pharmacology **Or** (I)- Pharmaceutical Entrepreneurship	0	8	--	--	40	160	200	**4**
			15	12	--	--	160	640	800	-

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

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.

Accountancy: Principles of Accountancy, Ledger posting and book entries preparation of trial balance, columns of a cash book, Bank reconciliation statement, rectification of errors, profits and loss account, balance sheet, purchase, keeping and pricing of stocks, treatment of cheques bills of exchange, promissory notes and bundles documentary bills.

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:

1. Koontz H, Weihrich H, Essentials of Management, Tata Mc Graw Hill.
2. Massie L. Joseph Essentials of Management / PHI.
3. Vidya sagar Pharmaceutical Industrial Management, Pharma Book Syndicate
4. Mukopadhyay Sekhar, Pharmaceutical Selling, Sterling Publishers.
5. Chary S.N, Production and Operative Management / Tata Mc Graw Hill.
6. Datta A.K., Material Management / PHI.
7. Chadwick Leslie, The essence of management accounting / PHI.
8. Barthwal R.R, Industrial Economics –/ New Age International.

PHR– 702

PHARMACEUTICS -VIII
(BIOPHARMACEUTICS & PHARMACOKINETICS)

Unit-1:

Introduction to Biopharmaceutics and Pharmacokinetics, Biopharmaceuitcal 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 [08]

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. [08]

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 [08]

Unit-IV:

(A) Dosage adjustment in patients with and without renal and hepatic failure.
(B) Pharmacokinetic drug interactions and their significance in combination therapy. [08]

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. [08]

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.
3. Absorption studies – in vitro.
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.
3. Wagner J.G. Fundamentals of Clinical Pharmacokinetics, Drugs Intelligence Publishers, Hamilton.
4. Gibaldi, Milo' Biopharmaceutics & Clinical pharcokinatics.
5. John. G.Wagner," Pharmacokinetics for the Pharmaceutical Scientist'.

PHR –703

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

(A) Androgens and Anabolic steroids – Testosterone, Stanazolol.

(B) Estrogens and Progestogens – Progesterone, Estradiol.

(C) 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, Methicilin, 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: Cholroquine, Primaquine, Artemesinin

Antiamoebics: Metronidazole, Tinidazole, Diloxanide

Antiseptics & Disinfectants – Benzalkonium chloride

Anthelmintics- Mebendazole

Antifungals: Griseofulvin, Clotrimazole Amphotericin 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:

1. Delagado J N and Remers W A R, Eds., Wilson And Giswold's Text book of Organic Medicinal and Pharmaceutical Chemistry, J. Lippincott Co., Philadelphia.
2. Foye W C, Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
3. Wolff ME, Ed. Burger's Medicinal Chemistry, John Wiley & Sons, New York.
4. Singh Harkrishan and Kapoor, V.K., Organic Pharmaceutical Chemistry, Vallabh Prakashan, Delhi.
5. Patrick G L. Medicinal Chemistry, Oxford University Press NY
6. Vardanayan R. Synthesis of Essential Drugs, Acacdemic press an imprint of Elsevier
7. Pharmacopoeia of India, Ministry of Health, Govt. of India.
8. Razdan B.K. Medicinal Chemistry, CBS Publication, New Delhi

PHR– 704

PHARMACOLOGY –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 Anatagonists.
B. **Bioassays-** Basic Principles, Bioassay of oxytocin and acetylcholine [07]

PHR-704P

PHARMACOLOGY- 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:

1. Goodman & Gilman, The Pharmacological basis of Therapeutics, Pergamon Press. Editors:- J.G. Hardman, Le Limbird, PB Molinoss, RW Ruddon & AG Gil, Pergamon Press.
2. Katzung, B.G. Basic & Clinical Pharmacology, Prentice Hall, International.
3. Laurene, DR & Bennet PN; Clinical Pharmacology, Churchill Livingstone.
4. Rang MP, Dale MM, Riter JM, Pharmacology Churchill Livingstone.
5. Tripathi, K.D. Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.
6. Barar F.S.K : Text Book of Pharmacology, Interprint, New Delhi.
7. Satoskar & Bhandarkar: Pharmacology & Pharmacotheropeutics, Popular Prakashan Pvt. Ltd., Bombay.
8. Paul. L., Principles of Pharmacology, Chapman and Hall.
9. Ghosh M.N. Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta.
10. Grover J.K., Experiments in Pharmacy & Pharmacology, CBS Publishers, New Delhi.
11. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.

PHR-705

PHARMACOGNOSY-IV

Unit-1: 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. [08]

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 [10]

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. [08]

Unit-IV

Biological sources, preparation, Identification tests and uses of following enzymes – [08]

Diastase, papain, Penicillinase, Hyalluronidase, Streptokinase. Plant Bitters & Sweeteners.

Unit-V:

Historical development of plant tissue culture, type of culture, Nutritional requirement, growth & their maintenance. Application of plant tissue culture in pharmacognosy. [08]

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:

1. Trease, G.E. & Evans, W.C. "Pharmacognosy" Bailliere Tindall East Bourne, U.K.
2. Tyler V.E. etal Pharmacognosy, Lea & Febiger Phjadelphia.
3. Wallis T.E. Text book of Pharmacognosy" J&A Churchill Ltd. London.
4. Atal & Kapur, Cultivation & Utilization of Medicinal Plants, RRL, Jammu.
5. Stahl. E, Thin Layer Chromatography. A laboratory handbook, Springer Verlog, Berlin.
6. Henry TA. The Plant Alkaloids, McGraw Hill, New York.
7. Ganborg & Wetter, Plant Tissue Culture Methods, National Research Council of Canada, Saskatchewan.
8. Clarke ECG, Isolation & Identification of drugs. The Pharmaceutical Press, London.
9. Street H.E. Tissue Culture & Plant Science, Academic Press, London.
10. Kokate, C.K. Gokhale AS, Gokhale SB, Cultivation of Medicinal Plants, Nirali Prakashan.
11. Indian Pharmacopoeia.
12. Kokate, C.K. Practical Pharmacognosy, Vallabh Prakashan, Delhi.
13. Wallis T.E. Analytical Microscopy, J&A Churchill Ltd, London.

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:

1. Manoharachary C., Jyaranama Reddy P. Principles of Environmental Studies, Pharma Book Syndicate, Hyderabad.
2. Trivedy R.K., Handbook of Environmental Laws, Acts, Guidelines, Compliances & Standards Vol. I &II. Pharma Book Syndiacte, Hyderabad
3. Relevant Acts & Rules published by Govt. of India with latest amendments.
4. Reddy, M.Anji , ‘ Text Book of Environmental Sciences & Technology”.
5. National Formulary of India, Latest edition

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 [08]

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.
2. Practice Standrds and Definitions- The Society of Hospital Pharmacists of Australia, 1997.
3. Clinical Pharmacokinetics-Rowland and Tozer, Williams and Wilkins Publication.
4. Biopharmaceutics and Applied Pharmacokinetics-Leon Shargel, Prentice Hall publication.
5. Relevant review articles from recent medical and pharmaceutical literature.
6. Parthasarthi G, Nyfort-Hansen K, Nahata M.C., A Text book of Clinical Pharmacy Practice –Essential Concepts and Skills, Orient Longman.
7. Davisson's Pranciples and Practice of Medicine, ELBS/Churchill Livingstone.
8. Herfindal E.T. and Hirashman J.L., Clinical Pharmacy and Therapeutics Williams and Wilkins
9. John g.Wagner," Pharmacokinetics for the Pharmaceutical Scientist".

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:

1. Willard H.H. and Merrit L. Jr and Dean J.A., Instrumental methods of analysis Van Nostrand Renhold, New York.
2. Skoog V, Principles of Instrumental Analysis, Holler-Neimen
3. Kemp William, organic spectroscopy, PALGRAVE NewYork
4. Silver stein RM & Webster FX, Spectrometric Identification of Organic Compounds, John Wiley & Sons.
5. Chatten L.G. A text book of Pharmaceutical Chemistry Vol. I & II Marcel, Dekker, New York.
6. Becket A.H. and Stenlake J.B. Practical Pharmaceutical Chemistry Vol. I and II, The Athlone Press of the University of London.
7. Pharmacopoeia of India, Ministry of Health, Govt of India.

PHR-804

PHARMACOPOEIAL STANDARDS

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
3. Wallis T.E..Text book of Pharmacognosy
4. Harborne Phytochemical methods of chemical analysis.
5. Pharmacoepial standards for Ayurvedic formulations CCRAS, Delhi.
6. Vapoorte, Swendson Chromatography of alkaloids.
7. Mottal.A.C. Clerk's isolation & identifications of drugs
8. Dhavan B.N. & Srimal R.C, The use of pharmacological techniques for evaluation of natural products. CDRI Lucknow.
9. Brain K.R. and Turner T.D, The practical evaluation of phytopharmaceuticals
10. Peach K. & Tracey MV, Modern methods of plant analysis
11. British herbal phamacopocia.
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, Sterochemical aspects in drug design, Bioisosterism. [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]
Computer Aided Drug Design-Introduction & Softwares used in CADD

Unit-V QSAR

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

BOOKS RECOMMEDED:

1. E.J, Ariens: Drug Design, Academic Press, New York (1975).
2. S.H. Salkovisky, A.A. Sinkula and S.C. Valvani, Physical Chemical Properties of Drugs, Marcel Dekker Inc. New York.
3. M.E. Wolff, Burger's Medical Chemistry, John Willey and Sons, New York.
4. R.F, Doerge, Wilson and Gisvold's Text Book of Organic Medicinal and Pharmaceutical Chemistry,J. Lippincott Co, Philadelphia.
5. Olson, Edward C "Computer Assisted Drug Design (American Chemical Society).
6. Burger A "A guide to chemical basis of Drug Design "John Wiley & Sons".
7. Thomas J.Perun "Computer aided Drug Design methods Applications".

(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-II MARKET RESEARCH: Measuring & Forecasting Market Demand - Major concept in demand measurement, Estimating current demand Geo-demo- graphic analysis. Estimating industry sales. Market share and future demand. Market segmentation & Market targeting. Drug development and the marketing research interface, Diversification and specialization, Marketing generic drugs. [08]

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

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

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

BOOKS RECOMMENDED

1. Smith, Mickey C, "Principles of pharmaceutical marketing", CBS Publishers & Distributors.
2. Kotler, Philip "Marketing Management". Pearson Education Asia.

(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.
2. Joseph D.O. Brien, Medical Device Packaging Handbook.
3. Griffin, Drug and cosmetic Packaging.
4. Barail, Packaging Engineering.
5. Harburn, Quality-Control of Packaging Materials in Pharmaceutical Industry.
6. Kac Chensney, Packaging of Cosmetics and Toiletories.
7. USP
8. BIS specifications

(E) NOVEL DRUG DELIVERY SYSTEM

Unit-I

1. Theory of controlled release drug delivery systems.

2. Release and diffusion of drugs from C.D.D.S., General methods of design and evaluation of C.D.D.S. [08]

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

1. Julian, Drug Delivery Systems.
2. Robinson and Vincent, Controlled Drug Delivery.
3. Robinson, Sustained and Conrolled Drug Delivery Systems.
4. Noxon, Microencapsulation.
5. Chien, Novel Drug Delivery Systems.
6. Deasy, Microencapsulation and Related Processes.
7. Gutcho, 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

Drugs & cosmetics rules with reference to G,H,M,P,P1, T,U,X

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 RECOMMEDED:

1.Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals.
2. OPPI, Quality Assurance.
3. Loftus and Nash, Pharmaceutical Process Validation.
4. Florey, Analytical Profile of Drugs (All volumes).
5. Indian Pharmacopoeia.
6. United States Pharmacopoeia.
7. British Pharmacopoeia.
8. Garfield, Quality Assurance Principles for Analytical Laboratories.
9. Manohar A. Potdar, C.GMP for Pharmaceuticals.
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:

1. Hasan, Hospital Pharmacy, Lea & Febiger, Philadelphia.
2. Merchant H.S. and Qadry J.S. Text Book of Hospital Pharmacy, B.S. Shah Prakashan, Ahmedabad.

(G) ***ADVANCED PHARMACOLOGY AND PHARMACOTHERAPEUTICS***

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
Antiulcer 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

1. M.N.Ghosh, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta, India.
2. Edinburg University Pharmacology Staff (ed.) Pharmacological Experiments on Isolated Preparations, Livingstone, UK
3. H.G.Vogel (ed), Drug Discovery and Evaluation-Pharmacological Assays, Springer Verlag, Berlin, Germany.
4. D.R.Laurence and A.L.Bacharach (eds), Evaluation of Drug Activities: Pharmacometerics, Vol. 1and 2, Academic Press, London, U.K.
5. David R. Gross, Animal Models in Cardiovascular Research, Kluwer Academic Publishers, London, U.K.

6. J.T. Dipiro, R.L. Talbert, G.C.Yee, G.R.Matzke, B.G.Wells, L.Michael Posey (eds.), Pharmacotherapy: A Pathophysiologic Approach, The McGraw Hill Companies, Inc.
7. E.T.Herfindal and D.R.Gourley, Text Book of Therapeutics: Drug and Disease Management, Lippincott Williams & Wilkins, USA.
10. T.M Speight and NHG Holford (ed.), Avery's Drug Treatment: Principals and Practice of Clinical Pharmacology and Therapeutics, ADIS Press, Sydney, Australia.
11. Dennis L. Kasper, Eugene Braunwald, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson, and Kurt J. Isselbacher, (eds.), Harrison's Principles of Internal Medicine, The McGraw Hill Companies, Inc.

(I)- Pharmaceutical Entrepreneurship

Unit-I

Entrepreneurship- history & concept, importance
Entrepreneur- Leadership Attributes, Innovations, Influences, Personality Traits And Characteristics. Types of Entrepreneurs. Business etiquettes, Business language and Communication. (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:

1. Welsh, J.A. & Jerry, F.W., 'Entrepreneur's Master Planning Guide, How to launch a successful business', Prentice Hall, Englewood cliff.
2. Srivastava U.K., 'Project Planning, Financing, Implementation and Evaluation, IIM, Ahmedabad.
3. Rao, T.V. & Pareek U, 'Developing Entrepreneurships: A Handbook'. Learning

Systems, New Delhi.
4. Handbook of Entrepreneurship Research: An Interdisciplinary Survey and Introduction
5. Duening, Thomas N., Hisrich, Robert D., Lechter, Michael A., Technology Entrepreneurship, Academic Press, 2009.
6. Lundström, Anders und Stevenson, Lois (2005), Entrepreneurship Policy: Theory and Practice, Springer.
7. Deakins, D.; Freel, M. (2009). Entrepreneurship and Small Firms, 5th Edition. McGraw Hill.
8. Pharmaceutical Industry: Innovation & Developments (Business Issues, Competition and Entrepreneurship) by David A. Mancuso, Isobel M. Grenada Publisher: Nova Science Publishers Inc (3 Aug 2011)
9. The Business of Healthcare Innovation [Hardcover]
Lawton Robert Burns, Publisher: Cambridge University Press; 2 edition
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.

PHR-805 P
Project on Elective