

[School of Pharmacy
Syllabus]

**Bachelor of Pharmacy 4th year (VIII Semester)
(Theory and Practical)**

S No.	Course	Subject name	Credits		Sessional			Exam	Total
			T	P	TA	MSE	Total	ESE	
1	GSP-801	Pharmacopoeial Standards	4	0	30	20	50	50	100
2	GSP-802	Clinical Pharmacy and Drug Interactions	4	0	30	20	50	50	100
3	GSP-803	Pharmaceutical Biotechnology	4	0	30	20	50	50	100
4	GSP-804	Pharmacology- IV	3	0	30	20	50	50	100
5	GSP-805	Medicinal Chemistry- IV							
6	GSP-806	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. Advanced Pharmacology h. Pharmaceutical Entrepreneurship	3	0	30	20	50	50	100
PRACTICAL									
7	GSP-804P	Pharmacology IV	0	2	30	20	50	50	100
8	GSP-805P	Medicinal Chemistry- IV	0	2	30	20	50	50	100
9	GSP-806P	Elective* (Project Report)			30	20	50	50	100
								Total	900

T- Theory, P- Practical, TA- Teacher Assessment, MSE- Mid Term Examination, ESE- End semester examination.

[School of Pharmacy
Syllabus]

GSP- 801

PHARMACOPOEIAL STANDARDS

Unit I

General notices, test methods- biological (Bioassay and in vitro assay) and chemical (Acid base, Non aqueous and blank titration with examples).

Unit II

General monograph of herbs includes quinine, ephedrine, vincristine, reserpine, ipecac and senna.

Unit III

Tests for vaccines & antisera includes hepatitis, polio, chicken pox, rabies, typhoid and tetanus.

Unit IV

General monograph of pharmaceutical products includes paracetamol, aspirin, ranitidine, digitoxin, acetazolamide and metformin.

Unit V

Pharmaceutical technical procedures: Introduction, uniformity of content for single dose preparation, uniformity of mass for single dose preparation, disintegration test for tablet and capsules, dissolution test for oral dosage form, method of sterilization, extractable volume for parenteral preparation, test for particulate contamination.

BOOKS RECOMMENDED:

1. Indian Pharmacopoeia 2010

CLINICAL PHARMACY AND DRUG INTERACTIONS

UNIT-1.

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.

UNIT-2.

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.

UNIT-3.

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.

UNIT- 4.

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-5.

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.

BOOKS RECOMMENDED:

1. Basic skills in interpreting laboratory data- Scott LT, American Society of Health System Pharmacists, Inc., USA.
2. Clinical Pharmacokinetics-Rowland and Tozer, Williams and Wilkins Publication.
3. Biopharmaceutics and Applied Pharmacokinetics-Leon Shargel, Prentice Hall publication.
4. Relevant review articles from recent medical and pharmaceutical literature.
5. Parthasarathi G, Nyfort-Hansen K, Nahata M.C., A Text book of Clinical Pharmacy Practice –Essential Concepts and Skills, Orient Longman.
6. Davisson's Principles and Practice of Medicine, ELBS/Churchill Livingstone.
7. Herfindal E.T. and Hirashman J.L., Clinical Pharmacy and Therapeutics Williams and Wilkins
8. John g.Wagner," Pharmacokinetics for the Pharmaceutical Scientist".

PHARMACEUTICAL BIOTECHNOLOGY

UNIT-I.

Immunology and Immunological preparations: Principles, Antigen and haptens, immune system, Cellular, and humoral immunity, immunological tolerance, antigen-antibody reactions and their applications, standardization and storage of BCG. Complementary system, Immunological disorder, Hypersensitivity reaction, Immunosuppression, Autoimmune disorders, immunodeficiency disorders.

UNIT-2.

Genetic Recombination- Genetic Code and inhibition of protein synthesis. Regulation of gene expression (Prokaryote and Eukaryote) Transformation, conjugation, transduction, protoplast fusion and gene cloning and their applications, development of hybridoma for monoclonal antibodies, study of drugs produced by biotechnology such as Human Insulin, Somatotropin, Streptokinase, Urokinase. Isolation and uses of mutants and factors affecting mutation and genetic analysis of mutants.

UNIT-3.

Microbial Transformation: Introduction, types of reactions mediated by microorganisms, Design of Bio-transformation process, selection of organisms, biotransformation processes and its improvements with special reference to steroids.

UNIT-4.

Enzyme immobilization: Techniques of immobilization of enzymes, factors affecting enzyme kinetics, multistep immobilized enzyme system. Application and future of enzyme engineering.

UNIT-5.

Antibiotics: Historical development of antibiotics, Screening of soil for organisms producing antibiotics Antimicrobial spectrum and methods used for their standardization. Fermentor, its design and control of different parameters.

BOOKS RECOMMENDED:

1. S.P. Vyas and V.K. Dixit, Pharmaceutical Biotechnology, CBS Publication, New Delhi.
2. Nagori, Foundations in pharmaceutical biotechnology, Pharma Med Press, Hyderabad
3. Thieman, introduction to biotechnology, Pearson education.
4. P.F. Standury & A. Whitaker & Hall S.J. Principles of Fermentation, Aditya Book Private Limited, New Delhi.
5. Crueger W. & Crueger A, Biotechnology-A Textbook of Industrial Microbiology.
6. Smith J.E., Biotechnology, 3rd edition, Cambridge university press.

[School of Pharmacy
Syllabus]

GSP-804

PHARMACOLOGY-IV

UNIT-1.

Bioassays- Basic Principles, advantages of bioassays, Bioassay of oxytocin and acetylcholine, serotonin, adrenaline, histamine, D-tubocurarine.

UNIT-2.

Chemotherapy- Introduction to chemotherapy, principles of chemotherapy, history of chemotherapy, classification of antimicrobial drugs, mechanism of development of resistance to antimicrobial agents, basic mechanism of action of antimicrobial agents, selection of an antimicrobial agents, complications of antimicrobial therapy.

UNIT-3.

Pharmacology of nucleic acid synthesis inhibitors- Sulfonamides, cotrimoxazole, quinolones & fluoroquinolones

Cell wall synthesis inhibitors, Beta lactams (Penicillins, cephalosporins etc.), Beta lactamase inhibitors, Vancomycin, Bacitracin, cyclosporine, Monobactams carbapenems.

UNIT-4.

Protein Synthesis inhibitors: Tetracyclines, Chloramphenicol, aminoglycosides, macrolides, ticoplanin, oxazolidinones, polypeptide antibiotics, urinary antiseptics,

Antitubercular Drugs, antileprotics, antifungals, antiprortozoals, anthelmintics & Antivirals.

UNIT-5.

Immunopharmacology, Chemotherapy of neoplastic diseases, gene therapy, stem cell therapy.

GSP-804P

PHARMACOLOGY-IV (PRACTICAL)

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

BOOKS RECOMMENDED:

1. Goodman & Gilman, The Pharmacological basis of Therapeutics, Editors:-JG Hardman, Le Limbird, PB Molinoss, RW Rudden & AG Gil, Pergamon Press.
2. Laurence, DR & Bannet PN; Clinical Pharmacology, Churchill Livingstone.
3. Rang MP, Dale MM, Riter JM, Pharmacology Churchill Livingstone.
4. Tripathi, K.D. Essentials of Medical Pharmacology, Jay Pee Publishers, New Delhi.
5. Barar FSK: Text Book of Pharmacology, Interprint, New Delhi.
6. Satoskar & Bhandarkar; Pharmacology & Pharmacotherapeutics, Popular Prakashan Pvt. Ltd., Bombay.
7. Turner, Screening methods in pharamacology, PharmaMed Press, Hyderabad
8. Ghosh, MN; Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta.
9. Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, Delhi.

[School of Pharmacy
Syllabus]

GSP 805

MEDICINAL CHEMISTRY – III

A study of the following classes of drugs including structure activity relationship (SAR), mechanism of action, synthesis of compounds superscribed by 's', chemical nomenclature, generic names, brand names (a few important marketed products) and side effects.

UNIT-1.

Antibacterials sulphonamides: Sulphamethoxazole, Sulphadiazine, Sulphacetamide.

Quinolones: Nalidixic acid, Norfloxacin.

Antiseptics & Disinfectants: Benzalkonium chloride.

UNIT-2.

Anti- HIV agents: Zidovudine, Zalcitabine, Saquinavir.

Antivirals: Amantadine, Acyclovir, Lamivudine.

UNIT-3.

Anti-cancer drugs: Alkylating Agents, Chlorambucil, Carmustine Antimetabolites, Methotrexate 6-Mercaptopurine, 5-Fluorouracil.

UNIT-4.

Hypoglycaemics: Insulin Chlorpropamide, Metformin, Tolbutamide, Glibenclamide.

UNIT-5.

Histamine and antihistaminic agents

Histamine: receptors and its actions

Antihistaminics: H1 antagonists Chlorpheniramine, Promethazine, Cetrizine

GSP-805P

MEDICINAL CHEMISTRY (PRACTICALS)

1. Synthesis of at least five selected drugs from the course content involving two or more steps.
2. Establishing the pharmacopoeial standards of the drugs synthesized.
3. Simple experiment demonstrating microwave assisted synthesis.

BOOKS Recommended

1. Beckett and Stenlake Practical Pharmaceutical Chemistry, the sthalone press, University of London
2. BS Furniss et al Vogel's TB of Practical Organic Chemistry including quantitative analysis, ELBS/Longman, London
3. Burger's Medicinal Chemistry, ME Walffed Johnwiley and sons
5. Essentials of Medicinal Chemistry Korolkovas
6. IP 2014 Govt. of India, Ministry of health
7. Mann and Saunders Practical Organic Chemistry Longman Green and Co London
8. Martindale the Extra Pharmacopoeia, JE Reynolds The pharmaceutical press, London
9. Medicinal Chemistry Ashutosh Kar, New Age international publishers, New Delhi
10. Organic Chemistry of Drug Synthesis Lednicer Mitzsher
11. Organic medicinal chemistry by Pandey

[School of Pharmacy
Syllabus]

**GSP –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. Advanced Pharmacology**
- H. Pharmaceutical Entrepreneurship**

STANDARDISATION OF HERBAL DRUGS AND COSMETICS

UNIT 1.

Commerce and quality control of natural medicinal plants products, organoleptic, microscopical, physical & chemical evaluation of crude drugs.

UNIT-2.

Standardization of plant material as per WHO guidelines.

UNIT-3.

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.

UNIT-4.

Analysis of official formulations derived from crude drugs including some ayurvedic preparations.

UNIT-5.

Role of markers in the standardization of herbal products.

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. Pharmacopial 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.

[School of Pharmacy
Syllabus]

12. Indian herbal pharmacopocia.

[School of Pharmacy
Syllabus]

DRUG DESIGN

UNIT-1.

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, Bioisosterism.

UNIT-2.

Drug metabolism-Phase I & Phase II Metabolic Reactions, Prodrugs & Soft drug concepts.

UNIT-3.

1. Analogous based drug design concept with suitable examples
2. Structure Based drug design concept with examples.

UNIT-4.

Combinatorial chemistry-Introduction, Parallel and Split & Mixed synthesis.

Computer Aided Drug Design-Introduction & Softwares used in CADD.

UNIT-5.

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

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BOOKS RECOMMENDED:

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".

PHARMACEUTICAL MARKETING

UNIT-1.

Principles of marketing management, Introduction to pharmaceutical marketing, Identification of the marketing, Market behaviour, Prescribing habits of physician, Patient motivation, Market analysis.

UNIT-2.

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.

UNIT-3.

Economic and competitive aspects of pharmaceutical industry- Advertising, Detailing, Retail competition, International marketing.

UNIT-4.

Distribution channels in pharmaceutical marketing– Manufacturer, Wholesaler, Retailer, Hospital & Government agencies, Selection of stockists and distributors.

UNIT-5.

Controls- Internal control and external control.

BOOKS RECOMMENDED

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

PHARMACEUTICAL PACKAGING

UNIT-1.

New concepts in pharmaceutical packaging.

Package systems, package design research, package design for international transit.

UNIT-2.

Packaging materials with special reference to polymers, metals, glass and plastics, control of packaging materials and their specifications

Blister and strip packaging materials, their testing and specifications including microbiology.

UNIT-3.

Testing of containers & closures, Pharmacopoeial tests and specifications, Defects in packages.

Stability of package and packaging material

Ancillary materials used in packaging, their design and specifications.

UNIT-4.

Sterilization of packaging materials, post-sterilization testing

Packaging of Parenterals, Ophthalmics, aerosols and testing

Corrugated fibre 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.

UNIT-5.

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).

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 Toiletries.
7. USP
8. BIS specifications

NOVEL DRUG DELIVERY SYSTEM

UNIT-1.

Theory of controlled release drug delivery systems.

Release and diffusion of drugs from C.D.D.S., General methods of design and evaluation of C.D.D.S.

UNIT-2.

Carriers for drug delivery systems, Prodrugs, Physical, chemical and biomedical engineering approach to achieve controlled drug delivery.

Microencapsulation: Methods, kinetics of drug release from microcapsules technology and applications.

UNIT-3.

Transdermal drug delivery systems: Theory, formulation and evaluation, iontophoresis.

Implants and inserts: Types, design and evaluation methods, Osmotic pumps.

UNIT-4.

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.

UNIT-5.

Advances in drug delivery systems. An Introduction to buccal, nose to brain, ocular, pulmonary colonic delivery, transmucosal delivery systems.

BOOKS RECOMMENDED

1. Julian, Drug Delivery Systems.
2. Robinson and Vincent, Controlled Drug Delivery.
3. Robinson, Sustained and Controlled 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.

[School of Pharmacy
Syllabus]

GMP, QUALITY ASSURANCE & VALIDATION

UNIT-1.

No GMP- GMP-cGMP-CGMP with reference to Indian scenario Drugs & cosmetics rules with reference to G,H,M,P,P1, T,U,X Requirements of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 series. & ICH.

UNIT-2.

Documentation- Protocols, Forms and maintenance of records in Pharmaceutical industry. Preparation of documents for new drug approval and export registration (schedule L1 & Y).

UNIT-3.

Basic concept of quality assurance, Quality assurance systems, Sources and control of quality variation- raw materials, containers, closures, personnel, environment etc.

UNIT-4.

Facility design- Concepts in validation, validation master plan, validation of product, process, equipment, machinery, systems. Cleaning, Building management systems.

UNIT-5.

In process quality control tests, IPQC problems in pharmaceutical industries. 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).

BOOKS RECOMMENDED:

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

[School of Pharmacy
Syllabus]

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 (ADP-ribose) polymerase (PARP), Peroxisome proliferator activator receptors (PPAR)- 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, 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

[School of Pharmacy
Syllabus]

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: Pharmacometrics, Vol. 1 and 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.
8. T.M Speight and NHG Holford (ed.), Avery's Drug Treatment: Principles and Practice of Clinical Pharmacology and Therapeutics, ADIS Press, Sydney, Australia.
9. Dennis L. Kasper, Eugene Braunwald, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo,
10. J. Larry Jameson, and Kurt J. Isselbacher, (eds.), Harrison's Principles of Internal Medicine, The McGraw Hill Companies, Inc.

[School of Pharmacy
Syllabus]

PHARMACEUTICAL ENTREPRENEURSHIP

UNIT-1.

Entrepreneurship- history & concept, importance

Entrepreneur- Leadership Attributes, Innovations, Influences, Personality Traits And Characteristics. Types of Entrepreneurs. Business etiquettes, Business language and Communication.

UNIT-2.

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.

UNIT-3.

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.

UNIT-4.

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.

UNIT-5.

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

BOOKS RECOMMENDED:

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

[School of Pharmacy
Syllabus]

Hill.

8. Pharmaceutical Industry: Innovation & Developments (Business Issues, Competition and Entrepreneurship) by David A. Mancuso, Isobel M. Grenada Publisher: Nova Science Publishers Inc.
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. 14 Environmental Protection Act.
15. 15. Central Excise Tariff Act and Import Policy.

GSP-805 P
Project on Elective