JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

B.PHARM. III YEAR COURSE STRUCTURE & SYLLABUS (R16)

Applicable From 2016-17 Admitted Batch

III YEAR I SEMESTER

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS501	Pharmaceutical Microbiology	4	1	0	4
2	PS502	Pharmaceutical Technology - I	4	1	0	4
3	PS503	Pharmacology – I	4	1	0	4
4	PS504	Pharmacognosy – II	3	1	0	3
5	 PS505 PS506 MS507	**Open Elective - II** Drug Regulatory Affairs Active Pharmaceutical Ingredient Process Development Entrepreneurship and Small Business Enterprises	3	0	0	3
6	PS508	Pharmaceutical Microbiology Lab	0	0	3	2
7	PS509	Pharmaceutical Technology - I Lab	0	0	3	2
8	PS510	Pharmacology – I Lab	0	0	3	2
9	*MC500	Professional Ethics	3	0	0	0
		Total	21	4	9	24

III YEAR II SEMESTER

S. No.	Course Code	Course Title	L	T	P	Credits
1	PS601	Medicinal Chemistry - I	3	1	0	3
2	PS602	Pharmaceutical Technology – II	3	1	0	3
3	PS603	Pharmacology – II	4	1	0	4
4	PS604	Chemistry of Natural Products	3	1	0	3
5	 PS605 PS606 PS607	**Open Elective - III** Generic Product Development Drug Design and Discovery Screening Methods in Pharmacology	3	0	0	3
6	PS608	Medicinal Chemistry - I Lab	0	0	3	2
7	PS609	Pharmaceutical Technology – II Lab	0	0	3	2
8	PS610	Pharmacology – II Lab	0	0	3	2
9	HS611	Advanced English Communication skills Lab	0	0	3	2
		Total	16	04	12	24

PS501: PHARMACEUTICAL MICROBIOLOGY

B. Pharm III Year I sem

L	T	P	C
4	1	0	4

Course Objectives: Microbiology is always considered to be an essential component of Pharmacy curriculum because of its relevance to pharmaceutical sciences and more specifically to pharmaceutical industry.
This course deals with the various aspects of microorganism their classification morphology, laboratory cultivation, identification, maintenance and control of microorganism, sterility testing and biosafety measures.
The course also covers bacterial genetics, drug resistance and microbiological assays and microbial limit tests.

Course Outcomes: Upon completion of the subject student shall be able to –

- know the anatomy, identification & cultivation of microorganisms
- Perform sterilization of various pharmaceutical products, equipment, culture media etc.
- Perform sterility testing of pharmaceutical products.
- Perform microbiological assay of antibiotics, Vitamins and amino acids
- Do microbiological analysis of air, water and milk

UNIT I

a. Introduction to Microbiology: Origin, scope and discovery of spontanesous generation theory, contributions of Antony Van Leewenhoek, Louis Pasteur, Robert Koch and Joseph Lister.
b. Diversity of Microorganisms: Prokaryotes versus eukaryotes – three domains of life (bacteria, archea and eurkaryotics). A detailed study of bacteria, yeasts, molds and viruses including their classification. Characterization and identification of microorganisms.

UNIT II

Nutrition and Growth of Microbes: Nutritional requirements, Types of nutrient media and growth conditions and Nutritional types based on energy source.
Isolation, cultivation (aerobic & anaerobic) and preservation of microorganisms, physiology of growth, bacterial growth curve, influence of various factors (including environmental factors) on microbial growth, Enumeration of bacteria. Exponential growth and generation time. Bacterial growth in batch and continous culture (chemostat and turbidostat) synchronous growth.

UNIT III

a. Control of Microorganisms: General concepts, Inhibition of growth and killing, sterilization and disinfection, antisepis and sanitation, mode of action applications & limitations of physical agents (moist and dry heat, radiation and filtration) and chemical agents. Various types of disinfectants, factors affecting sterilization and disinfection, evaluation of antimicrobial activity.
b. Official methods of sterility testing of pharmaceuticals and biosafety measures.

UNIT IV

Bacterial Genetics: Genetic recombination in bacteria, DNA replication, transcription and translation. Gene regulation (lac operon and tryptophan operon). Mutagenesis, chemical and physical mutagens. A study on drug resistance.

UNIT V

a. Introduction to Microbiology of Air, Water and milk. Methods of quantitative evaluation of microbial Contamination.

b. Microbiological Assays: Principles and methods involved in assay of Antibiotics, Vitamins, Amino acids &
Bio-Sensors in Analysis.
c. Microbial limit tests official in IP

TEXT BOOKS

1. Pelzar and Reid, Text Book of Microbiology
2. Anantha Narayan and Jayram Panikar, Text Book of Microbiology, Orient Longman, Delhi, Hyderabad.
3. Indian Pharmacopoeia, 1996

REFERENCES

1. Tortora / Funke / Care / Microbiology an introduction.
2. Stephen. P, Denyer, N.A. Hodger- Hugo & Russel's Pharmaceutical Microbiology .

PS502: PHARMACEUTICAL TECHNOLOGY – I

B. Pharm III Year I sem

L	T	P	C
4	1	0	4

Course Objectives: The student shall be taught on preformulation factors and objectives of preformulation, stability and Bioavailability of formulation, concept of products, semisolids, aerosols and cosmetic preparations.

Course Outcome: Student will know the preformulation parameters in designing the dosage form, ICH guidelines, preparation and evaluation of semisolids, ophthalmic and cosmetics.

UNIT I

Preformulation:

a. Introduction and objectives of preformulation study and development of dosage forms, Physical and Chemical aspects.
b. Stability and bioavailability study of prodrugs in solving problems related to stability bio availability in formulations.
c. Stability testing of finished products as per ICH guidelines.

UNIT II

a) **Tablets: Formulation and evaluation of tablets:**

Conventional, matrix, chewable, multi-layered tablets, buccal and sublingual, fast dissolving tablets and gastric retention drug delivery systems

b) Machinery used in granulation techniques like rapid mixer granulation, fluidised bed systems and tablet compression

UNIT III

Coating of Tablets: Types of coating, coating materials and their selection, formulation of coating solution, equipment for coating, coating processes and evaluation of coated tablets. Pellet technology

UNIT IV

a) Capsules: Advantage and disadvantages of capsule dosage forms, material for production of hard and soft gelatin capsules, sizes of capsules, capsule filling, processing problems in capsule manufacturing, importance of base absorption and minimum/gm factors in soft capsules, quality control, stability testing and storage of capsule dosage forms.

b) Microencapsulation: Types and importance in pharmacy, microencapsulation by coacervation phase separator, multi orifice centrifugal separation. Spray drying, spray congealing, polymerization complex emulsion, air suspension technique, and pan coating techniques and evaluation of microcapsules.

UNIT V

Cosmeticology and Cosmetic Preparations: Fundamentals of cosmetic science, Formulation, preparation and packaging of cosmetics for skin, hair, dentrificers like tooth powders, paste, gels and manicure preparations like nail polish, lipsticks, eye lashes, baby care products etc.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
2. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.

REFERENCES

1. Shobha Rani, Text of Industrial Pharmacy, Hiremath Orient Longman
2. Essentials of pharmaceutical technology by Ajay semelty, Mona Semalty

PS503: PHARMACOLOGY – I

B. Pharm III Year I sem

L	T	P	C
4	1	0	4

Course Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, and route of administration, precautions, contraindications and interaction with other drugs.

Course Outcome: Understand the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically.

UNIT I

General Pharmacology: Introduction to pharmacology, sources of drugs, dosage forms and routes of administration, Absorption, distribution, Metabolism and excretion of drugs, mechanism of action, combined effect of drugs, factors modifying drug action, Adverse drug reactions, tolerance and dependence, pharmacogenetics., principles of drug discovery and phases of drug development.

UNIT II

Pharmacology of Peripheral Nervous System:

a. Neurohumoral transmission (autonomic and Somatic)
b. Parasympathomimetics, parasympatholytics, sympathomimetics & sympatholytics
c. Skeleton muscle relaxants

UNIT III

Pharmacology of Central Nervous System:

a. Neurohumoral transmission in the C.N.S.
b. General anesthetics.
c. Alcohols and disulfiram.
d. Pharmacology of Sedatives, hypnotics, anti-anxiety agents

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UNIT IV

a. Analgesics, Antipyretics, Anti-inflammatory and Anti-gout drugs.
b. Narcotic analgesics and antagonists.
c. C.N.S. stimulants
d. Drug Addiction and Drug Abuse.
e. Local anesthetic agents

UNIT V

a. Psychopharmacological agents (antipsychotics) Antidepressants, anti- maniacs and hallucinogens.
b. Pharmacology of Anti-epileptic drugs
c. Anti-Parkinsonian Drugs

TEXT BOOKS

1. Tripathi, Textbook of Pharmacology, JAYPEE
2. F.S.K Barar, Essentials of Pharamcotheraptics.
3. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology,: Churchill Living stone, 4th Ed.

REFERENCES

1. Sathoskar, Pharmacology and pharmaco therapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
2. Pharmacology, An illustrated review by Mark A Simmons

PS504: PHARMACOGNOSY – II

B. Pharm III Year I sem

L	T	P	C
3	1	0	3

Course Objectives: To have knowledge on the formation of pharmaceutically important secondary metabolites in plants and their commercial significance. The role of fibres, natural sweetening agents, colorants, volatile oils, tannins, resins in pharmaceutical, cosmetic and food industry. To make the student aware of what is Ayurveda and its various preparations.

Course Outcome: After the study of the course, the student shall be able to know about the phytopharmaceuticals of commercial significance and the various applications of the crude drugs in the preparation of formulations as medicaments and excipients (Flavors, perfumes, sweeterners and colorants).

UNIT I

Biogenesis of Natural Products:

a. A brief account of primary and secondary metabolite production in plants.
b. Shikimic acid pathway and acetate mevolonate path way
c. Biosynthesis of Alkaloids- Atropine, Morphine, Ergotamine, Reserpine, Isoprenoid compounds –Diosgenin and scillaren

UNIT II

a) General introduction to Volatile oils.
b) Systematic pharmacognostic study of the following: Cinnamon, Cassia, Clove and Cardamom.
c) Biological source, collection preparation, chemical constituents uses of the following crude drugs – Fennel, Dill, Ginger, Eucalyptus oil, Gaultheria, Lemon grass oil, Oil of Citronella,
d) Mentha oil.

UNIT III

a) General introduction to Tannins and Resins

b) Biological source, collection and preparation, chemical constituents, tests for identification and uses of following – Black Catechu, Pale Catechu, Myrobalan, Arjuna, Balsam of Tolu, Benzoin, Guggul and Podophyllum.

UNIT IV

a) Herbal cosmetics: History and concept development of herbal cosmetics.A brief account on the following herbs in cosmetic preparation.

Skin care: Aloe, Neem, Turmeric, Saffron and Sandal wood.

Hair care: Amla, Henna, Hibiscus, Bringraj.

b) An introduction to potential cardiovascular, anticancer/cytotoxic and antibiotic drugs from marine sources.

UNIT V

a) Study of Fibres used in Pharmacy such as Cotton, Silk, Wool and Glass wool.
b) Study of mineral drugs:Asbestos, Bentonite, Kaolin ,kesulgurh and Talc

TEXT BOOKS

1. Kokate C.K , Purohit AP & Gokhale, The Pharmacognosy S.B (Nirali)
2. Trease and Evans, Pharmacognosy, Latest Edition.
3. Tyler, Brady & Robert, Pharmacognosy.

REFERENCES

1. Atal C.R & Kapur B.M, Cultivation & Utilization of Medicinal Plants.
2. Mohammad Ali, Pharmacognosy. CBS Publications.

PS505: DRUG REGULATORY AFFAIRS
(Open Elective – II)

B. Pharm III Year I sem

L	T	P	C
3	0	0	3

Course Objectives - Various procedures for approval of API and formulations for manufacture, sale, export and import of drugs.

Course Outcome: The clear information about the regulations in India and abroad is gained by the students.

UNIT I
Introduction to Drug regulatory affairs, organisation structure of India, in central and state Division of drug controller of India and their function

UNIT II
Procedure for obtaining manufacturing for basic drug and formulation, sale of drugs, import &export of drugs and their permission procedures.

UNIT III
Application for procedures for approval for formulations and Active Pharmaceutical Ingredient.

UNIT IV
USFDA & Europe, Japan guidelines for obtaining approval for API and formulations

UNIT V
Salient features and principles of Quality by Design (QBD), ICH and WHO, obtaining for API and formulations approval

TEXT BOOKS
1. Laws of drugs in India, Hussain
2. New drug approval process,5th edition, by Guarino
3. Commercial Manual on Drugs and Cosmetics 2004, 2nd edition

REFERENCES
1. Good Manufacturing Practices for Pharmaceuticals, S.H. Wiling, Vol. 78, Marcel Decker.
2. fda.org, hc-sc.gc.ca,ich.org,cder.org

PS506: ACTIVE PHARMACEUTICAL INGREDIENT PROCESS DEVELOPMENT
(Open Elective – II)

B. Pharm III Year I sem	**L**	**T**	**P**	**C**
	3	**0**	**0**	**3**

Course Objectives: Mainly emphasizes on development of process from pilot preparation to bulk drug synthesis in pharmaceutical industries.

Course Outcome: Students would understand the various aspects regarding process development and synthesis from pilot preparation to bulk drug.

Basic principles, salient features and applications for the following units:

UNIT-I:
Development and scale up techniques for the manufacture of new pharmaceutical active ingredients.

UNIT-II
Process optimisation, maximisation of synthetic route from pilot plant.

UNIT-III
Commercial production of bulk drugs like (i) reaction sequence (ii) process flow and engineering aspects.

UNIT-IV
Process technologies for natural products from plants, animals, marine and microbial sources.

UNIT-V
ICH Q11 for API development.

TEXT BOOKS:

1. Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up ,
2. Peter J. Harrington ,John Wiley and Sons Inc. Publication 2011
3. Strategies for Organic Drug Synthesis and Design by Daniel Lednicer, 2nd Edition,John Wiley and Sons Inc. Publication, 2008

REFERENCE:

1. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance by Sharp John, CRC Press; 1st edition Management Information Systems by Laudon Kenneth C. Prentice Hall; 12th edition, 2011.
2. ICH Guidelines, www.ich.org

MS507: ENTREPRENEURSHIP AND SMALL BUSINESS ENTERPRISES
(Open Elective – II)

B. Pharm III Year I sem

L	T	P	C
3	0	0	3

Course Objective: The aim of this course is to have a comprehensive perspective of inclusive learning, ability to learn and implement the Fundamentals of Entrepreneurship.

Course Outcome: It enables students to learn the basics of Entrepreneurship and entrepreneurial development which will help them to provide vision for their own Start-up.

Unit – I:
Entrepreneurial Perspectives:
Evolution, Concept of Entrepreneurship, Types of Entrepreneurs, Entrepreneurial Competencies, Capacity Building for Entrepreneurs.
Entrepreneurial Training Methods; Entrepreneurial Motivations; Models for Entrepreneurial Development, The process of Entrepreneurial Development.

Unit – II:
New Venture Creation:
Introduction, Mobility of Entrepreneurs, Models for Opportunity Evaluation; Business plans – Purpose, Contents, Presenting Business Plan, Procedure for setting up Enterprises, Central level - Startup and State level - T Hub, Other Institutions initiatives.

Unit – III:
Management of MSMEs and Sick Enterprises
Challenges of MSMEs, Preventing Sickness in Enterprises – Specific Management Problems; Industrial Sickness; Industrial Sickness in India – Symptoms, process and Rehabilitation of Sick Units.

Units – IV:
Managing Marketing and Growth of Enterprises:
Essential Marketing Mix of Services, Key Success Factors in Service Marketing, Cost and Pricing, Branding, New Techniques in Marketing, International Trade.

Units – V:
Strategic perspectives in Entrepreneurship:
Strategic Growth in Entrepreneurship, The Valuation Challenge in Entrepreneurship, The Final Harvest of New Ventures, Technology, Business Incubation, India way – Entrepreneurship; Women Entrepreneurs – Strategies to develop Women Entrepreneurs, Institutions supporting Women Entrepreneurship in India.

Text Books:
1. Entrepreneurship Development and Small Business Enterprises, Poornima M. Charantimath, 2e, Pearson, 2014.
2. Entrepreneurship, A South – Asian Perspective, D. F. Kuratko and T.V.Rao, 3e, Cengage, 2012.

REFERENCES:
1. Entrepreneurship, Arya Kumar, 4 e, Pearson 2015.
2. The Dynamics of Entrepreneurial Development and Management, Vasant Desai, Himalaya Publishing House, 2015.

PS508: PHARMACEUTICAL MICROBIOLOGY LAB

B. Pharm III Year I sem

L	T	P	C
0	0	3	2

1. Introduction to equipment and glassware used in microbiology laboratory.
2. Study of morphology of different microbes
3. Preparation of various culture media, cultivation of microbes and observation of colony characteristics.
4. Sterilization techniques (moist and dry heat) and their validations.
5. Aseptic transfer of culture into different types of media.
6. Characterisation of microbes by staining techniques (simple, gram's, acid fast and negative staining).
7. Study of motility of bacteria by hanging drop method.
8. Characterization of microbes through Bio chemical reactions:
   a. Indole test.
   b. Methyl red test.
   c. Voges proskauer test.
   d. Starch hydrolysis test.
   e. Fermentation of carbohydrates.
9. Isolation of pure cultures by streak plate, spread plate & pour plate techniques.
10. Enumeration of bacteria by pour plate/spread plate technique
11. Enumeration of bacteria by direct microscopic count.
12. Evaluation of any disinfectant by phenol coefficient test
13. Study of Oligodynamic action (of metals on bacteria)
14. Preservation of microrganisms (slant and stab cultures)
15. Microbiological Analysis of Water.

REFERENCE

1. Garg,F C Experimental Microbiology
2. Gaud.R.S, Gupta G.D, Practical Microbiology
3. Vanitha Kale and kishore Bhusari, Pratical microbiology principles and Techniques

PS509: PHARMACEUTICAL TECHNOLOGY - I LAB

B. Pharm III Year I sem

L	T	P	C
0	0	3	2

1. Preformulation studies
   Bulk properties, different densities, size and size distribution analysis, compessibility, Carr's index, Angle of repose, hausner's ratio
2. Solubility profile estimation in different pH media
3. Partition coefficient determination
4. Effect of crystallinity/amorphous structures on the solubility of the given drugs
5. Preparation and evaluation of official ointements and gels (in each category any two)
6. Preparation and evaluation of dry syrups (ampicillin, amoxicillin)
7. Preparation and evaluation of the following cosmetics
   a. Shampoos, tooth pastes, tooth powders, nail polish, baby shampoo,
   b. Baby powders, lipsticks, vanishing cream, cold cream, depillators.
8. Evaluation of packaging materials such as glass, plastics, cotton (hydrolytic resistance test for glass) and light absorption test for rubber and closures.

PS510: PHARMACOLOGY – I LAB

B. Pharm III Year I sem

L	T	P	C
0	0	3	2

1. **Introduction to Experimental Pharmacology**
   a) Preparation of different solutions for experiments.
   b) Drug dilutions, use of molar and w/v solutions in experimental Pharmacology.
   c) Common laboratory animals and anesthetics used in animal studies.
   d) Commonly used instruments in experimental pharmacology.
   e) Some common and standard techniques.
   f) Bleeding and intravenous injection, intragastric administration.
2. **Experiments on intact preparations:**
   Study of different routes of administration of drugs in mice/rats.
3. **Experiments in Central Nervous system:**
   Recording of spontaneous motor activity, stereotype, analgesia, anticonvulsant activity, anti-inflammatory activity,
4. **To study the effect of autonomic drugs on rabbit's eye**
5. **Experiments on Isolated Preparations:**
   To study the effects of various agonists and antagonists and their characterisation using isolated preparations like frog's rectus abdominus muscle and isolated ileum preparation of rat& guinea pig.
   a) To record the concentration response curve (CRC) of acetylcholine using rectus abdominus muscle preparation of frog.
   b) To study the effects of physostigmine and d-tubocurarine on the CRC of acetylcholine using frog rectus abdominus muscle preparation of frog.
   c) To record the CRC of 5-HT on rat fundus preparation.
   d) To record the CRC of histamine on guineapig ileum preparation.
   e) To study the inotropic and chronotropic effects of drugs on isolated frog heart.
   f) To study the effects of drugs on normal and hypodynamic frog heart.
6. **Experiments pertaining to analgesia, anti-convulsant activity, anti-inflammatory activity** (**Only demonstration)**.

REFERENCE:

Experimental Pharmacology, M.C. Prabhakar.

MC500: PROFESSIONAL ETHICS

B. Pharm III Year I sem

L	T	P	C
3	0	0	0

Course Objective: To enable the students to imbibe and internalize the Values and Ethical Behaviour in the personal and Professional lives.

Course Outcome: The students will understand the importance of Values and Ethics in their personal lives and professional careers. The students will learn the rights and responsibilities as an employee, team member and a global citizen.

UNIT - I

Introduction to Professional Ethics: Basic Concepts, Governing Ethics, Personal & Professional Ethics, Ethical Dilemmas, Life Skills, Emotional Intelligence, Thoughts of Ethics, Value Education, Dimensions of Ethics, Profession and professionalism, Professional Associations, Professional Risks, Professional Accountabilities, Professional Success, Ethics and Profession.

UNIT - II

Basic Theories: Basic Ethical Principles, Moral Developments, Deontology, Utilitarianism, Virtue Theory, Rights Theory, Casuist Theory, Moral Absolution, Moral Rationalism, Moral Pluralism, Ethical Egoism, Feminist Consequentialism, Moral Issues, Moral Dilemmas, Moral Autonomy.

UNIT - III

Professional ethics in pharmacy: general introduction to code of pharmaceutical ethics, objectives, pharmacists in relation to his job, his trade, to his profession and relation to medicinal professions. Pharmacists oath.

UNIT - IV

Work Place Rights & Responsibilities, Ethics in changing domains of Research, Engineers and Managers; Organizational Complaint Procedure, difference of Professional Judgment within the Nuclear Regulatory Commission (NRC), the Hanford Nuclear Reservation.

Ethics in changing domains of research - The US government wide definition of research misconduct, research misconduct distinguished from mistakes and errors, recent history of attention to research misconduct, the emerging emphasis on understanding and fostering responsible conduct, responsible authorship, reviewing & editing.

UNIT - V

Global issues in Professional Ethics: Introduction – Current Scenario, Technology Globalization of MNCs, International Trade, World Summits, Issues, Business Ethics and Corporate Governance, Sustainable Development Ecosystem, Energy Concerns, Ozone Deflection, Pollution, Ethics in Manufacturing and Marketing, Media Ethics; War Ethics; Bio Ethics, Intellectual Property Rights.

TEXT BOOKS:

1. Professional Ethics: R. Subramanian, Oxford University Press, 2015.
2. Ethics in Engineering Practice & Research, Caroline Whitbeck, 2e, Cambridge University Press 2015.

PS601: MEDICINAL CHEMISTRY – I

B. Pharm III Year II sem

L	T	P	C
3	1	0	3

Course Objectives: The basic consideration of drug activity, drug metabolism and medicinal substances belonging to different categories are discussed in an elaborative manner. The synthesis and mechanism of action of the medicinal compounds are explained in an organized way which helps the students to understand the medicinal uses of the compounds.

Course Outcome: The students gain good knowledge about the usage of medicinal substances, the synthesis and drug-drug interactions, so that they can get involved with confidence in the patient counseling.

UNIT I

a. Basic considerations of Drug activity: Physico chemical properties of drug molecules in relation to biological activity – Solubility, lipophilicity, partition-coefficient, Ionization, hydrogen bonding, Chelation, redox potential and surface activity. Bioisosterism and steric features of drugs, drug distribution and protein binding: Introduction to Pro and soft drug approaches.

b. Drug metabolism and inactivation: Introduction, Phase-I and Phase-II reactions.

***Note*: Introduction, definition, nomenclature, chemical classification, structure, synthesis, general mechanism, and mode of action, SAR including physicochemical and stereo chemical aspects, metabolism and therapeutic uses of the drugs from each category shall be studied for the following units. An outline of synthetic procedure of only the drugs mentioned in each category.**

UNIT II

Drugs acting on CNS: *A brief study of the chemistry of neurotransmitters*.

a. Hypnotics and Anxiolytics: Phenobarbital, diazepam, alprazolam, glutethimide

Anti-psychotics: Chlorpromazine, haloperidol, clozapine, oxypentine.

Anti-epileptics: Phenytoin, valproic acid, carbamazepine, ethosuximide.

Anti-depressants: Imipramine, fluoxetine, doxepine

b. Local anesthetic and General anesthetic agents: benzocaine, procaine, dibucaine and lidocaine, halothane and thiopental sodium.

UNIT III

a. Adrenergic agents and adrenergic blockers. Isoproterenol, atenolol, henoxybenzamine, amphetamine,
ephedrine, salbutamol,

b. Cholinergic agents and acetyl cholinesterase inhibitors

Cholinergics: Carbachol, bethanichol

Anticholinesterase: Neostigmine, pyridostigmine

Neuromuscular blockers: succinyl choline.

c. Anti-cholinergics: atropine, ipratropium bromide, dicyclomine, bipyridine, propantheline

UNIT IV

a. Prostaglandins. Introduction, nomenclature, functions,bio synthesis of prostaglandin E1, Structures of clinically useful prostaglandins**.**

b. Analgesics and NSAIDS (Non-steroidal anti-inflamatory agents):

i. Introduction and types of pain and inflammation

ii Classification and systematic development of analgesics of morphine, mild analgesics and strong analgesics: Meperidine and Methadone

iii. NSAIDS – Aspirin, paracetamol, oxyphenbutazone, ibuprofen, indomethacin, diclofenac and meloxicam
iv. A brief account on Cox-2 inhibitors and nimsulide.

UNIT V

General account of cardiovascular diseases

a. Antihypertensives: methyldopa, amlodipine, enalapril, losartan.
b. Anti-arrhythmics: procainamide
c. Diuretics: acetazolamide, hydrochlorthiazide, furosemide
d. Anticoagulants, Anti-anginals and Coronary vasodilators: Isosorbide dinitrate, verapamil, diltiazem

TEXT BOOKS:

1. William O. Foye, Textbook of Medicinal Chemistry, Lea Febiger, Philadelphia.
2. JH Block & JM Beale (Eds), Wilson & Giswold's Text book of organic Medicinal Chemistry and pharmaceutical chemistry, 11th Ed, Lipcott, Raven, Philadelphia, 2004.
3. Medicinal Chemistry by Korol Kavas.

REFERENCES

1. D. Abraham (Ed), Burger Medicinal chemistry ad Drug discovery, Vol. 1 & John Wiley & Sons, New York 2003, 6th Ed.
2. Daniel lednicer, Strategies for Organic Drug Synthesis and Design, John Wiley, N. Y. 1998.

PS602: PHARMACEUTICAL TECHNOLOGY – II

B. Pharm III Year II sem

L	T	P	C
3	1	0	3

Course Objectives: Student will know the formulation and evaluation of tablets, coated tablets, capsules, micro-encapsules and parenteral preparations in laboratories and industrial scale.

Course Outcome: The students shall be exposed to various aspects of pharmaceutical product preparations and evaluations of tablets, capsules etc.

UNIT I

Semisolid dosage forms: Definitions, types, mechanisms of drug penetration, factors influencing penetration, semisolid bases and their selection. General formulation of semi solids, clear gels manufacturing procedure, evaluation and packaging.

UNIT II

a. Pharmaceutical aerosols: Definition, propellants general formulation, manufacturing and packaging methods, pharmaceutical applications and evaluation.

b. Dry Syrups, Formulation, Preparation, Evaluation and special applications with examples.

UNIT III

Parenteral Products

a. Preformulation factors, routes of administration, water for injection, treatment apyrogenicity, non-aqueous vehicles, isotonicity and methods of its adjustment.
b. Formulation details, container and closures and selection.
c. Prefilling treatment, washing and sterilization of containers and closures, preparation of solution and suspensions, filling and closing of ampules, vials, infusion flulids, lyophillization & preparation of sterile powders, equipment for large-scale manufacture and evaluation of parenteral products.

Opthalmic Preparations: Requirements, formulation, methods of preparation, containers and evaluation.

UNIT IV

Aseptic techniques, sources of contamination and method of prevention. Design of aseptic area, laminar flow benches, services and maintenance.

UNIT V

a. Packaging of Pharmaceutical products: Packaging components, types, specifications and methods of evaluation as per I.P. Factors influencing choice of containers, package testing, legal and other official requirements for containers, packing testing.

b. Methods of packing of solid, liquid and semi-solid dosage forms, Factors influencing packing material and stability aspects of packaging.

TEXT BOOKS

1. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy, Lea & Febieger, Philadelphia Latest Edn
2. HC Ansel introduction to Pharmaceutical Dosage forms
3. CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.

REFERENCES

1. Sagarian & MS Balsam, Cosmetics Sciences &Technology,Vol.1, 2 & 3
2. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences

PS603 PHARMACOLOGY – II

B. Pharm III Year II sem

L	T	P	C
4	1	0	4

Course Objectives: This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs.

Course Outcome: Understands the pharmacological aspects of drugs, importance of pharmacology subject as a basis of therapeutics and correlate the knowledge therapeutically.

UNIT I

Pharmacology of drugs acting in cardiovascular diseases

a. Congestive heart failure
b. Hypertension.
c. Shock.
d. Arrhythmias

UNIT II

a. Pharmacology of Drugs used in coronary artery disease and Hyperlipidemias.
b. Pharmacology of Drugs acting on hematopoietic system
   Anti-coagulants, Anti-platelets, Thrombolytics & Hematinics.
c. Pharmacology of Drugs acting on Urinary system
   Diuretics

UNIT III

Autacoids

a. Histamine, 5-HT and their antagonists.
b. Prostaglandins, thromboxanes and leukotrienes
c. Bradykinin and substance P.

UNIT IV

a. Drugs acting on the respiratory system
   Anti-asthmatic drugs.
   Anti-tussives and expectorants.
   Respiratory stimulants
b. Bioassays: Applications, Principles and Methods of Bioassays.
c. Study of bioassay methods for the following drugs
   a. Digitalis, b. D – tubocurarine, c. Oxytocine
   d. HCG.

UNIT V

Drugs acting on Endocrine system

a. Insulin, Oral hypoglycaemic agents
b. Adrenal steroids
c. Anti thyroid agents.
d. Oral contraceptives

TEXT BOOKS

1. Tripathi, Textbook of Pharmacology, JAYPEE
2. F.S.K Barar, Essentials of Pharamcotheraptics
3. H.P Rang, M. M. dale & J.M. Ritter, Pharmacology,: Churchill Living stone, 4th Ed.

REFERENCES

1. Crossland, Lewis ‘s Pharmacology, Church living stone
2. Mark A. Simmons, Pharmacology An Illustrated Review

PS604: CHEMISTRY OF NATURAL PRODUCTS

B. Pharm III Year II sem

L	T	P	C
3	1	0	3

Course Objectives: The chemistry including the structure elucidation of the natural products belonging to different groups such as amino acids, alkaloids, carbohydrates, steroids etc. are discussed in depth.

Course Outcome: The knowledge of the students is enhanced with the clear information about the natural products which are having medicinal importance.

UNIT I

Poly Functional Natural Products

(a) Carbohydrates: Introduction, Definition, Classification, Isolation, General Properties (including isomerism) and Pharmaceutical importance of Carbohydrates, Chemistry (Structme, Nomenclatme and Reactions) of glucose, fructose, sucrose, maltose, cellulose and starch.

(b) Oils & Fats: Introduction, Definition, Classification, Isolation, General properties and Pharmaceutical importance of oils and fats. Chemistry (structure, nomenclature and reactions) of oils and fats and analysis according to Pharmacopoeial methods

UNIT II

Amino Acids and Proteins

Introduction, definition, classification, isolation, general properties and pharmaceutical importance of amino acids and their relationship to proteins and polypeptides.

Chemistry of Protein Hormones: Insulin, Oxytocin, Thyroxin and Anti-thyroid drugs

UNIT III

a. Flavonoids: Sources, uses, chemistry and General methods of structural determination (chemical & spectral analysis) of Amygdalin, arbutin and quercetin

b. Terpenoids: Definiton and Classification: Isoprene rule, Special Isoprene rule for terpenes, General methods of isolation. Chemistry and structure elucidation of citral, menthol and camphor.

UNIT IV

a. Alkaloids

Introduction, definition, occurence, classification, isolation, general properties and pharmaceutical importance of alkaloids. General methods of extraction, structure elucidation and chemistry (structure, nomenclatme and reactions) of ephedrine, atropine, papaverine and quinine

b.Purine and Xanthine Derivatives

Chemistry and Pharmaceutical importance Caffeine, Theophylline, Theobromine and Uric acid.

UNIT V

Steroids

Introduction, Definition, Occurence, Classification, Isolation, General properties and Pharmaceutical importance of Sterols: color reactions of cholesterol, stigmasterol, ergosterol. Importance & general concepts of bile acids. Steroidal saponins: Diosgenin and hecogenin. Androgens, Estrogens, Progestational agents, Steroidal contraceptives. Adrenocorticoids, Deoxycorticosterone, Cortisone, Prednisone, Aldosterone. Cardiac Glycosides of Digitalis other Cardiac drugs, Strophanthus and Squill.

TEXT BOOKS

1. Organic Chemistry, Vol.II by I.L. Finar, The English Language Book Society, London.
2. Natural Products Vol.I & II by O.P. Agarwal Goel publications – Meerut.

3. F.G.Mann & B. Saunders, Practical Organic Chemistry Longamans Green & Co. Ltd., U.K

REFERENCE BOOKS

1. Burger's Medicinal Chemistry, M.E. – Wolff, Ed., John Wiley & Sons, New York.
2. R. M. Acheson, An Introduction to the Chemistry of Heterocyclic Compounds, Interscience NY.

PS605: GENERIC DRUG PRODUCT DEVELOPMENT
(Open Elective – III)

B. Pharm III Year II sem

L	T	P	C
3	0	0	3

Course Objectives: To learn the generic drug product development process, dosage form design and development, analytical method development and dossier approval process.

Course Outcome: The knowledge of the students is enhanced with the clear information about the generic product development.

Unit I:

a) Concept of generic drug product development, Hatch-Waxman act and its amendments.
b) History of generic product development in US

Unit II:

Design of dosage form to meet equivalence to reference listed drug, product development steps, formula optimization, process optimization and packaging selection.

Unit III:

Analytical method development for verification and validation for active ingredient, in-process samples and finished dosage forms.

Unit IV:

a) Stability studies on active ingredient and finished dosage forms, accelerated stability studies, stability studies at different conditions, determination or expiration date.
b) Scale up studies to optimize manufacturing process and execution of exhibit batches.

Unit V:

a) Bioequivalence studies, various designs of bioequivalence studies, bioequivalence criteria and in-vitro tests to ensure bioequivalence of test product.
b) Introduction to electronic Common Technical Document (eCTD), various modules and the important information in each module.
c) Drug product approval process in India and US.

REFERENCE

1. Generic Drug product Development: Solid oral dosage forms-Leon Shargel.
2. ICH guidelines.

PS606: DRUG DESIGN AND DISCOVERY
(Open Elective - III)

B. Pharm III Year II sem

L	T	P	C
3	0	0	3

Course Objectives: Emphasizes on the conceptual background and development of medicinal chemistry and drug design. Identification of lead for new drug design. Modification of lead aimed at changing Pharmacodynamic and Pharmacokinetics.

Course Outcome: The students would be in a position to identify lead for new drug design, to design and discover the novel drus with the knowledge they gained through the study of the various topics of the syllabus.

Basic principles, salient features and applications for the following units:

Unit-I
Introduction of modern drug discovery concept and technologies.

Unit-II
Principles of combinatorial chemistry.

Unit-III
Introduction to structure based drug design.

Unit-IV
Molecular modelling and drug design.

Unit-V
QSAR.

TEXT BOOKS

1. Textbook of Drug Design and Discovery, 4th Ed.,by Larsen
2. Structure-based Drug Discovery by Jhoti, Harren
3. William H, Malick JB “Drug Discovery and Development” Humana Press Clifton.

REFERENCE

1. Robert GCK, ed., “Drug Action at the Molecular Level” University Prak Press Baltimore.
2. Martin YC. “Quantitative Drug Design” Dekker, New York.

PS607: SCREENING METHODS IN PHARMACOLOGY
(Open Elective – III)

B. Pharm III Year II sem

L	T	P	C
3	0	0	3

Course Objectives:- The students is going to study about various techniques for screening of drugs for various pharmacological activities and guide lines for handling animals and human and animal ethics for screening of drugs.

Course Outcome: - The expected outcomes are student will know how to handle animals and know about various techniques for screening drugs for different pharmacological activities and guidelines and regulations for screening new drug molecules on animals and human volunteers.

UNIT I

Care Handling and breeding techniques of laboratory animals, CPCSEA guidelines, alternatives to animal studies, Good laboratory Practices.

UNIT II

Bioassays: Basic principles of Biological standardization, Merits and demerits, methods used in the bio-assay of Rabbis Vaccine and Oxytocin. Test for pyrogens.

UNIT III

Toxicity tests: OECD guidelines, determination of LD50, acute, subacute and chronic toxicity studies.

UNIT IV

Screening: Definition, types of screening methods. Pharmacological activity of new substances with emphasis on the evaluation of analgesic, antipyretic and anti-inflammatory activity.

UNIT V

Screening for the Pharmacological activity of epilepsy, cardiac, psychopharmacological, anti diabetic and anticancer.

TEXT BOOKS

1. Screening methods in Pharmacology, Vol.-1&2 by Robert .A. Turner and Peter Hebborn.
2. Pharmacological Screening Methods & Toxicology by Srinivasa Rao A,Pharmamed press publishers.
3. Handbook of experimental pharmacology by S.K. Kulkarni, Vallabh Prakashan, Delhi.

REFERENCE BOOKS

1. ICH of technical requirements for registration of pharmaceuticals for human use, ICH harmonized Tripartite guidelines - Guidelines for good clinical practice, E6, May 1996.
2. Good clinical practice - Guidelines for Clinical trails on pharmaceutical products in India, Central drug standard control organization, New Delhi, Minister of Health- 2001

PS608: MEDICINAL CHEMISTRY – I LAB

B. Pharm III Year II sem

L	T	P	C
0	0	3	2

i. **Synthesis of some medicinal compounds and their analogues.**
   a. Barbituric acid from Diethyl Malonate.
   b. Phenytion from Benzoin or Benzil.
   c. Paracetomol from *para*- nitro phenol or *para*- aminophenol.
   d. 1,4- di hydro pyridine from ethyl aceto acetate.
   e. Quinazolinone from anthranilic acid via benzoxazinone.
   f. Systhesis of Finofibrate
   g. Isoniazid from γ-picoline.
   h. Antipyrine from ethyl aceto acetate.
   i. Benzocaine from *para*- nitro benzoic acid.

ii. **Qualitative estimation of some functional groups.** *
   a. Halogens (Strepheno's method).
   b. Hydroxyl groups (acetylation method)
   c. Methoxyl groups (Zeissel's method)
   d. Carboxyl groups (silver salt method).

REFERENCES

1) A.I. Vogel, Text Book of Practical Organic Chemistry, 5th Edition.
2) R.K. Bansal, Laboratory Manual of Organic Chemistry.
3) F.G. Mann & B.C. Saunders, Pratical Organic Chemistry, 4th Edition.
4) Advacned medicinal chemistry lab guide by N. Raghu Prasad and M. Raghuram Rao
5) Organic chemistry a Lab manual, Cengage learning India Pvt. Ltd. By Pavia

PS609: PHARMACEUTICAL TECHNOLOGY – II LAB

B. Pharm III Year II sem

L	T	P	C
0	0	3	2

1. Experiments to illustrate preparation, stabilization and evaluation of pharmaceutical products like capsules and tablets like conventional, matrix, fast dissolving, multilayered, chewable, buccal, sublingual and Gastric retention

2. Coating of tablets like sugar, film, enteric coating and evaluation

PS610: PHARMACOLOGY – II LAB

B. Pharm III Year II sem

L	T	P	C
0	0	3	2

. Experiments on Isolated Preparations:

a. To calculate the PA_2 value of atropine using acetylcholine as an agonist on rat ileum preparation.
b. To calculate the PA_2 value of mepyramine or chloramphenіramine using histamine as agonist on guinea pig ileum.
c. To find out the strength of the given sample on (e.g. Acetycholine, Histamine, 5-HT. Oxytocin etc.) Using a suitable isolated muscle preparation by
    i. Matching Assay
    ii. Two point Assay
    iii. Three point Assay

2. Pharmacology of the Gastrointestinal Tract

To study the anti-secretory and anti-ulcer activity using pylorus ligated rats.

HS611: ADVANCED COMMUNICATION SKILLS (ACS) LAB

B. Pharm III Year II sem

L	T	P	C
0	0	3	2

Introduction

A course on *Advanced English Communication Skills (AECS) Lab* is considered essential at the third year level of B.Tech and B.Pharmacy courses. At this stage, the students need to prepare themselves for their career which requires them to listen to, read, speak and write in English both for their professional and interpersonal communication. The main purpose of this course is to prepare the students of Engineering for their placements.

Course Objectives: This Lab focuses on using multi-media instruction for language development to meet the following targets:

- To improve students' fluency in spoken English
- To enable them to listen to English spoken at normal conversational speed
- To help students develop their vocabulary
- To read and comprehend texts in different contexts
- To communicate their ideas relevantly and coherently in writing
- To make students industry-ready
- To help students acquire behavioral skills for their personal and professional life
- To respond appropriately in different socio-cultural and professional contexts

Course Outcomes: Students will be able to:

- Acquire vocabulary and use it contextually
- Listen and speak effectively
- Develop proficiency in academic reading and writing
- Increase possibilities of job prospects
- Communicate confidently in formal and informal contexts

Syllabus

The following course activities will be conducted as part of the Advanced English Communication Skills (AECS) Lab:

1. **Inter-personal Communication and Building Vocabulary** - Starting a Conversation – Responding Appropriately and Relevantly – Using Appropriate Body Language – Role Play in Different Situations - Synonyms and Antonyms, One-word Substitutes, Prefixes and Suffixes, Idioms and Phrases and Collocations.
2. **Reading Comprehension** –General Vs Local Comprehension, Reading for Facts, Guessing Meanings from Context, , Skimming, Scanning, Inferring Meaning.
3. **Writing Skills** – Structure and Presentation of Different Types of Writing – Letter Writing/Resume Writing/ e-correspondence/ Technical Report Writing.
4. **Presentation Skills** – Oral Presentations (individual or group) through JAM Sessions/Seminars/PPTs and Written Presentations through Posters/Projects/Reports/ e-mails/Assignments… etc.,
5. **Group Discussion and Interview Skills** – Dynamics of Group Discussion, Intervention, Summarizing, Modulation of Voice, Body Language, Relevance, Fluency and Organization of Ideas and Rubrics of Evaluation- Concept and Process, Pre-interview Planning, Opening Strategies, Answering Strategies, Interview through Tele-conference & Video-conference and Mock Interviews.

Minimum Hardware Requirement

Advanced English Communication Skills (AECS) Laboratory shall have the following infrastructural facilities to accommodate at least 35 students in the lab:

- **Spacious room with appropriate acoustics**
- **Eight round tables with five movable chairs for each table.**
- **Audio-visual aids**
- **LCD Projector**

- **Public Address system**
- **Computer with suitable configuration**

Suggested Software: The software consisting of the prescribed topics elaborated above should be procured and used.

- **Oxford Advanced Learner's Compass**, 8th Edition
- **DELTA's key to the Next Generation TOEFL Test: Advanced Skill Practice.**

REFERENCES:

1. Kumar, Sanjay and Pushp Lata. ***English for Effective Communication***, Oxford University Press, 2015.
2. Konar, Nira. ***English Language Laboratories – A Comprehensive Manual,*** PHI Learning Pvt. Ltd., 2011.