

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

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

Applicable From 2016-17 Admitted Batch

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		Open Elective - III	3	0	0	3
	PS605	Generic Product Development				
	PS606	Drug Design and Discovery				
	PS607	Screening Methods in Pharmacology				
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

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, hexoxybenzamine, 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-inflammatory 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 Iednicer, 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 fluids, lyophilization & preparation of sterile powders, equipment for large-scale manufacture and evaluation of parenteral products.

Ophthalmic 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

- Congestive heart failure
- Hypertension.
- Shock.
- Arrhythmias

UNIT II

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

UNIT III

Autacoids

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

UNIT IV

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

UNIT V

Drugs acting on Endocrine system

- Insulin, Oral hypoglycaemic agents
- Adrenal steroids
- Anti thyroid agents.
- Oral contraceptives

TEXT BOOKS

- Tripathi, Textbook of Pharmacology, JAYPEE
- F.S.K Barar, Essentials of Pharamcotherapeutics
- 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 (Structure, Nomenclature 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: Definition 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, occurrence, classification, isolation, general properties and pharmaceutical importance of alkaloids. General methods of extraction, structure elucidation and chemistry (structure, nomenclature 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, Occurrence, 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 Longmans 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 drug 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 Park 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. Phenyntion from Benzoin or Benzil.
- c. Paracetamol 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. Synthesis 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 chlorampheniramine using histamine as agonist on guinea pig ileum.
 - c. To find out the strength of the given sample on (e.g. Acetylcholine, 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.