

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		Open Elective - II	3	0	0	3
	PS505	Drug Regulatory Affairs				
	PS506	Active Pharmaceutical Ingredient Process Development				
	MS507	Entrepreneurship and Small Business Enterprises				
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

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 spontaneous 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 eukaryotes). 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 continuous culture (chemostat and turbidostat) synchronous growth.

UNIT III

a. Control of Microorganisms: General concepts, Inhibition of growth and killing, sterilization and disinfection, antiseptics 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:

- Introduction and objectives of preformulation study and development of dosage forms, Physical and Chemical aspects.
- Stability and bioavailability study of prodrugs in solving problems related to stability bio availability in formulations.
- 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

- L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial Pharmacy, Lea & Febieger, Philadelphia Latest Edn.
- CVS. Subramanyam, Pharmaceutical production and management, Vallabh Prakashan, New Delhi 2005.
- 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:

- Neurohumoral transmission (autonomic and Somatic)
- Parasympathomimetics, parasympatholytics, sympathomimetics & sympatholytics
- Skeleton muscle relaxants

UNIT III

Pharmacology of Central Nervous System:

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

UNIT IV

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

UNIT V

- Psychopharmacological agents (antipsychotics) Antidepressants, anti-manics and hallucinogens.
- Pharmacology of Anti-epileptic drugs
- Anti-Parkinsonian Drugs

TEXT BOOKS

- Tripathi, Textbook of Pharmacology, JAYPEE
- F.S.K Barar, Essentials of Pharmacotherapeutics.
- H.P Rang, M. M. Dale & J.M. Ritter, Pharmacology,; Churchill Living stone, 4th Ed.

REFERENCES

- Sathoskar, Pharmacology and pharmacotherapeutics Vol. 1 & 2, Publ by Popular Prakashan, Mumbai.
- 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, sweeteners and colorants).

UNIT I

Biogenesis of Natural Products:

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

UNIT II

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

UNIT III

- General introduction to Tannins and Resins
- 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

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

UNIT V

- Study of Fibres used in Pharmacy such as Cotton, Silk, Wool and Glass wool.
- Study of mineral drugs: Asbestos, Bentonite, Kaolin, kieselguhr and Talc

TEXT BOOKS

- Kokate C.K, Purohit AP & Gokhale, The Pharmacognosy S.B (Nirali)
- Trease and Evans, Pharmacognosy, Latest Edition.
- 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 microorganisms (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, Practical 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, compressibility, 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 ointments 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 guinea pig 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.