

Dr. D. Y. Patil Pratishthan's

Dr. D. Y. PATIL COLLEGE OF PHARMACY

Dr. D. Y. Patil Educational Complex, Sector - 29, Pradhikaran, Akurdi, Pune 411 044.

Tel. : 020-27656141, Tel. Fax : 020-27656141

E-mail : info@dyppharmaakurdi.ac.in Web : www.dyppharmaakurdi.ac.in

Approved by : All India Council for Technical Education, New Delhi

Pharmacy Council of India, New Delhi. Recognized by : Government of Maharashtra

Affiliated to Savitribai Phule Pune University, Pune



Dr. Sanjay D. Patil
President

Padmashree Dr. D. Y. Patil
Founder

Shri. Satej D. Patil
Vce-President & Chairman

Dr. N. S. Vyawahare
Principal

**Ref. No. : DYPCOP/
Date :**

1.3.1

Professional Ethics, Gender, Human Values, Environment and Sustainability in Curriculum



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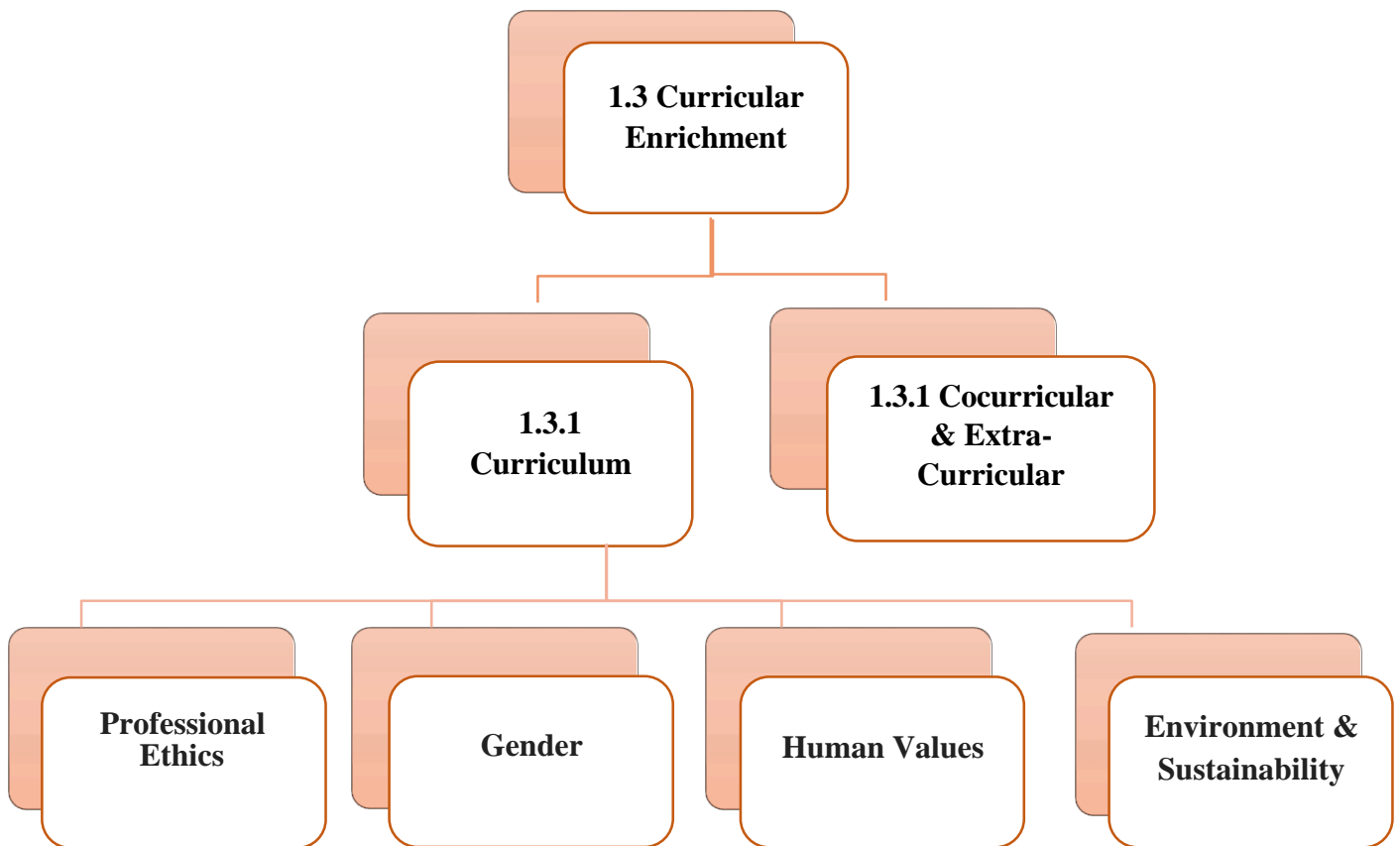
Shri. Satej D. Patil
Vce-President & Chairman

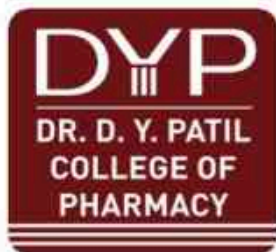
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**Ref. No. : DYPCOP/
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1.3 Curriculum Enrichment

1.3.1 Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability in Transacting the Curriculum.





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1.3: Curriculum Enrichment

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Professional Ethics (Syllabus)

Sr. No.	Class	Course Code
1.	B. Pharm (Sem - I, II, IV, V, VI, VII, VIII)	BP103T, BP204T, BP408P, BP405T, BP409P, BP502T, BP506P, BP504T, BP508P, BP505T, BP603T, BP606T, BP701T, BP702T, BP706PS, BP805ET
2.	M. Pharm (Sem - I, II)	MPH104T, MPH105P, MQA102T, MPL103T, MPL202T, MPL204T
3.	Pharm D (I, II, III rd year Pharm D)	1.2T, 2.4P, 2.5T, 2.6T, 3.3T, 3.3P, 3.4T

Human Values

4.	B. Pharm (Sem - I, VII, VIII)	BP105T, BP703T, BP802T
5.	Pharm D (II, III rd year Pharm D)	2.5T, 2.6P, 3.3P

Gender

6.	B. Pharm (Sem - I, II, V)	BP106RBT, BP201T, BP501T, BP503T, BP505T,
	M. Pharm (Sem - II)	MPL202T
	Pharm D (I st year Pharm D)	1.1T, 1.1P

Environment & Sustainability

7.	B. Pharm (Sem - I, II, III)	BP105T, BP205T, BP206T, BP304T
8.	M. Pharm (Sem - I, II)	MQA201T, Research Projects (of all Courses)

**Dr. D. Y. Patil Pratishthan's
Dr. D. Y. Patil College of Pharmacy
Akurdi-44**

Criteria 1

1.3.1. Institution integrates crosscutting issues relevant to Professional Ethics, Gender, Human Values, Environment and Sustainability into the curriculum

Sr. No.	Class	Course Code	Course	Description
Professional Ethics				
1.	F.Y. B. Pharm (Sem – I)	BP103T	Pharmaceutics- I	<ul style="list-style-type: none"> • Understand the professional way of handling the prescription • Prescription: definition, parts of prescription, handling of prescription, and errors in prescription
2.	F.Y. B. Pharm (Sem – II)	BP204T	Pathophysiology	<ul style="list-style-type: none"> • This course will help to get a baseline knowledge to practice medicine safely, confidently, rationally, and effectively
3.	S. Y. B. Pharm (Sem – IV)	BP408P	Pharmacology - I	<ul style="list-style-type: none"> • Maintenance of laboratory animals as per CPCSEA guidelines
4.	S. Y. B. Pharm (Sem – IV)	BP405T BP409P	Pharmacognosy And Phytochemistry	<ul style="list-style-type: none"> • To know the crude drugs, their uses, and their chemical nature • Know the evaluation techniques for herbal drugs Inculcate the ethics to prevent adulteration of herbal drugs.
5.	T. Y. B. Pharm (Sem – V)	BP502T BP506P	Industrial Pharmacy - I	<ul style="list-style-type: none"> • Formulate solid, liquid, and semisolid dosage forms and evaluate them for their quality • Quality testing of pharmaceutical products as per official limits
6.	T. Y. B. Pharm (Sem – V)	BP504T BP508P	Pharmacognosy And Phytochemistry – II (Theory & Practical)	<ul style="list-style-type: none"> • To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents and maintain their quality.
7.	T. Y. B. Pharm (Sem – V)	BP505T	Pharmaceutical Jurisprudence	<ul style="list-style-type: none"> • Various Indian pharmaceutical acts and laws • The regulatory authorities and agencies govern the manufacture and sale of pharmaceuticals. • The subject also emphasizes good manufacturing practices (GMP), patenting and regulatory issues of herbal drugs. • Schedule t-good manufacturing practice of Indian systems of medicine code of ethics during the pharmaceutical practice.

8.	T. Y. B. Pharm (Sem – VI)	BP603T	Herbal Drug Technology (Theory)	<ul style="list-style-type: none"> • Understand the cGMP aspects in a pharmaceutical industry • Appreciate the importance of documentation. • Understand the scope of quality certifications applicable to pharmaceutical industries. • Understand the responsibilities of the qa & qe departments
9.	T. Y. B. Pharm (Sem – VI)	BP606T	Pharmaceutical Quality Assurance (Theory)	<ul style="list-style-type: none"> • This subject emphasizes theoretical and practical knowledge of modern analytical instruments that are used for drug
10.	Final Y. B. Pharm (Sem – VII)	BP701T	Instrumental Methods of Analysis (Theory)	<ul style="list-style-type: none"> • Know different laws and acts that regulate the pharmaceutical industry 4. Understand the approval process and regulatory requirements for the drug product.
11.	Final Y. B. Pharm (Sem-VII)	BP702T	Industrial Pharmacy- II	<ul style="list-style-type: none"> • The course aims to provide an understanding of marketing concepts, marketing ethics, and techniques and their applications in the pharmaceutical industry.
12.	Final Y. B. Pharm (Sem – VII)	BP706PS	Practice School	<ul style="list-style-type: none"> • The student shall opt for any one of the domains for practice school and the report submitted will be evaluated on the basis of knowledge and skills.
13.	Final Y. B. Pharm (Sem – VIII)	BP805ET	Pharmacovigilance	<ul style="list-style-type: none"> • The course aims to provide the methods to generate safety data during the pre-clinical, clinical, and post-approval phases of drugs' life cycle.
14.	F. Y. M. Pharm (Sem – I)	MPH104T	Regulatory Affairs	<ul style="list-style-type: none"> • Post-approval regulatory requirements for actives and drug products. • Submission of global documents in CTD/ eCTD formats • Clinical trial requirements for approvals for conducting clinical trials. • Pharmacovigilance and process of monitoring in clinical trials.
15.	F.Y. M. Pharm (Sem – I)	MPH105P	Pharmaceutics Practical - I	<ul style="list-style-type: none"> • This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.
16.	F.Y. M. Pharm (Sem – I)	MQA102T	Quality Management Systems	<ul style="list-style-type: none"> • This course aids in understanding quality evaluation in the pharmaceutical industry.
17.	F.Y. M. Pharm (Sem – I)	MPL103T	Pharmacological and Toxicological Screening Methods- I	<ul style="list-style-type: none"> • Upon completion of the course, the student shall be able to, appraise the regulations and ethical requirements for the usage of experimental animals. Describe the various animals used in the drug discovery process and good laboratory

				practices in the maintenance and handling of experimental animals
18.	F. Y. M. Pharm (Sem – II)	MPL202T	Pharmacological and Toxicological Screening Methods- II	<ul style="list-style-type: none"> Upon completion of the course, the student shall be able to appreciate the importance of ethical and regulatory requirements for toxicity studies
19.	F. Y. M. Pharm (Sem – II)	MPL204T	Clinical Research and Pharmacovigilance	<ul style="list-style-type: none"> This subject will provide value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students about conceptualizing, designing, conducting, managing and reporting clinical trials. This subject also focuses on the global scenario of Pharmacovigilance in different methods that can be used to generate safety data. Ethical Guidelines for Biomedical Research
20.	F. Y. Pharm D	1.2T	Pharmaceutics	<ul style="list-style-type: none"> After completing this course students will appreciate the importance of A good formulation for effectiveness
21.	S. Y. Pharm D	2.4P	Pharmacology- I (Practical)	<ul style="list-style-type: none"> Care and handling of common laboratory animals, animal welfare and introduction of CPCSEA and its guidelines, OECD guidelines.
22.	S. Y. Pharm D	2.5	Community Pharmacy (Theory)	<ul style="list-style-type: none"> Students shall be able to know pharmaceutical care services.
23.	S. Y. Pharm D	2.6T	Pharmacotherapeutics – I (Theory)	<ul style="list-style-type: none"> This course is designed to impart knowledge and skills necessary for contribution to the quality use of medicine. Discuss controversies in drug therapy.
24.	T. Y. Pharm D	3.3T	Pharmacotherapeutics – II (Theory)	<ul style="list-style-type: none"> This course is designed to impart knowledge and skills necessary for contribution to the quality use of medicines.
25.	T. Y. Pharm D	3.3P	Pharmacotherapeutics – II (Practical)	<ul style="list-style-type: none"> The student shall be trained to understand the principle and practices involved in the selection of drug therapy including clinical discussion.
26.	T. Y. Pharm D	3.4T	Pharmaceutical Jurisprudence (Theory)	<ul style="list-style-type: none"> This course exposes the student to several important legislations related to the profession of pharmacy in India.
Gender				
1.	F. Y. B. Pharm (Sem – I)	BP106RBT	Remedial Biology	<ul style="list-style-type: none"> Male and female reproductive system. Spermatogenesis, Oogenesis. Menstrual cycle.
2.	F. Y. B. Pharm (Sem – II)	BP201T	Human Anatomy & Physiology II	<ul style="list-style-type: none"> Male and female reproductive system Spermatogenesis, Oogenesis

				<ul style="list-style-type: none"> • Menstrual cycle
3.	T. Y. B. Pharm (Sem – V)	BP501T	Medicinal Chemistry II	<ul style="list-style-type: none"> • Stereochemistry and metabolism of steroids testosterone, progesterone, • estriol, estradiol. • Sildenafil, tadalafil
4.	T. Y. B. Pharm (Sem – V)	BP503T	Pharmacology II	<ul style="list-style-type: none"> • Androgens, metabolic steroids, estrogens, contraceptives, drugs acting on uterus
5.	T. Y. B. Pharm (Sem – V)	BP505T	Pharmaceutical Jurisprudence	<ul style="list-style-type: none"> • Medical Termination of Pregnancy Act
6.	F. Y. M. Pharm (Sem – II)	MPL202T	Pharmacological & Toxicological Screening Methods	<ul style="list-style-type: none"> • Male and female reproductive system
7.	F. Y. Pharm D	1.1T	Human Anatomy & Physiology	<ul style="list-style-type: none"> • Male and female reproductive system • Spermatogenesis, Oogenesis, menstruation. • Contraceptive devices
8.	F. Y. Pharm D	1.1P	Human Anatomy & Physiology	<ul style="list-style-type: none"> • Male and female reproductive system. • Spermatogenesis, Oogenesis, menstruation • Contraceptive devices
Human Values				
1.	F. Y. B. Pharm (Sem – I)	BP105T	Communication Skills	<ul style="list-style-type: none"> • Students shall understand the behavioral needs of a pharmacist to function effectively in the area of pharmaceutical operation. • Effectively manage the team as a team player • Develop leadership qualities and essentials
2.	Final Y. B. Pharm (Sem – VII)	BP703T	Pharmacy Practice	<ul style="list-style-type: none"> • Upon completion of the course, the student shall be able to do patient • counseling in community pharmacy. • Appreciate the concept of rational drug therapy.
3.	Final Y. B. Pharm (Sem – VIII)	BP802T	Social and Preventive Pharmacy	<ul style="list-style-type: none"> • After the successful completion of this course, the student shall be able to: • Acquire high consciousness/realization of current issues related to health • and pharmaceutical problems within the country and worldwide. • Have a critical way of thinking based on current healthcare development. Evaluate alternative ways of solving problems related to health and pharmaceutical issues.

4.	S. Y. Pharm D	2.5T	Community Pharmacy	<ul style="list-style-type: none"> • Upon completion of the course, the student shall be able to Know the business and professional practice management skills in community pharmacies. • Do patient counseling & provide health screening services to the public in community pharmacies. • Show empathy and sympathy to patients
5.	S. Y. Pharm D	2.6P	Pharmacotherapeutics- I (Practical)	<ul style="list-style-type: none"> • Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; following up on the progress and changes made in drug therapy in allotted patients; case presentation upon discharge
6.	T. Y. Pharm D	3.3P	Pharmacotherapeutics- II (Practical)	<ul style="list-style-type: none"> • Hospital postings in various departments are designed to complement the lectures by providing practical clinical discussion; attending ward rounds to follow up on the progress and changes made in drug therapy in allotted patients.
Environment and Sustainability				
1.	F. Y. B. Pharm (Sem – I)	BP105T	Communication Skills	<ul style="list-style-type: none"> • Understand the Behavioural needs for pharmacists to function effectively in the areas of pharmaceutical operations. • Develop Interview Skills • Develops Leadership Qualities and essentials. • Effectively manage the team as a team coordinator.
2.	F.Y. B. Pharm (Sem – II)	BP205T	Computer Applications in Pharmacy	<ul style="list-style-type: none"> • Understand the various types of applications of computers in pharmacy. • Understand various types of databases. • Impart basic knowledge about the use of databases in pharmacy.
3.	F.Y. B. Pharm (Sem – II)	BP206T	Environmental Sciences	<ul style="list-style-type: none"> • Impart basic knowledge about the environment and its allied problems. • Develop an attitude of concern for the environment. • Motivate learners to participate in environment protection and environment improvement. • Acquire skills to help the concerned individuals in identifying and solving environmental problems. • Strive to attain harmony with nature.

4.	S. Y. B. Pharm (Sem - III)	BP304T	Pharmaceutical Engineering (Theory)	<ul style="list-style-type: none"> • To carry out various tests to prevent environmental pollution. • To appreciate the various preventive methods used for corrosion control in pharmaceutical industries.
5.	F.Y. M. Pharm (Sem - II)	MQA201T	Hazards And Safety Management	<ul style="list-style-type: none"> • At the completion of this course students will be able to • Understand environmental problems among learners. • Impart basic knowledge about the environment and its allied problems. • Develop an attitude of concern for the industry environment.
6.	S.Y. M. Pharm	-	Research Projects	<ul style="list-style-type: none"> • Research guides emphasize on designing projects based on waste management and green synthesis to impart environmental sustainability.

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY



RULES & SYLLABUS

**FIRST YEAR BACHELOR OF PHARMACY (B. Pharm.) COURSE –
2019 pattern (EFFECTIVE FROM ACADEMIC YEAR 2019-2020)**

Table-I: Course of study for semester I

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I- Theory	3/45	1	4
BP102T	Pharmaceutical Analysis I – Theory	3/45	1	4
BP103T	Pharmaceutics I – Theory	3/45	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3/45	1	4
BP105T	Communication skills – Theory *	2/30	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics – Theory*	2/30	-	D
BP107P	Human Anatomy and Physiology – Practical	4/60	-	2
BP108P	Pharmaceutical Analysis I – Practical	4/60	-	2
BP109P	Pharmaceutics I – Practical	4/60	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4/60	-	2
BP111P	Communication skills – Practical*	2/30	-	1
BP112RBP	Remedial Biology – Practical*	2/30	-	D
Total		32/34^S/36[#]/480/510^S/540[#]	4	27

#Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course. However for Remedial biology and Mathematics no credits to be allotted only 50 % passing i.e D grade will be prerequisite.

\$Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II Theory	3/45	1	4
BP202T	Pharmaceutical Organic Chemistry I Theory	3/45	1	4
BP203T	Biochemistry – Theory	3/45	1	4
BP204T	Pathophysiology – Theory	3/45	1	4
BP205T	Computer Applications in Pharmacy Theory *	3/45	-	3
BP206T	Environmental sciences – Theory *	3/45	-	3
BP207P	Human Anatomy and Physiology II Practical	4/60	-	2
BP208P	Pharmaceutical Organic Chemistry I Practical	4/60	-	2
BP209P	Biochemistry – Practical	4/60	-	2
BP210P	Computer Applications in Pharmacy Practical*	4/60	-	1
Total		32/480	4	29

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II Theory	3/45	1	4
BP302T	Physical Pharmaceutics I – Theory	3/45	1	4
BP303T	Pharmaceutical Microbiology – Theory	3/45	1	4
BP304T	Pharmaceutical Engineering – Theory	3/45	1	4
BP305P	Pharmaceutical Organic Chemistry II Practical	4/60	-	2
BP306P	Physical Pharmaceutics I – Practical	4/60	-	2
BP307P	Pharmaceutical Microbiology – Practical	4/60	-	2
BP 308P	Pharmaceutical Engineering –Practical	4/60	-	2
Total		28/420	4	24

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:

UNIT – I

10 Hours

- **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II

10 Hours

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

COURSE CONTENT

UNIT – I

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

07 Hours

UNIT – II

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each - Direct Communication Style, Spirited Communication Style, Systematic c) Communication Style, Considerate Communication Style

07 Hours

UNIT – III

- **Basic Listening Skills:** Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- **Effective Written Communication:** Introduction, When and When Not to Use

07 Hours

- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

05 Hours

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis

UNIT V

Plant respiration:Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

04 Hours

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

Definition, types of tissues, location and functions.

Text Books

1. Text book of Biology by S. B. Gokhale
2. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.

Reference Books

1. A Text book of Biology by B.V. Sreenivasa Naidu
2. A Text book of Biology by Naidu and Murthy
3. Botany for Degree students By A.C.Dutta.
4. Outlines of Zoology byM. Ekambaranatha ayyer and T. N. Ananthakrishnan.
5. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

Urinary system

4 hours

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit-IV

08 hours

Endocrine system

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit-V

09 hours

Reproductive system

07 Hours

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

Introduction to genetics

02 hours

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

Recommended Books

1. Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers medical publishers, New Delhi.
2. Anatomy and Physiology in Health and Illness by Kathleen J.W. Wilson, Churchill Livingstone, New York
3. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
4. Text book of Medical Physiology- Arthur C, Guyton and John.E. Hall. Miamisburg, OH, U.S.A.
5. Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A.
6. Textbook of Human Histology by Inderbir Singh, Jaypee brothers medical publishers, New Delhi.
7. Textbook of Practical Physiology by C.L. Ghai, Jaypee brothers medical publishers, New Delhi.
8. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee brother's medical publishers, New Delhi.

BP 204T. PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively. Pharmacotherapy of drugs is particularly not to be considered as a part of this subject from examination point of view as the subject deals with pathophysiological aspects of the diseases.

Objectives: Upon completion of the subject, student shall be able to –

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases

Unit-I	Basic principles of Cell injury and Adaptation Introduction & definitions Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, Hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intracellular accumulation, Calcification, Enzyme leakage and cell death, acidosis and alkalosis, Electrolyte imbalance Basic mechanism involved in the process of inflammation and repair Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin	10 Hrs
Unit -II.	Cardiovascular System: Hypertension, Congestive heart failure, Ischemic heart diseases (angina, myocardial infarction, atherosclerosis and arteriosclerosis) Respiratory system: Asthma, Chronic obstructive airways diseases Renal system: Acute and chronic renal failure	10 Hrs
Unit-III	Haematological Diseases: Iron deficiency anaemia, Megaloblastic anaemia (Vit B12 and folic acid), Sickle cell anemia, Thalassemia, Hereditary acquired anemia, Hemophilia Endocrine system: Diabetes, Thyroid diseases (Hypothyroidism, hyperthyroidism, Goitre) Disorders of sex hormones (Amenorrhoea, polycystic ovarian syndrome, hypogonadism) Nervous system:	12 Hrs

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory) 30 Hrs

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

COURSE CONTENT

UNIT – I

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division **06 hours**

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database **06 hours**

UNIT – III

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System **06 hours**

UNIT – IV

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery. **06 hours**

UNIT-V

Computers as data analysis in Preclinical development: Chromatographic data analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMMS) **06 hours**

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

30 hours

Scope: Environmental Sciences is the scientific study of the environmental system and the status of its inherent or induced changes on organisms. It includes not only the study of physical and biological characters of the environment but also the social and cultural factors and the impact of man on environment.

Objectives: Upon completion of the course the student shall be able to:

1. Create the awareness about environmental problems among learners.
2. Impart basic knowledge about the environment and its allied problems.
3. Develop an attitude of concern for the environment.
4. Motivate learner to participate in environment protection and environment improvement.
5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.
6. Strive to attain harmony with Nature.

COURSE CONTENT

Unit-I

The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources:

10hours

Natural resources and associated problems

a) Forest resources; b) Water resources; c) Mineral resources; d) Food resources; e) Energy resources; f) Land resources: Role of an individual in conservation of natural resources

Unit-II

Ecosystems

- Concept of an ecosystem.
- Structure and function of an ecosystem.
- Introduction, types, characteristic features, structure and function of the ecosystems: Forest ecosystem; Grassland ecosystem; Desert ecosystem; Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries)

10hours

Unit- III

Environmental Pollution: Air pollution; Water pollution; Soil pollution

10 hours

Recommended Books:

1. Y.K. Sing, Environmental Science, New Age International Pvt, Publishers, Bangalore
2. Agarwal, K.C. 2001 Environmental Biology, Nidi Publ. Ltd. Bikaner.
3. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India,
4. Brunner R.C., 1989, Hazardous Waste Incineration, McGraw Hill Inc. 480p
5. Clark R.S., Marine Pollution, Clarendon Press Oxford
6. Cunningham, W.P. Cooper, T.H. Gorhani, E & Hepworth, M.T. 2001, Environmental Encyclopedia, Jaico Publ. House, Mumbai, 1196p
7. De A.K., Environmental Chemistry, Wiley Eastern Ltd.
8. Down of Earth, Centre for Science and Environment

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY



RULES & SYLLABUS

**FIRST YEAR BACHELOR OF PHARMACY (B. Pharm.) COURSE
(EFFECTIVE FROM ACADEMIC YEAR 2018-2019)**

9. Course of study

The course of study for B. Pharm shall include Semester Wise Theory & Practical as given in Table – I to VIII. The number of hours to be devoted to each theory, tutorial and practical course in any semester shall not be less than that shown in Table – I to VIII.

Table-I: Course of study for semester I

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I– Theory	3	1	4
BP102T	Pharmaceutical Analysis I– Theory	3	1	4
BP103T	Pharmaceutics I – Theory	3	1	4
BP104T	Pharmaceutical Inorganic Chemistry – Theory	3	1	4
BP105T	Communication skills – Theory *	2	-	2
BP106RBT	Remedial Biology/			
BP106RMT	Remedial Mathematics – Theory*	2	-	2
BP107P	Human Anatomy and Physiology – Practical	4	-	2
BP108P	Pharmaceutical Analysis I – Practical	4	-	2
BP109P	Pharmaceutics I – Practical	4	-	2
BP110P	Pharmaceutical Inorganic Chemistry – Practical	4	-	2
BP111P	Communication skills – Practical*	2	-	1
BP112RBP	Remedial Biology – Practical*	2	-	1
Total		32/34[§]/36[#]	4	27/29[§]/30[#]

[#]Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB)course.

[§]Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM)course.

* Non University Examination (NUE)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3	1	4
BP203T	Biochemistry – Theory	3	1	4
BP204T	Pathophysiology – Theory	3	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3	-	3
BP206T	Environmental sciences – Theory *	3	-	3
BP207P	Human Anatomy and Physiology II – Practical	4	-	2
BP208P	Pharmaceutical Organic Chemistry I – Practical	4	-	2
BP209P	Biochemistry – Practical	4	-	2
BP210P	Computer Applications in Pharmacy – Practical*	2	-	1
Total		32	4	29

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3	1	4
BP302T	Physical Pharmaceutics I – Theory	3	1	4
BP303T	Pharmaceutical Microbiology – Theory	3	1	4
BP304T	Pharmaceutical Engineering – Theory	3	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4	-	2
BP306P	Physical Pharmaceutics I – Practical	4	-	2
BP307P	Pharmaceutical Microbiology – Practical	4	-	2
BP 308P	Pharmaceutical Engineering – Practical	4	-	2
Total		28	4	24

Scope: This course is designed to impart a fundamental knowledge on the preparatory pharmacy with arts and science of preparing the different conventional dosage forms.

Objectives: Upon completion of this course the student should be able to:

- Know the history of profession of pharmacy
- Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations
- Understand the professional way of handling the prescription
- Preparation of various conventional dosage forms

Course Content:**UNIT – I****10 Hours**

- **Historical background and development of profession of pharmacy:** History of profession of Pharmacy in India in relation to pharmacy education, industry and organization, Pharmacy as a career, Pharmacopoeias: Introduction to IP, BP, USP and Extra Pharmacopoeia.
- **Dosage forms:** Introduction to dosage forms, classification and definitions
- **Prescription:** Definition, Parts of prescription, handling of Prescription and Errors in prescription.
- **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

UNIT – II**10 Hours**

- **Pharmaceutical calculations:** Weights and measures – Imperial & Metric system, Calculations involving percentage solutions, alligation, proof spirit and isotonic solutions based on freezing point and molecular weight.
- **Powders:** Definition, classification, advantages and disadvantages, Simple & compound powders – official preparations, dusting powders, effervescent, efflorescent and hygroscopic powders, eutectic mixtures. Geometric dilutions.
- **Liquid dosage forms:** Advantages and disadvantages of liquid dosage forms. Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques

BP105T.COMMUNICATION SKILLS (Theory)

30 Hours

Scope: This course will prepare the young pharmacy student to interact effectively with doctors, nurses, dentists, physiotherapists and other health workers. At the end of this course the student will get the soft skills set to work cohesively with the team as a team player and will add value to the pharmaceutical business.

Objectives:

Upon completion of the course the student shall be able to

1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation
2. Communicate effectively (Verbal and Non Verbal)
3. Effectively manage the team as a team player
4. Develop interview skills
5. Develop Leadership qualities and essentials

Course content:

UNIT – I

07 Hours

- **Communication Skills:** Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- **Barriers to communication:** Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- **Perspectives in Communication:** Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

UNIT – II

07 Hours

- **Elements of Communication:** Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- **Communication Styles:** Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

UNIT III

07 Hours

Excretory products and their elimination

- Modes of excretion
- Human excretory system- structure and function
- Urine formation
- Rennin angiotensin system

Neural control and coordination

- Definition and classification of nervous system
- Structure of a neuron
- Generation and conduction of nerve impulse
- Structure of brain and spinal cord
- Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata

Chemical coordination and regulation

- Endocrine glands and their secretions
- Functions of hormones secreted by endocrine glands

Human reproduction

- Parts of female reproductive system
- Parts of male reproductive system
- Spermatogenesis and Oogenesis
- Menstrual cycle

UNIT IV

05 Hours

Plants and mineral nutrition:

- Essential mineral, macro and micronutrients
- Nitrogen metabolism, Nitrogen cycle, biological nitrogen fixation

Photosynthesis

- Autotrophic nutrition, photosynthesis, Photosynthetic pigments, Factors affecting photosynthesis.

UNIT V

04 Hours

Plant respiration:Respiration, glycolysis, fermentation (anaerobic).

Plant growth and development

- Phases and rate of plant growth, Condition of growth,Introduction to plant growth regulators

Cell - The unit of life

- Structure and functions of cell and cell organelles.Cell division

Tissues

- Definition, types of tissues, location and functions.

and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT.

- **Energetics**

Formation and role of ATP, Creatinine Phosphate and BMR.

Unit III

- **Respiratory system**

10 hours

Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration

Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods.

- **Urinary system**

Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney.

Unit IV

10 hours

- **Endocrine system**

Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus and their disorders.

Unit V

09 hours

- **Reproductive system**

Anatomy of male and female reproductive system, Functions of male and female reproductive system, sex hormones, physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition

- **Introduction to genetics**

Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

Recommended Books (Latest Editions)

1. Principles of Biochemistry by Lehninger.
2. Harper's Biochemistry by Robert K. Murray, Daryl K. Granner and Victor W. Rodwell.
3. Biochemistry by Stryer.
4. Biochemistry by D. Satyanarayan and U.Chakrapani
5. Textbook of Biochemistry by Rama Rao.
6. Textbook of Biochemistry by Deb.
7. Outlines of Biochemistry by Conn and Stumpf
8. Practical Biochemistry by R.C. Gupta and S. Bhargavan.
9. Introduction of Practical Biochemistry by David T. Plummer. (3rd Edition)
10. Practical Biochemistry for Medical students by Rajagopal and Ramakrishna.
11. Practical Biochemistry by Harold Varley.

BP 204T.PATHOPHYSIOLOGY (THEORY)

45Hours

Scope: Pathophysiology is the study of causes of diseases and reactions of the body to such disease producing causes. This course is designed to impart a thorough knowledge of the relevant aspects of pathology of various conditions with reference to its pharmacological applications, and understanding of basic pathophysiological mechanisms. Hence it will not only help to study the syllabus of pathology, **but also to get baseline knowledge required to practice medicine safely, confidently, rationally and effectively.**

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

1. Describe the etiology and pathogenesis of the selected disease states;
2. Name the signs and symptoms of the diseases; and
3. Mention the complications of the diseases.

Course content:

Unit I

10Hours

- **Basic principles of Cell injury and Adaptation:**
Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

30 Hrs (2 Hrs/Week)

Scope: This subject deals with the introduction Database, Database Management system, computer application in clinical studies and use of databases.

Objectives: Upon completion of the course the student shall be able to

1. know the various types of application of computers in pharmacy
2. know the various types of databases
3. know the various applications of databases in pharmacy

Course content:

UNIT – I

06 hours

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division

Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

UNIT –II

06 hours

Web technologies: Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products
Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

UNIT – III

06 hours

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring

Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY



Syllabus of Second Year B. Pharmacy

2019 PATTERN

(EFFECTIVE FROM ACADEMIC YEAR 2020-2021)

Table-II: Course of study for semester II

Course Code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP201T	Human Anatomy and Physiology II – Theory	3/45	1	4
BP202T	Pharmaceutical Organic Chemistry I – Theory	3/45	1	4
BP203T	Biochemistry – Theory	3/45	1	4
BP204T	Pathophysiology – Theory	3/45	1	4
BP205T	Computer Applications in Pharmacy – Theory *	3/45	-	3
BP206T	Environmental sciences – Theory *	3/45	-	3
BP207P	Human Anatomy and Physiology II –Practical	4/60	-	2
BP208P	Pharmaceutical Organic Chemistry I- Practical	4/60	-	2
BP209P	Biochemistry – Practical	4/60	-	2
BP210P	Computer Applications in Pharmacy – Practical*	4/60	-	1
Total		32/480	4	29

*Non University Examination (NUE)

Table-III: Course of study for semester III

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP301T	Pharmaceutical Organic Chemistry II – Theory	3/45	1	4
BP302T	Physical Pharmaceutics I – Theory	3/45	1	4
BP303T	Pharmaceutical Microbiology – Theory	3/45	1	4
BP304T	Pharmaceutical Engineering – Theory	3/45	1	4
BP305P	Pharmaceutical Organic Chemistry II – Practical	4/60	-	2
BP306P	Physical Pharmaceutics I – Practical	4/60	-	2
BP307P	Pharmaceutical Microbiology – Practical	4/60	-	2
BP 308P	Pharmaceutical Engineering –Practical	4/60	-	2
Total		28/420	4	24

7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Pepler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
14. "Nutrition Probiotics and prebiotics" by Pamela Mason; The Pharmaceutical Journal Vol 266 No 7132 p118-121.
15. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

45 Hours

Scope:

This course is designed to impart a fundamental knowledge on the art and science of various unit operations used in pharmaceutical industry.

Objectives:

Upon completion of the course student shall be able:

1. To know various unit operations used in Pharmaceutical industries.
2. To understand the material handling techniques.
3. To perform various processes involved in pharmaceutical manufacturing process.
4. To carry out various test to prevent environmental pollution.
5. To appreciate and comprehend significance of plant lay out design for optimum use of resources.
6. To appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory) - 45 Hours

Scope: The subject involves the fundamentals of Pharmacognosy like scope, classification of crude drugs, their identification and evaluation, phytochemicals present in them and their medicinal properties.

Objectives: Upon completion of the course, the student shall be able

1. to know the techniques in the cultivation and production of crude drugs
2. to know the crude drugs, their uses and chemical nature
3. know the evaluation techniques for the herbal drugs
4. to carry out the microscopic and morphological evaluation of crude drugs

Course Content:

UNIT-I

10 Hours

Introduction to Pharmacognosy:

- (a) Definition, history, scope and development of Pharmacognosy
- (b) Sources of Drugs – Plants, Animals, Marine & Tissue culture
- (c) Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins).

Classification of drugs:

Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero taxonomical classification of drugs

Quality control of Drugs of Natural Origin:

- Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.
- Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida.

13. Determination of effect of salts on stability of hydrophobic sols

Recommended Books:

1. Physical Pharmacy by Alfred Martin, Sixth edition
2. Experimental pharmaceutics by Eugene, Parott.
3. Tutorial pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical calculations, Lea & Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to 3, Marcel Dekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C, and Manavalan R.

BP 408 P. PHARMACOLOGY-I (Practical)

4Hrs/Week

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals and its possible use.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.
6. Study of different routes of drugs administration in mice/rats.
7. Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleeping time in mice.
8. Effect of drugs on ciliary motility of frog oesophagus
9. Effect of drugs on rabbit eye.
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer.
12. Anticonvulsant effect of drugs by MES and PTZ method.
13. Study of stereotype and anti-catatonic activity of drugs on rats/mice.
14. Study of anxiolytic activity of drugs using rats/mice.
15. Study of local anaesthetics by different methods

SAVITRIBAI PHULE PUNE UNIVERSITY

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Syllabus of Third Year B. Pharmacy

2019 PATTERN (Revised)

(EFFECTIVE FROM ACADEMIC YEAR 2021-2022)

Table-IV: Course of study for semester IV

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit Points
BP401T	Pharmaceutical Organic Chemistry III– Theory	3/45	1	4
BP402T	Medicinal Chemistry I – Theory	3/45	1	4
BP403T	Physical Pharmaceutics II – Theory	3/45	1	4
BP404T	Pharmacology I – Theory	3/45	1	4
BP405T	Pharmacognosy and Phytochemistry I– Theory	3/45	1	4
BP406P	Medicinal Chemistry I – Practical	4/60	-	2
BP407P	Physical Pharmaceutics II – Practical	4/60	-	2
BP408P	Pharmacology I – Practical	4/60	-	2
BP409P	Pharmacognosy and Phytochemistry I – Practical	4/60	-	2
Total		31/465	5	28

Table-V: Course of study for semester V

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP501T	Medicinal Chemistry II – Theory	3/45	1	4
BP502T	Industrial Pharmacy-I– Theory	3/45	1	4
BP503T	Pharmacology II – Theory	3/45	1	4
BP504T	Pharmacognosy and Phytochemistry II– Theory	3/45	1	4
BP505T	Pharmaceutical Jurisprudence – Theory	3/45	1	4
BP506P	Industrial Pharmacy-I - Practical	4/60	-	2
BP507P	Pharmacology II – Practical	4/60	-	2
BP508P	Pharmacognosy and Phytochemistry II – Practical	4/60	-	2
Total		27/405	5	26

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3/45	1	4
BP602T	Pharmacology III – Theory	3/45	1	4
BP603T	Herbal Drug Technology – Theory	3/45	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3/45	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3/45	1	4
BP606T	Quality Assurance – Theory	3/45	1	4
BP607P	Medicinal chemistry III – Practical	4/60	-	2
BP608P	Pharmacology III – Practical	4/60	-	2
BP609P	Herbal Drug Technology – Practical	4/60	-	2
Total		30/450	6	30

Table-VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy-II – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		28/420	5	24

* Non University Examination (NUE)

UNIT-III

10 Hours

Drugs acting on cardiovascular system (Continued)

- a) **Anti-arrhythmic Drugs:** Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate, Phenytoin sodium, Lidocaine hydrochloride, Tocainide hydrochloride, Mexiletine hydrochloride, Lorcaïnide hydrochloride, Amiodarone, Sotalol.
- b) **Anti-hyperlipidemic agents**
HMG Co-A reductase inhibitors: Lovastatin, Simvastatin, Atorvastatin
Misc. class-Ezetimibe, Clofibrate
- c) **Coagulant & Anticoagulants:** Menadione, Warfarin, Clopidogrel
- d) **Drugs used in Congestive Heart Failure:** Digoxin, Digitoxin, Nesiritide, Bosentan
[Amiodarone, Atorvastatin]

UNIT-IV

08 Hours

Drugs acting on Endocrine system

- a) **Chemistry, Nomenclature, Stereochemistry and metabolism of steroids**
- b) **Sex hormones:** Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol.
- c) **Drugs for erectile dysfunction:** Sildenafil, Tadalafil.
- d) **Oral contraceptives:** Mifepristone, Norgestrel, Levonorgestrol
- e) **Corticosteroids:** Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone
- f) **Thyroid and antithyroid drugs:** L-Thyroxine, L-Thyronine, Propylthiouracil, Methimazole.

UNIT - V

07 Hours

Antidiabetic agents and Local anaesthetics

- a) **Antidiabetic agents:**

Insulin and its preparations

Sulfonyl ureas: Tolbutamide, Chlorpropamide, Glipizide, Glimepiride.

Biguanides: Metformin.

Meglitinides: Repaglinide, Nateglinide.

Objectives:

Upon completion of the course the student shall be able to

1. illustrate various pharmaceutical dosage forms and their manufacturing techniques.
2. describe various factors to be considered in development of pharmaceutical dosage forms
3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

Course content:

3 hours/ week

UNIT-I

03 Hours

Preformulation Studies: Introduction to preformulation, goals and objectives, study of physicochemical characteristics of drug substances.

UNIT-II

14 Hours

Tablets:

a. Introduction, ideal characteristics of tablets, classification of tablets. Excipients, preformulation and Formulation of tablets, granulation methods, compression and processing problems, Equipments and tablet tooling.

b. Tablet coating: Types of coating, coating materials, formulation of coating composition, methods of coating, equipment employed and defects in coating.

c. Quality control tests: In process and finished product tests

Liquid orals: Preformulation, Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; evaluation of liquid orals official in pharmacopoeia

UNIT-III

08 Hours

Capsules:

a. Hard gelatin capsules: Introduction, Production of hard gelatin capsule shells. Size of capsules, Filling, finishing and special techniques of formulation of hard gelatin capsules, manufacturing defects. In process and final product quality control tests for capsules.

UNIT-IV

Pharmacology of drugs acting on endocrine system

08hr

- a. Basic concepts in endocrine pharmacology.
- b. Anterior Pituitary hormones- analogues and their inhibitors.
- c. Thyroid hormones- analogues and their inhibitors.
- d. Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D.
- d. Insulin, Oral Hypoglycemic agents and glucagon.
- e. ACTH and corticosteroids.

UNIT-V

Pharmacology of drugs acting on endocrine system

07hr

- a. Androgens and Anabolic steroids.
- b. Estrogens, progesterone and oral contraceptives.
- c. Drugs acting on the uterus.

Bioassay

- a. Principles, applications and types of bioassay.
- b. Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT

Recommended Books (Latest Editions)

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K. D. Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher

8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,

BP504 T PHARMACOGNOSY AND PHYTOCHEMISTRY-II (Theory) 45 Hours

Scope:

The main purpose of subject is to impart the students the knowledge of how the secondary metabolites are produced in the crude drugs, how to isolate and identify and produce them industrially. Also this subject involves the study of producing the plants and phytochemicals through plant tissue culture, drug interactions and basic principles of traditional system of medicine

Objectives: Upon completion of the course, the student shall be able

1. To know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

2. To understand the production of of Phytoconstituents /herbal formulation.

3. To understand the metabolic pathways in formation of secondary metabolites and application of biogenetic studies.

4. To carryout isolation and identification of phytoconstituents

Course Content:

UNIT-I

7 Hours

Metabolic pathways in higher plants and their determination

a) Brief study of basic metabolic pathways and formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway.

b) Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.

UNIT-II

14 Hours

General introduction, composition, chemistry & chemical classes, bio sources, methods of extraction, therapeutic uses and commercial applications of following secondary metabolites:

Alkaloids: Vinca, Rauwolfia, Belladonna, Opium,

Phenylpropanoids and Flavonoids: Lignans, Tea, Ruta

Steroids, Cardiac Glycosides & Triterpenoids: Liquorice, Dioscorea, Digitalis

Objectives: Upon completion of the course, the student shall be able to understand:

1. The Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.
2. Various Indian pharmaceutical Acts and Laws
3. The regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
4. The code of ethics during the pharmaceutical practice

Course Content:

UNIT-I

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945:

Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs,

Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-II

10 Hours

Drugs and Cosmetics Act, 1940 and its rules 1945.

Detailed study of Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and restricted license. Offences and penalties Labeling & packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.

Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-V

07 Hours

Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath

Medical Termination of Pregnancy Act

Right to Information Act

Introduction to Intellectual Property Rights (IPR)

Recommended books: (Latest Edition)

1. Forensic Pharmacy by B. Suresh
2. Text book of Forensic Pharmacy by B.M. Mithal
3. Hand book of drug law-by M.L. Mehra
4. A text book of Forensic Pharmacy by N.K. Jain
5. Drugs and Cosmetics Act/Rules by Govt. of India publications.
6. Medicinal and Toilet preparations act 1955 by Govt. of India publications.
7. Narcotic drugs and psychotropic substances act by Govt. of India publications
8. Drugs and Magic Remedies act by Govt. of India publication
9. Bare Acts of the said laws published by Government. Reference books (Theory) 124

BP 506 P. Industrial Pharmacy I (Practical)

4 Hours/week

1. Preformulation studies on paracetamol/aspirin/or any other drug
2. Preparation and evaluation of Paracetamol tablets
3. Preparation and evaluation of Aspirin tablets
4. Coating of tablets- film coating of tablets/granules
5. Preparation and evaluation of Tetracycline capsules

2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point LippincottWilliams &Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers MedicalPublishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
9. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

Scope: This subject gives the student the knowledge of basic understanding of herbal drug industry, the quality of raw material, guidelines for quality of herbal drugs, herbal cosmetics, natural sweeteners, nutraceutical etc. **The subject also emphasizes on Good Manufacturing Practices (GMP), patenting and regulatory issues of herbal drugs**

Objectives: Upon completion of this course the student should be able to:

1. understand raw material as source of herbal drugs from cultivation to herbal drug product
2. know the WHO and ICH guidelines for evaluation of herbal drugs
3. know the herbal cosmetics, natural sweeteners, nutraceuticals
4. appreciate patenting of herbal drugs, GMP .

Course content:

UNIT-I

11 Hours

Herbs as raw materials

Market overview, Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products.

Herbal excipients:

Market overview, Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes.

Herbal formulations :

Market overview, Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes

UNIT- IV

12 Hours

Evaluation of Drugs WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs.

Patenting and Regulatory requirements of natural products:

- a) Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy
- b) Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem.

Regulatory Issues - Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs.

Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)

UNIT-V

05Hours

General Introduction to Herbal Industry

- Herbal drugs industry: Present scope and future prospects.
- A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India.

Schedule T – Good Manufacturing Practice of Indian systems of medicine

6. S.B. Primrose: Molecular Biotechnology (Second Edition) BlackwellScientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., NewDelhi.

BP 606T PHARMACEUTICAL QUALITY ASSURANCE (Theory) 45 Hours

Scope:

This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It deals with the important aspects like cGMP, QC tests, documentation, quality certifications and regulatory affairs.

Objectives:

Upon completion of the course student shall be able to:

1. Understand the cGMP aspects in a pharmaceutical industry
2. Appreciate the importance of documentation
3. Understand the scope of quality certifications applicable to pharmaceutical industries
4. Understand the responsibilities of QA & QC departments

COURSE CONTENT

UNIT – I

10 Hours

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP, Introduction to Regulatory agencies like CDSCO, USFDA, WHO, PIC/S.

Total Quality Management (TQM): Definition, elements, philosophies

ICH Guidelines: Brief overview of QSEM, ICH stability testing guidelines

Quality by design (QbD): Definition, Overview, Elements of QbD program

ISO 9000 & ISO14000: Overview, Benefits and Elements

NABL accreditation : Principles and procedures

SAVITRIBAI PHULE PUNE UNIVERSITY

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COURSE STRUCTURE AND SYLLABUS

**FINAL YEAR BACHELOR OF PHARMACY (B. Pharm.) 2019 PATTERN
(EFFECTIVE FROM ACADEMIC YEAR 2022 – 2023)**

Table-I: Course of study for semester I

Course code	Name of the course	No.of Hours per week/Total no of hours	Tutorial	Credit points
BP101T	Human Anatomy and Physiology I- Theory	3/45	1	4
BP102T	Pharmaceutical Analysis I- Theory	3/45	1	4
BP103T	Pharmaceutics I- Theory	3/45	1	4
BP104T	Pharmaceutical Inorganic Chemistry- Theory	3/45	1	4
BP105T	Communication skills - Theory *	2/30	-	2
BP106RBT BP106RMT	Remedial Biology/ Remedial Mathematics - Theory*	2/30	-	D
BP107P	Human Anatomy and Physiology - Practical	4/60	-	2
BP108P	Pharmaceutical Analysis I- Practical	4/60	-	2
BP109P	Pharmaceutics I - Practical	4/60	-	2
BP110P	Pharmaceutical Inorganic Chemistry - Practical	4/60	-	2
BP111P	Communication skills - Practical*	2/30	-	1
BP112RBP	Remedial Biology - Practical*	2/30	-	D
Total		32/34^S/36[#]/480/510^S/540[#]	4	27

Applicable ONLY for the students who have studied Mathematics / Physics / Chemistry at HSC and appearing for Remedial Biology (RB) course. However for Remedial biology and Mathematics no credits to be allotted only 50 % passing i.e D grade will be prerequisite.

S Applicable ONLY for the students who have studied Physics / Chemistry / Botany / Zoology at HSC and appearing for Remedial Mathematics (RM) course.

* Non University Examination (NUE)

Table-VI: Course of study for semester VI

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP601T	Medicinal Chemistry III – Theory	3/45	1	4
BP602T	Pharmacology III – Theory	3/45	1	4
BP603T	Herbal Drug Technology – Theory	3/45	1	4
BP604T	Biopharmaceutics and Pharmacokinetics – Theory	3/45	1	4
BP605T	Pharmaceutical Biotechnology – Theory	3/45	1	4
BP606T	Quality Assurance –Theory	3/45	1	4
BP607P	Medicinal chemistry III – Practical	4/60	-	2
BP608P	Pharmacology III – Practical	4/60	-	2
BP609P	Herbal Drug Technology – Practical	4/60	-	2
Total		30/450	6	30

Table – VII: Course of study for semester VII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP701T	Instrumental Methods of Analysis – Theory	3/45	1	4
BP702T	Industrial Pharmacy-II – Theory	3/45	1	4
BP703T	Pharmacy Practice – Theory	3/45	1	4
BP704T	Novel Drug Delivery System – Theory	3/45	1	4
BP705P	Instrumental Methods of Analysis – Practical	4/60	-	2
BP706PS	Practice School*	12/180	-	6
Total		28/420	5	24

* Non University Examination (NUE)

Table – VIII: Course of study for semester VIII

Course code	Name of the course	No. of Hours per week/Total no of hours	Tutorial	Credit points
BP801T	Biostatistics and Research Methodology	3/45	1	4
BP802T	Social and Preventive Pharmacy	3/45	1	4
BP803ET	Pharma Marketing Management	3 + 3 = 6/90	1 + 1 = 2	4 + 4 = 8
BP804ET	Pharmaceutical Regulatory Science			
BP805ET	Pharmacovigilance			
BP806ET	Quality Control and Standardizations of Herbals			
BP807ET	Computer Aided Drug Design			
BP808ET	Cell and Molecular Biology			
BP809ET	Cosmetic Science			
BP810ET	Experimental Pharmacology			
BP811ET	Advanced Instrumentation Techniques			
BP812ET	Dietary Supplements and Nutraceuticals			
BP813PW	Project Work	12/180	-	6
Total		24/360	4	22

Table-IX: Semester wise credits distribution

Semester	Credit Points
I	27
II	29
III	24
IV	28
V	26
VI	30
VII	24
VIII	22
Extracurricular/ Co curricular activities	01*
Total credit points for the program	211

BP702T	INDUSTRIAL PHARMACY -II (Theory)	45 Hours
<p>Scope:</p> <p>This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.</p> <p>Objectives: Upon completion of the course, the student shall be able to:</p> <ol style="list-style-type: none"> 1. Know the process of pilot plant and scale up of pharmaceutical dosage forms 2. Understand the process of technology transfer from lab scale to commercial batch 3. Know different Laws and Acts that regulate pharmaceutical industry 4. Understand the approval process and regulatory requirements for drug products <p>Course Content:</p>		
<p>UNIT-I</p> <p>Pilot plant scale up techniques:</p> <p>General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.</p>		10 Hours
<p>UNIT-II</p> <p>Technology development and transfer:</p> <p>WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization- practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoU's, legal issues</p>		10 Hours

BP703T	PHARMACY PRACTICE (Theory)	45 Hour s
<p>Scope: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counseling for improved patient care in the community setup.</p> <p>Objectives: Upon completion of the course, the student shall be able to:</p> <ol style="list-style-type: none"> 1. Know various drug distribution methods in a hospital 2. Appreciate the pharmacy stores management and inventory control 3. Monitor drug therapy of patient through medication chart review and clinical review. 4. Obtain medication history interview and counsel the patients 5. Identify drug related problems 6. Detect and assess adverse drug reactions 7. Interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states 8. Know pharmaceutical care services 9. Do patient counseling in community pharmacy. 10. Appreciate the concept of rational drug therapy <p>Course Content:</p>		
<p>UNIT-I</p> <p>Hospital and its organization Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions.</p> <p>Hospital pharmacy and its organization Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.</p> <p>Adverse drug reaction Classifications - Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage</p>		<p>10 Hours</p>

BP802T	SOCIAL AND PREVENTIVE PHARMACY (Theory)	45 Hours
<p>Scope: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.</p> <p>Objectives: After the successful completion of this course, the student shall be able to:</p> <ol style="list-style-type: none"> 1. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide. 2. Develop a critical way of thinking based on current health care development. 3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues. <p>Course Content:</p>		
<p>UNIT-I Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.</p> <p>Sociology and health Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health</p> <p>Hygiene and health Personal hygiene and health care; avoidable habits.</p>		10 Hours
<p>UNIT-II Preventive medicine General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse</p>		10 Hours
<p>UNIT-III National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.</p>		10 Hours
<p>UNIT-IV National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program</p>		08 Hours

BP805ET	PHARMACOVIGILANCE (Theory)	45 Hours
<p>Scope: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions</p> <p>Objectives:</p> <ul style="list-style-type: none"> • At completion of this paper it is expected that students will be able to (know, do, and appreciate): • Understand importance of drug safety monitoring. • Explain History, development, National and international scenario of pharmacovigilance & comprehend dictionaries, coding and terminologies used in pharmacovigilance • Understand detection and assessment of new adverse drug reactions, Adverse drug reaction reporting systems and communication in pharmacovigilance, Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning. CIOMS requirements for ADR reporting • Comprehend methods of safety data during pre-clinical, clinical and post approval phases of drugs lifecycle • Write case narratives of adverse events and their quality. <p>Course Content:</p>		
<p>UNIT-I</p> <p>Introduction to Pharmacovigilance History and development of Pharmacovigilance, Importance of safety monitoring of Medicine, WHO international drug monitoring programme, Pharmacovigilance Program of India (PvPI)</p> <p>Introduction to adverse drug reactions Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions</p> <p>Basic terminologies used in pharmacovigilance Terminologies of adverse medication related events, Regulatory terminologies</p>		<p>10 Hours</p>

SAVITRIBAI PHULE PUNE UNIVERSITY

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RULES & SYLLABUS

FIRST YEAR MASTER OF PHARMACY (M. Pharm.) COURSE
(EFFECTIVE FROM ACADEMIC YEAR 2019-2020)

Table - 2: Course of study for M. Pharm. (Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPH102T	Drug Delivery System	4	4	4	100
MPH103T	Modern Pharmaceutics	4	4	4	100
MPH104T	Regulatory Affair	4	4	4	100
MPH105P	Pharmaceutics Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
SEMESTER II					
MPH201T	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	4	100
MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	4	4	4	100
MPH203T	Computer Aided Drug Development	4	4	4	100
MPH204T	Cosmetic & Cosmeceuticals	4	4	4	100
MPH205P	Pharmaceutics Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table - 6: Course of study for M. Pharm. (Pharmaceutical Quality Assurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MQA102T	Quality Management System	4	4	4	100
MQA103T	Quality Control and Quality Assurance	4	4	4	100
MQA104T	Product Development and Technology Transfer	4	4	4	100
MQA105P	Pharmaceutical Quality Assurance Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
SEMESTER II					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	Pharmaceutical Validation	4	4	4	100
MQA203T	Audits and Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical Manufacturing Technology	4	4	4	100
MQA205P	Pharmaceutical Quality Assurance Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

Table - 10: Course of study for (Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SEMESTER I					
MPAT101T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPL102T	Advanced Pharmacology - I	4	4	4	100
MPL 103T	Pharmacological and Toxicological Screening Methods-I	4	4	4	100
MPL104T	Cellular and Molecular Pharmacology	4	4	4	100
MPL105P	Pharmacology Practical I	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650
SEMESTER II					
MPL201T	Advanced Pharmacology II	4	4	4	100
MPL 202T	Pharmacological and Toxicological Screening Methods-II	4	4	4	100
MPL203T	Principles of Drug Discovery	4	4	4	100
MPL204T	Clinical Research and Pharmacovigilance	4	4	4	100
MPL205P	Pharmacology Practical II	12	6	12	150
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	650

REGULATORY AFFAIRS (MPH 104T)

SCOPE

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA

- To know the approval process of
- To know the chemistry, manufacturing controls and their regulatory importance
- To learn the documentation requirements for
- To learn the importance and

OBJECTIVES

Upon completion of the course, it is expected that the students will be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials.
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY

60 Hrs

1. a) Documentation in Pharmaceutical industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development Introduction , Hatch– Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION) ,drug product performance, in–vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in -vivo, scale up process approval changes, post marketing surveillance, outsourcing BA and BE to CRO. **12 Hrs**
b) Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. **12 Hrs**
2. CMC, post approval regulatory affairs. Regulation for combination products and medical devices.CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries. **12 Hrs**
3. Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB). **12 Hrs**

PHARMACEUTICAL QUALITY ASSURANCE (MQA)
QUALITY MANAGEMENT SYSTEMS (MQA 102T)

60 Hrs

Scope

This course is designed to impart fundamental knowledge and concepts about various quality management principles and systems utilized in the manufacturing industry. **It also aids in understanding the quality evaluation in the Pharmaceutical industries.**

Objectives

Upon completion of the course the student shall be able to

- The importance of quality
- Tools for quality improvement
- Analysis of issues in quality
- Quality evaluation of pharmaceuticals
- Stability testing of drug and drug substances
- Statistical approaches for quality

COURSE CONTENT

UNIT-I

- **Introduction to Quality: Evolution of Quality**
- **Definition of Introduction to Quality:** Evolution of Quality, Definition of Quality, Dimensions of Quality
- **Quality as a Strategic Decision:** Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality
Customer Focus: Meaning of customer and customer focus, Classification of customers, Customer focus, Customer perception of quality, Factors affecting customer perception, Customer requirements, Meeting customer needs and expectations, Customer satisfaction and Customer delight, Handling customer complaints, Understanding customer behaviour, concept of internal and external customers. Case studies.
- **Cost of Quality:** Cost of quality, Categories of cost of Quality, Models of cost of quality, Optimising costs, preventing cost of quality.

08 Hrs

UNIT-II

- **Pharmaceutical quality Management:** Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004, Pharmaceutical Quality Management-ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review. OSHAS guidelines, NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements.

16 Hrs

UNIT-III

- **Six System Inspection model :** Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self inspection.
- **Quality systems:** Change Management / Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT),
- **Complaints** - evaluation and handling, Investigation and determination

12 Hrs

Scope

This course is designed to convey the knowledge necessary to understand issues related to different kinds of hazard and their management. Basic theoretical and practical discussions integrate the proficiency to handle the emergency situation in the pharmaceutical product development process and provides the principle based approach to solve the complex tribulations.

Objectives

At completion of this course it is expected that students will be able to

- Understand about environmental problems among learners.
- Impart basic knowledge about the environment and its allied problems.
- Develop an attitude of concern for the industry environment.
- Ensure safety standards in pharmaceutical industry
- Provide comprehensive knowledge on the safety management
- Empower an ideas to clear mechanism and management in different kinds of hazard management system
- Teach the method of Hazard assessment, procedure, methodology for provide safe industrial atmosphere.

UNIT-I

- Multidisciplinary nature of environmental studies Natural Resources and associated problems, Renewable and non-renewable resources, a) Forest resources; b) Water resources; c) Mineral resources; d) Energy resources; e) Land resources
- **Ecosystems:** Concept of an ecosystem, Structure and function of an ecosystem. Environmental hazards: Hazards based on Air, Water, Soil and Radioisotopes.

12 Hrs

UNIT-II

- Air based hazards Sources, Types of Hazards, Air circulation, Air handling system, HVAC system, air maintenance in industry for sterile area and non sterile area.

12 Hrs

UNIT-III

- **Chemical based hazards:** Sources of chemical hazards, Hazards of Organic synthesis, sulphonating hazard, Organic solvent hazard. Control measures for chemical hazards. Management of combustible gases, Toxic gases and Oxygen displacing gases management, Regulations for chemical hazard, MSDS, Labelling guidelines, Management of over-exposure to chemicals and TLV concept, Disposal of hazardous material.

12 Hrs

UNIT-IV

- **Fire and Explosion:** Introduction, Industrial processes and hazards potential, Mechanical, electrical, thermal and process hazards, mechanical and chemical explosion, multiphase reactions, Safety and hazards regulations
- **Fire protection system:** Fire prevention, types of fire extinguishers and critical Hazard management system, Preventive and protective management from fires and explosion- electricity passivation, ventilation, and sprinkling, proofing, fire walls, bunds, relief systems - relief valves, flares, scrubbers.

12 Hrs

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS - I (MPL 103T)

SCOPE

This subject is designed to impart the knowledge on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes

OBJECTIVES

Upon completion of the course the student shall be able to,

- Appraise the regulations and ethical requirement for the usage of experimental animals.
- Describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals
- Describe the various newer screening methods involved in the drug discovery process
- Appreciate and correlate the preclinical data to humans

THEORY		60 Hrs
Unit-I	Laboratory Animals Common Laboratory animals: Description, handling and applications of different species and strains of animals. Transgenic animals: Production, maintenance and applications. CPCSEA Guidelines for experimental animals. Anesthesia and euthanasia of experimental animals Maintenance and breeding of laboratory animals. Good laboratory Practice.	12 Hrs
Unit -II	Preclinical screening of new substances for the pharmacological activity using <i>in vivo</i>, <i>in vitro</i> and other possible alternative methods in animals. CNS Pharmacology: General principles of preclinical screening, screening of behavioral and muscle coordination, CNS stimulants and depressants, anxiolytics, anti-psychotics, anti-epileptics, nootropics, Parkinsonism and Alzheimer's. Drugs acting on Autonomic nervous system.	12 Hrs
Unit-III	Preclinical screening of new substances for the pharmacological activity using <i>in vivo</i>, <i>in vitro</i> and other possible alternative methods in animals. Respiratory Pharmacology: Anti-asthmatics, drugs for COPD and anti-allergic. Reproductive Pharmacology: Aphrodisiacs and ant-fertility agents Gastrointestinal drugs:	12 Hrs

PHARMACOLOGICAL AND TOXICOLOGICAL SCREENING METHODS-II (MPL202T)

SCOPE

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug and new chemical entity. This knowledge will make the student competent in regulatory toxicological evaluation.

OBJECTIVES

Upon completion of the course the student shall be able to:

- Explain the various types of toxicity studies.
- Appreciate the importance of ethical and regulatory requirements for toxicity studies.
- Demonstrate the practical skills require conducting the preclinical toxicity studies.

THEORY

	60 Hrs	
Unit-I	Basic definition and types of toxicology (general, mechanistic, regulatory and descriptive) Regulatory guidelines for conducting toxicity studies OECD, ICH, EPA and Schedule Y OECD principles of Good laboratory practice. History, concept and its importance in drug development	12 Hrs
Unit -II	Acute, Sub-acute and chronic-oral, dermal and inhalational studies as per OECD guidelines. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies. Test item characterization- importance and methods in regulatory toxicity studies.	12 Hrs
Unit-III	Reproductive toxicity studies, Male reproductive toxicity studies, Female reproductive studies (segment I and III), teratogenicity studies (segment II) Genotoxicity studies (Ames Test, <i>in vitro</i> and <i>in vivo</i> Micronucleus and Chromosomal aberrations studies) In vivo carcinogenicity studies	12 Hrs
Unit-IV	IND enabling studies (IND studies): Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission. Safety pharmacology studies: origin, concepts and importance of safety pharmacology Tier 1- CVS, CNS and respiratory safety pharmacology, HERG assay. Tier 2- GI, renal and other studies.	12 Hrs
Unit-V	Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	12 Hrs

CLINICAL RESEARCH AND PHARMACOVIGILANCE (MPL204T)

SCOPE:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will reach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

OBJECTIVES:

Upon completion of the course, the student shall be able to:

- Explain the regulatory requirements for conducting clinical trial.
- Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials.
- Execute safety monitoring, reporting and close-out activities.
- Explain the principles of Pharmacovigilance.
- Detect new adverse drug reaction and their assessment.
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

THEORY	60 Hrs
Unit-I Regulatory Perspective of Clinical Trials: Origin and Principles of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines. Ethical Committee: Institutional Review Board, Ethical guidelines for Biomedical Research and Human Participant Schedule Y, ICMR. Inform Consent Process: Structure and content of an Inform Consent Process Ethical principles governing informed consent process.	12 Hrs
Unit -II Clinical Trials: Types and Design Experimental Study- RCT and Non RCT Observation Study: Cohort , Case control, Cross sectional Clinical trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	12 Hrs
Unit-III Clinical Trial Documentation- Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety monitoring in CT Adverse Drug Reactions: definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions ; terminologies of ADR	12 Hrs
Unit-IV Basic aspects, terminologies and establishment of Pharmacovigilance History and progress of Pharmacovigilance, Significant of safety	12 Hrs

SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY



RULES & SYLLABUS

**DOCTOR OF PHARMACY (PHARM.D) COURSE
&
DOCTOR OF PHARMACY -POST BACCALAUREATE
(PHARM.D-PB) COURSE**

(EFFECTIVE FROM ACADEMIC YEAR 2019-2020)

b) Pharm.D. (Post Baccalaureate) Course -

A pass in B.Pharm from an institution approved by the Pharmacy Council of India under section 12 of the Pharmacy Act:

Provided that there shall be reservation of seats for the students belonging to the Scheduled Castes, Scheduled Tribes and other Backward Classes in accordance with the instructions issued by the Central Government/State Government/Union Territory Administration as the case may be from time to time.

5. Number of admissions in the above said programmes shall be as prescribed by the Pharmacy Council of India from time to time and presently be restricted as below –
 - i) Pharm.D. Programme – 30 students.
 - ii) Pharm.D. (Post Baccalaureate) Programme – 10 students.
6. Institutions running B.Pharm programme approved under section 12 of the Pharmacy Act, will only be permitted to run Pharm.D. programme. Pharm.D. (Post Baccalaureate) programme will be permitted only in those institutions which are permitted to run Pharm.D. programme.
7. Course of study. – The course of study for Pharm.D. shall include the subjects as given in the Tables below. The number of hours in a week, devoted to each subject for its teaching in theory, practical and tutorial shall not be less than that noted against it in columns (3), (4) and (5) below.

TABLES

First Year :

S.No.	Name of Subject	No. of hours of Theory	No. of hours of Practical	No. of hours of Tutorial
(1)	(2)	(3)	(4)	(5)
1.1	Human Anatomy and Physiology	3	3	1
1.2	Pharmaceutics	2	3	1
1.3	Medicinal Biochemistry	3	3	1
1.4	Pharmaceutical Organic Chemistry	3	3	1
1.5	Pharmaceutical Inorganic Chemistry	2	3	1
1.6	Remedial Mathematics/ Biology	3	3*	1
	Total hours	16	18	6 = (40)

* For Biology

- 10 Nervous system (08)
- Definition and classification of nervous system
 - Anatomy, physiology and functional areas of cerebrum
 - Anatomy and physiology of cerebellum
 - Anatomy and physiology of mid brain
 - Thalamus, hypothalamus and Basal Ganglia
 - Spinal cord: Structure & reflexes – mono-poly-planter
 - Cranial nerves – names and functions
 - ANS – Anatomy & functions of sympathetic & parasympathetic N.S.
- 11 Urinary system (03)
- Anatomy and physiology of urinary system
 - Formation of urine
 - Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
 - Clearance tests and micturition
- 12 Endocrine system (07)
- Pituitary gland
 - Adrenal gland
 - Thyroid and Parathyroid glands
 - Pancreas and gonads
- 13 Reproductive system (07)
- Male and female reproductive system
 - Their hormones – Physiology of menstruation
 - Spermatogenesis & Oogenesis
 - Sex determination (genetic basis)
 - Pregnancy and maintenance and parturition
 - Contraceptive devices
- 14 Sense organs (06)
- Eye
 - Ear
 - Skin
 - Tongue & Nose
- 15 Skeletal muscles (05)
- Histology
 - Physiology of Muscle contraction
 - Physiological properties of skeletal muscle and their disorders (definitions)
- 16 Sports physiology (04)
- Muscles in exercise, Effect of athletic training on muscles and muscle performance,
 - Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
 - Drugs and athletics

(e) Digestive system.

(f) Urinary system.

(g) Nervous system.

(h) Special senses.

(i) Reproductive system.

10. Study of different family planning appliances.

11. To perform pregnancy diagnosis test.

12. Study of appliances used in experimental physiology.

13. To record simple muscle curve using gastrocnemius sciatic nerve preparation.

14. To record simple summation curve using gastrocnemius sciatic nerve preparation.

15. To record simple effect of temperature using gastrocnemius sciatic nerve preparation.

16. To record simple effect of load & after load using gastrocnemius sciatic nerve preparation.

17. To record simple fatigue curve using gastrocnemius sciatic nerve preparation.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

1.2 PHARMACEUTICS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope and objectives:** This course is designed to impart a fundamental knowledge on the art and science of formulating different dosage forms. It prepares the students for most basics of the applied field of pharmacy.
2. **Upon the completion of the course the student should be able to:**
 - a. know the formulation aspects of different dosage forms;
 - b. do different pharmaceutical calculation involved in formulation;
 - c. formulate different types of dosage forms; and
 - d. appreciate the importance of good formulation for effectiveness.

3. Course material

- s: Text books**
- a. Cooper and Gunns Dispensing for pharmacy students.
 - b. A text book Professional Pharmacy by N.K.Jain and S.N.Sharma.

Reference books

- a. Introduction to Pharmaceutical dosage forms by Howard C. Ansel.
- b. Remington's Pharmaceutical Sciences.
- c. Register of General Pharmacy by Cooper and Gunn.
- d. General Pharmacy by M.L.Schroff.

4. Lecture wise programme:

Toples

- 1 a. Introduction to dosage forms - classification and definitions
- b. Prescription: definition, parts and handling (06)
- c. Posology: Definition, Factors affecting dose selection. Calculation of children and infant doses.
- 2 Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief. (02)
- 3 Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary. (04)
- 4 Weights and measures, Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc. (04)
- 5 Powders and Granules: Classification advantages and disadvantages, Preparation of simple, compound powders, Insufflations, Dusting powders, Eutectic and Explosive powders, Tooth powder and effervescent powders and granules. (06)
- 6 Monophasic Dosage forms: Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavours with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions. (06)

4. **Pharmacology of drugs acting on Central Nervous System** (14)
- General anesthetics
 - Sedatives and hypnotics
 - Anticonvulsants
 - Analgesic and anti-inflammatory agents
 - Psychotropic drugs*
 - Alcohol and methyl alcohol
 - CNS stimulants and cognition enhancers
 - Pharmacology of local anaesthetics
5. **Pharmacology of Drugs acting on Respiratory tract** (08)
- Bronchodilators
 - Mucolytics
 - Expectorants
 - Antitussives
 - Nasal Decongestants
6. **Pharmacology of Hormones and Hormone antagonists** (10)
- Thyroid and Antithyroid drugs
 - Insulin, Insulin analogues and oral hypoglycemic agents
 - Sex hormones and oral contraceptives
 - Oxytocin and other stimulants and relaxants
7. **Pharmacology of autocooids and their antagonists** (08)
- Histamines and Antihistaminics
 - 5-Hydroxytryptamine and its antagonists
 - Lipid derived autocooids and platelet activating factor

2.4 PHARMACOLOGY – I (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

- Introduction to commonly used instruments in experimental pharmacology.
- Care and handling of common laboratory animals, animal welfare and introduction of CPCSEA and its guidelines, OECD guidelines.
- Introduction to animal physiology with their biochemical reference values in various Animal species.
- Study of various routes of drug administration
- Study of various anesthetics employed to anesthetize laboratory animals.
- Introduction to the techniques of Euthanasia
- Study of physiological salt solutions, drug solution and use of molar solution in various animal experiments.
- Study of various methods for collection of blood, body fluids and urine from Experimental animals.
- Computer simulations of following experiments through computerized simulated Software programme using software such as Ex-Pharm, X-cology etc.

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases

Title of the topic

- | | | |
|---|--|--------------|
| 1 | Cardiovascular system: Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, , Hyperlipidaemias , Electrophysiology of heart and Arrhythmias | (36) |
| 2 | Respiratory system : Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system : Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis | (14)
(24) |
| 3 | General prescribing guidelines for
a. Paediatric patients
b. Geriatric patients
c. Pregnancy and breast feeding | (06) |
| 4 | Ophthalmology: Glaucoma, Conjunctivitis- viral & bacterial | (08) |
| 5 | Introduction to rational drug use
Definition, Role of pharmacist Essential drug concept Rational drug formulations | (02) |

2.6 PHARMACOTHERAPEUTICS - I (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

2.6 PHARMACOTHERAPEUTICS - I (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. summarise the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. discuss the controversies in drug therapy;
 - i. discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication.
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange.

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication.
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication.
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication.
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

2.5 COMMUNITY PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, Community Pharmacists are expected to offer various pharmaceutical care services. In order to meet this demand, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling, health screening services for improved patient care in the community set up.
2. **Objectives:** Upon completion of the course, the student shall be able to–
 - a. know pharmaceutical care services;
 - b. know the business and professional practice management skills in community pharmacies;
 - c. do patient counselling & provide health screening services to public in community pharmacy;
 - d. respond to minor ailments and provide appropriate medication;
 - e. show empathy and sympathy to patients; and
 - f. appreciate the concept of Rational drug therapy.

Text Books:

- a. Health Education and Community Pharmacy by N.S.Parmar.
- b. WHO consultative group report.
- c. Drug store & Business management by Mohammed Ali & Jyoti.

Reference books:

- a. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.
- b. Comprehensive Pharmacy Review – Edt. Leon Shargel. Lippincott Williams & Wilkins.

Special requirements:

1. Either the college is having model community pharmacy (meeting the schedule N requirement) or sign MoU with at least 4-5 community pharmacies nearby to the college for training the students on dispensing and counselling activities.
2. Special equipments like B.P apparatus, Glucometer, Peak flow meter, and apparatus for cholesterol estimation.

3. Scheme of evaluation (80 Marks)

1. Synopsis	10
2. Major Experiment (Counselling of patients with specific diseases – emphasis should be given on Counselling introduction, content, process and conclusion)	30
3. Minor Experiment (Ability to measure B.P/ CBG / Lung function)	15
4. Prescription Analysis (Analyzing the prescriptions for probable drug interaction and ability to tell the management)	15
5. Viva – Voce	10

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

1. **Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time-course of clinical and laboratory indices of therapeutic response and adverse effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

1. **Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis (40)
2. **Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus. (15)
3. **Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders (15)

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancerchemotherapeutic agents, Chemotherapy of breast cancer, leukemia. (12)
Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo (08)

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal, B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise

schedule: Title of the topic

1. **Pharmaceutical Legislations – A brief review.** (04)
2. **Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.** (04)
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.** (12)
Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
Sales, Import, labeling and packaging of Drugs And Cosmetics Provisions Relating to Indigenous Systems.
Constitution and Functions of DTAB, DCC, CDL.
Qualification and duties - Govt. analyst and Drugs Inspector.