

## **BP 106RBT.REMEDIAL BIOLOGY (Theory)**

**30 hours**

**Scope:** To learn and understand the components of living world, structure and functional system of plant and animal kingdom.

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

- know the classification and salient features of five kingdoms of life
- understand the basic components of anatomy & physiology of plant
- know understand the basic components of anatomy & physiology animal with special reference to human

### **COURSE CONTENT**

#### **UNIT I**

##### **Living world:**

- Definition and characters of living organisms
- Diversity in the living world
- Binomial nomenclature
- Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus,

**07 Hours**

##### **Morphology of Flowering plants**

- Morphology of different parts of flowering plants – Root, stem, inflorescence, flower, leaf, fruit, seed.
- General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidons.

#### **UNIT II**

##### **Body fluids and circulation**

- Composition of blood, blood groups, coagulation of blood
- Composition and functions of lymph
- Human circulatory system
- Structure of human heart and blood vessels
- Cardiac cycle, cardiac output and ECG

##### **Digestion and Absorption**

- Human alimentary canal and digestive glands
- Role of digestive enzymes
- Digestion, absorption and assimilation of digested food

**07 Hours**

##### **Breathing and respiration**

- Human respiratory system
- Mechanism of breathing and its regulation
- Exchange of gases, transport of gases and regulation of respiration
- Respiratory volumes

#### **UNIT III**

##### **Excretory products and their elimination**

- Modes of excretion

**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

## **BP112RBP.REMEDIAL BIOLOGY (Practical)**

**2 Hours/week**

1. Introduction to experiments in biology
  - a) Study of Microscope
  - b) Section cutting techniques
  - c) Mounting and staining
  - d) Permanent slide preparation
2. Study of cell and its inclusions
3. Study of Stem, Root, Leaf, seed, fruit, flower and their modifications
4. Detailed study of frog by using computer models
5. Microscopic study and identification of tissues pertinent to Stem, Root  
Leaf, seed, fruit and flower
6. Identification of bones
7. Determination of blood group
8. Determination of blood pressure
9. Determination of tidal volume

### **Reference Books**

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi

BP 201T. HUMAN ANATOMY AND PHYSIOLOGY-II (Theory) **45 Hours**

**Scope:** This subject is designed to impart fundamental knowledge on the structure and functions of the various systems of the human body. It also helps in understanding both homeostatic mechanisms. The subject provides the basic knowledge required to understand the various disciplines of pharmacy.

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

1. Explain the gross morphology, structure and functions of various organs of the human body.
2. Describe the various homeostatic mechanisms and their imbalances.
3. Identify the various tissues and organs of different systems of human body.
4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc. and also record blood pressure, heart rate, pulse and respiratory volume.
5. Appreciate coordinated working pattern of different organs of each system
6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body.

**Course Content:**

<b>Unit-I</b>	<b>Nervous system</b>	<b>10 hours</b>
	Organization of nervous system, neuron, neuroglia, classification and properties of nerve fiber, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum), spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity)	
<b>Unit -II</b>	<b>Digestive system</b>	<b>08hours</b>
	Anatomy of GI Tract with special reference to anatomy and functions of stomach, ( Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, anatomy and functions of salivary glands, pancreas and liver, movements of GIT, digestion and absorption of nutrients and disorders of GIT. <b>Energetics:</b> Formation and role of ATP, Creatinine Phosphate and BMR.	
<b>Unit-III</b>		<b>10 hours</b>
	<b>Respiratory system</b>	<b>6 hours</b>
	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**

**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.

9. Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA
10. Text book of Medical Physiology- Arthur C, Guyton and John. E. Hall. Miamisburg, OH, U.S.A.
11. Human Physiology (vol 1 and 2) by Dr. C.C. Chatterrje ,Academic Publishers Kolkata

### **BP 207 P. HUMAN ANATOMY AND PHYSIOLOGY (Practical)**

#### **4 Hours/week**

Practical physiology is complimentary to the theoretical discussions in physiology. Practicals allow the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals or normal human beings. This is helpful for developing an insight on the subject.

1. To study the integumentary and special senses using specimen, models, etc.,
2. To determine the Platelet count.
3. To perform the differential leukocyte count (DLC).
4. To determine the Arneth index.
5. Determination of osmotic fragility of RBCs.
6. To study the nervous system using specimen, models, etc.,
7. To study the endocrine system using specimen, models, etc
8. To demonstrate the general neurological examination
9. To demonstrate the function of olfactory nerve
10. To examine the different types of taste.
11. To demonstrate the visual acuity
12. To demonstrate the reflex activity
13. Recording of body temperature
14. To demonstrate positive and negative feedback mechanism.
15. Determination of tidal volume and vital capacity.
16. Study of Digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens.
17. Recording of basal mass index.
18. Study of familyplanning devices and pregnancy diagnosis test.

19. Demonstration of total blood count by cell analyzer.
20. Permanent slides of vital organs and gonads.
21. Visit to Hospital/ Pathology Laboratory.

**Recommended Books:**

1. Godkar P.B and Godkar D.P., Textbook of Medical Laboratory Technology. Bhalani Publishing House, Mumbai.
2. Joshi V.D. Practical Physiology. Vora Medical Publications, Mumbai.
3. DiFiore-Mariano S.H., Atlas of Human Histology. Lea and Febiger, Philadelphia.
4. Mukherjee, K.L., Medical Laboratory Technology. Tata McGraw Hill Publishing Company Ltd. New Delhi.
5. Beck, W.S., Human Design: Molecular, Cellular and Systemic Physiology. Harcourt Brace Jovanovich Inc. New York.
6. Chatterjee, C.C., Human Physiology. Medical Allied Agency, Kolkata.
7. Ganong, W.F., Review of Medical Physiology. Prentice-Hall International, London.
8. Guyton, A.C., Textbook of Medical Physiology. W. B. Saunders Co., Philadelphia, USA.
9. Tortora, G.J. and Grabowski, S.R., 2005.
10. Principles of Anatomy and Physiology. Harper Collins College Publishers, New York.
11. Vander, A.J., Sherman, J.H. and Luciano, D.S., Human Physiology. McGraw-Hill Publishing Co., USA.
12. Garg K., Bahel I. and Kaul M., A Textbook of Histology. CBS Publishers and Distributors, New Delhi.
13. Practical workbook of Human Physiology by K. Srinageswari and Rajeev Sharma, Jaypee Brother's medical publishers, New Delhi.

## T.Y.B.PHARM SEMESTER – V

### **BP501T. MEDICINAL CHEMISTRY – II (Theory)**

**45 Hours**

#### **Scope:**

This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasizes on structure activity relationships of drugs, importance of physicochemical properties and metabolism of drugs. The syllabus also emphasizes on chemical synthesis of important drugs under each class.

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

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship of different class of drugs
4. Study the chemical synthesis of selected drugs

#### **Course Content:**

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs mentioned in bracket [ ] only to be covered.

#### **UNIT- I**

**10 Hours**

#### **Antihistaminic agents and autacoids**

- a) **Antihistaminic agents:** Histamine, receptors and their distribution in the human body
- b) **H<sub>1</sub>-antagonists:** Diphenhydramine hydrochloride, Dimenhydrinate, Doxylamine succinate, Clemastine fumarate, Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride, Phenindamine tartarate, Promethazine hydrochloride, Trimeprazine tartrate, Fexofenadine, Astemizole, Loratadine, Cetirizine, Cromolyn sodium
- c) **H<sub>2</sub>-antagonists:** Cimetidine, Famotidine, Ranitidine
- d) **Gastric Proton pump inhibitors:** Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole



e) **Autacoids:** Prostaglandins, Prostanoids, Leucotriene antagonists

**[Diphenhydramine hydrochloride, Cetirizine, Promethazine hydrochloride, Ranitidine]**

**UNIT – II**

**10 Hours**

**Drugs acting on Cardiovascular system**

a) **Anti-anginals:**

**Vasodilators:** Amyl nitrite, Nitroglycerin, Pentaerythritol tetranitrate, Isosorbide dinitrite, Dipyridamole.

**Calcium channel blockers:** Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine.

b) **Diuretics:**

**Carbonic anhydrase inhibitors:** Acetazolamide, Methazolamide, Dichlorphenamide.

**Thiazides:** Chlorthiazide, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide

**Loop diuretics:** Furosemide, Bumetanide, Ethacrynic acid.

**Potassium sparing Diuretics:** Spironolactone, Triamterene, Amiloride.

**Osmotic Diuretics:** Mannitol

c) **Anti-hypertensive Agents:**

**$\alpha$  blockers-** Prazosin, Terazosin

**$\beta$  blockers-** Propranolol, Timolol, Atenolol

**ACE inhibitors-** Captopril, Lisinopril, Enalapril, Quinapril hydrochloride

**Angiotensin II receptor antagonists-** Losartan, Telmisartan, Valsartan

**Misc.class-** Methyldopate hydrochloride, Clonidine hydrochloride, Guanethidine monosulphate, Reserpine, Hydralazine hydrochloride.

**[Isosorbide dinitrite, Nifedipine, Chlorthiazide, Furosemide, Lisinopril, Atenolol]**

### 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, Lorcainide 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, Glimperide.

**Biguanides:** Metformin.

**Meglitinides:** Repaglinide, Nateglinide.

**Glucosidase inhibitors:** Acarbose, Voglibose.

**DPP IV inhibitors** -Sitagliptin, Teneligliptin

**SGLT2 inhibitors** – Empagliflozin, Canagliflozin

b) **Local Anesthetics:** SAR of Local anesthetics

**Benzoic Acid derivatives;** Meprylcaine, Cyclomethycaine, Piperocaine.

**Amino Benzoic acid derivatives:** Benzocaine, Procaine, Butacaine, Propoxycaine, Tetracaine.

**Lidocaine/Anilide derivatives:** Lignocaine, Mepivacaine, Prilocaine, Etidocaine.

**Miscellaneous:** Phenacaine

**[Tolbutamide, Benzocaine]**

#### **Recommended Books (Latest Editions)**

1. Wilson and Giswold's Organic medicinal and Pharmaceutical Chemistry.
2. Foye's Principles of Medicinal Chemistry.
3. Graham L. Patrick's An Introduction to Medicinal Chemistry
4. Burger's Medicinal Chemistry, Vol I to IV.
5. Introduction to principles of drug design- Smith and Williams.
6. Remington's Pharmaceutical Sciences.
7. Martindale's extra pharmacopoeia.
8. Organic Chemistry by I.L. Finar, Vol. II.
9. The Organic Chemistry of Drug Synthesis by Lednicer, Vol. 1 to 5.
10. Indian Pharmacopoeia.
11. Text book of practical organic chemistry-A.I.Vogel.

#### **BP 502 T. Industrial Pharmacy I (Theory)**

**45 Hours**

#### **Scope:**

Course enables the student to understand and appreciate the influence of pharmaceutical additives and various pharmaceutical dosage forms on the performance of the drug product.

### **Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

### **BP503.T. PHARMACOLOGY-II (Theory)**

**45 Hours**

#### **Scope:**

This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on different systems of body and in addition, emphasis on the basic concepts of bioassay.

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

1. Understand the mechanism of drug action and its relevance in the treatment of different diseases

2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
3. Demonstrate the various receptor actions using isolated tissue preparation
4. Appreciate correlation of pharmacology with related medical sciences

**Course Content:**

**UNIT-I**

**10hr**

**Pharmacology of drugs acting on cardiovascular system**

- a. Introduction to hemodynamic and electrophysiology of heart.
- b. Drugs used in congestive heart failure
- c. Anti-hypertensive drugs.
- d. Anti-anginal drugs.
- e. Anti-arrhythmic drugs.
- f. Anti-hyperlipidemic drugs.

**UNIT-II**

**Pharmacology of drugs acting on cardiovascular system**

**10hr**

- a. Drug used in the therapy of shock.
- b. Hematinics, coagulants and anticoagulants.
- c. Fibrinolytics and anti-platelet drugs
- d. Plasma volume expanders

**Pharmacology of drugs acting on urinary system**

- a. Diuretics
- b. Anti-diuretics.

**UNIT-III**

**Autocoids and related drugs**

**10hr**

- a. Introduction to autacoids and classification
- b. Histamine, 5-HT and their antagonists.
- c. Prostaglandins, Thromboxanes and Leucotrienes
- d. Angiotensin, Bradykinin and Substance P.
- e. Non-steroidal anti-inflammatory agents
- f. Anti-gout drugs
- g. Antirheumatic drugs

## **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

**Volatile oils:** Mentha, Clove, Cinnamon, Fennel, Coriander,

**Tannins:** Catechu, Pterocarpus

**Resins:** Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony

**Glycosides:** Senna, Aloes, Bitter Almond

**Iridoids, Other terpenoids & Naphthaquinones:** Gentian, Artemisia, taxus, carotenoids

### **UNIT-III**

**06 Hours**

#### **Isolation, Identification and Analysis of Phytoconstituents**

- a) Terpenoids: Menthol, Citral, Artemisin
- b) Glycosides: Glycyrrhetic acid & Rutin
- c) Alkaloids: Atropine, Quinine, Reserpine, Caffeine
- d) Resins: Podophyllotoxin, Curcumin

### **UNIT-IV**

**06 Hours**

Industrial production, estimation and utilization of the following phytoconstituents:

Forskolin, Sennoside, Artemisinin, Diosgenin, Digoxin, Atropine, Podophyllotoxin, Caffeine, Taxol, Vincristine and Vinblastine

### **UNIT V**

**12 Hours**

#### **Basics of Phytochemistry**

Methods of extraction (Soxhlet, Maceration, Percolation, Supercritical fluid extraction, Microwave assisted extraction, Ultrasound assisted extraction, Solid Phase Extraction)

Application of latest techniques like Spectroscopy, Chromatography and electrophoresis in the isolation, purification and identification of crude drugs

**Non-chromatographic separation techniques:** Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth floatation technique.

### **BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)**

**45 Hours**

#### **Scope:**

This course is designed to impart basic knowledge on important legislations related to the profession of pharmacy in India.

**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-III

10 Hours

**Pharmacy Act –1948:** Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and 122 Penalties

**Medicinal and Toilet Preparation Act –1955:** Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.

**Narcotic Drugs and Psychotropic substances Act-1985 and Rules:** Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

### UNIT-IV

08 Hours

**Study of Salient Features of Drugs and Magic Remedies Act and its rules:** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties

**Prevention of Cruelty to animals Act-1960:** Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties

**National Pharmaceutical Pricing Authority:** Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

## **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

6. Preparation of Calcium Gluconate injection
7. Preparation of Ascorbic Acid injection
8. Quality control test of (as per IP) marketed tablets and capsules
9. Preparation of Eye drops/ and Eye ointments
10. Preparation of Creams (cold / vanishing cream)
11. Evaluation of Glass containers (as per IP)

**Recommended Books: (Latest Editions)**

1. Pharmaceutical dosage forms - Tablets, volume 1 -3 by H.A. Liberman, Leon Lachman & J.B. Schwartz
2. Pharmaceutical dosage form - Parenteral medication vol- 1&2 by Liberman & Lachman
3. Pharmaceutical dosage form disperse system VOL-1 by Liberman & Lachman
4. Modern Pharmaceutics by Gilbert S. Banker & C.T. Rhodes, 3rd Edition
5. Remington: The Science and Practice of Pharmacy, 20th edition Pharmaceutical Science (RPS)
6. Theory and Practice of Industrial Pharmacy by Liberman & Lachman
7. Pharmaceutics- The science of dosage form design by M.E. Aulton, Churchill livingstone, Latest edition
8. Introduction to Pharmaceutical Dosage Forms by H. C. Ansel, Lea & Febiger, Philadelphia, 5th edition, 2005
9. Drug stability - Principles and practice by Cartensen & C.J. Rhodes, 3rd Edition, Marcel Dekker Series, Vol 107.

**BP 507 P. PHARMACOLOGY-II (Practical)**

**4Hrs/Week**

**Sr. No Experiment**

1. Introduction to in-vitro pharmacology and physiological salt solutions.
2. Effect of drugs on isolated frog heart.
3. Effect of drugs on blood pressure and heart rate of dog.
4. Study of diuretic activity of drugs using rats/mice.
5. DRC of acetylcholine using frog rectus abdominis muscle.
6. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus

**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**

<b>Unit-I</b>	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	<b>12 Hrs</b>
<b>Unit -II</b>	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.	<b>12 Hrs</b>
<b>Unit-III</b>	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	<b>12 Hrs</b>
<b>Unit-IV</b>	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.	<b>12 Hrs</b>
<b>Unit-V</b>	Toxicokinetics – Toxicokinetic evaluation in preclinical studies, saturation kinetics. Importance and applications of toxicokinetic studies. Alternative methods to animal toxicity testing.	<b>12 Hrs</b>

## REFERENCES

1. Hand book on GLP, Quality practices for regulated non-clinical research and development (<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>).
2. Schedule Y Guideline: drugs and cosmetics (second amendment) rules,2005, ministry of health and family welfare (department of health) New Delhi.
3. Drugs from discovery to approval by Rick NG.
4. Animal Models in Toxicology, 3rd Edition, Lower and Bryan.
5. OECD test guidelines.
6. Principles of toxicology by Karen E. Stine, Thomas M. Brown.
7. Guidance for Industry M3(R2) Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals  
(<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073246.pdf>)