



PHARMACY COUNCIL OF INDIA

(Constituted under the Pharmacy Act, 1948)

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Ref. No.14-55/2021-PCI(A) 3642-45

23 SEP 2021

✓ To

- All institutions approved for D.Pharm Course.
- All State Governments (Technical Education and Health Departments) and admission making authorities.
- All Examining Authorities.

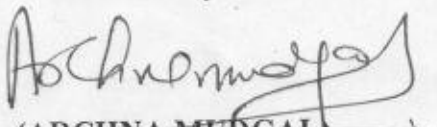
Sub: "Syllabus framed under Regulation 7, List of prescribed equipments and apparatus under Appendix-A of The Education Regulations, 2020 for Diploma Course in Pharmacy."

Sir/Madam

With reference to the subject cited above, it is informed that -

- With due approval of the Ministry of Health and Family Welfare, Government of India, PCI has notified the Education Regulations, 2020 for Diploma course in Pharmacy in the Gazette of India, Extraordinary No. 435, Part-III, Section-4, dt.16.10.2020.
- As empowered under regulation 7 and Appendix-A of ER-20, the PCI has framed the syllabus. A copy of the same titled as under is enclosed as **Annexure-I**.
"Syllabus framed under Regulation 7, List of prescribed equipments and apparatus under Appendix-A of The Education Regulations, 2020 for Diploma Course in Pharmacy."
- It is for implementation and strict compliance from 2021-2022 academic session.

Yours faithfully


(ARCHANA MUDGAL)
Registrar-cum-Secretary



SATHYABAMA

INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)

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School of Pharmacy

Diploma in Pharmacy

Syllabus(ER91)

**PROGRAMME : D.PHARMACY
CURRICULUM**

First Year										
S. NO	Course Type	Course code	Course Title	L	T	P	C	Marks		Page No.
								CAE	ESE	
1	Theory	101T	Pharmaceutics -I	3	0	0	3	20	80	3
2	Theory	102T	Pharmaceutical Chemistry-I	3	0	0	3	20	80	5
3	Theory	103T	Pharmacognosy	3	0	0	3	20	80	6
4	Theory	104T	Biochemistry & Clinical Pathology	2	0	0	2	20	80	8
5	Theory	105T	Human Anatomy and Physiology	3	0	0	3	20	80	9
6	Theory	106T	Health Education & Community Pharmacy	2	0	0	2	20	80	10
7	Practical	107P	Pharmaceutics –I	0	0	4	2	20	80	11
8	Practical	108P	Pharmaceutical Chemistry-I	0	0	3	1	20	80	11
9	Practical	109P	Pharmacognosy	0	0	3	1	20	80	12
10	Practical	110P	Biochemistry & Clinical Pathology	0	0	3	1	20	80	12
11	Practical	111P	Human Anatomy and Physiology	0	0	2	1	20	80	12
Total Credits for First Year 1 -22										
Total Marks for First Year 1 -1100										

L - LECTURE HOURS, T – TUTORIAL HOURS, P – PRACTICAL HOURS, C – CREDITS

CAE – CONTINUOUS ASSESSMENT EXAMINATION, ESE – END SEMESTER EXAMINATION

CURRICULUM

Second Year										
S. NO	Course Type	Course code	Course Title	L	T	P	C	Marks		Page No.
								CAE	ESE	
1	Theory	201T	Pharmaceutics -I I	3	0	0	3	20	80	13
2	Theory	202T	Pharmaceutical Chemistry-II	4	0	0	4	20	80	14
3	Theory	203T	Pharmacology & Toxicology	3	0	0	3	20	80	16
4	Theory	204T	Pharmaceutical Jurisprudence	2	0	0	2	20	80	18
5	Theory	205T	Drug store and Business Management	3	0	0	3	20	80	19
6	Theory	206T	Hospital & Clinical Pharmacy	2	0	0	2	20	80	20
7	Practical	207P	Pharmaceutics –II	0	0	4	2	20	80	21
8	Practical	208P	Pharmaceutical Chemistry-II	0	0	3	1	20	80	22
9	Practical	209P	Pharmacology & Toxicology	0	0	2	1	20	80	22
10	Practical	210P	Hospital & Clinical Pharmacy	0	0	2	1	20	80	22
Total Credits for Second Year 1 -22										
Total Marks for Second Year 1 -1000										

L - LECTURE HOURS, T – TUTORIAL HOURS, P – PRACTICAL HOURS, C – CREDITS

CAE – CONTINUOUS ASSESSMENT EXAMINATION, ESE – END SEMESTER EXAMINATION

101T	PHARMACEUTICS- I	L	T	P	Credits	Total Marks
		3	0	0	3	100

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

Introduction of different dosage forms. Their classification with examples-their relative applications. Familiarization with new drug delivery systems. Introduction to Pharmacopoeias with special reference to the Indian Pharmacopoeia.

Metrology-System of weights and measures. Calculations including conversion from one to another system. Percentage calculations and adjustment of products .Use of alligation method in calculations
.Isotonic solutions.

Packaging of pharmaceuticals-Desirable features of a container and types of containers. Study of glass & plastics as materials for containers and rubber as a material for closure-their merits and demerits. Introduction to aerosol packaging.
Size reduction, objectives, and factors affecting size reduction, methods of size reduction- study of Hammer mill, ball mill, Fluid energy mill and Disintegrator.

Size separation-size separation by sifting. Official standards for powders. Sedimentation methods of size separation. Construction and working of Cyclone separator.

Mixing and Homogenization-Liquid mixing and powder mixing, Mixing of semisolids. Study of silverson Mixer-Homogenizer, planetary Mixer; Agitated powder mixer; Triple Roller Mill; Propeller Mixer, colloid Mill and Hand Homogeniser. Double cone mixer.

Clarification and Filtration-Theory of filtration, Filter media; Filter aids and selection of filters. Study of the following filtration equipments-Filter Press, sintered filters, Filter candles, Metafilter.

Extraction and Galenicals-

(a) Study of percolation and maceration and their modification, continuous hot extraction-
Application in the preparation of tinctures and extracts.

(b) Introduction to Ayurvedic dosage forms.

Heat process-Evaporation-Definition-Factors affecting evaporation-study of evaporating still and Evaporating pan.

Distillation-Simple distillation and Fractional distillation, steam distillation and vacuum distillation. Study of vacuum still, preparation of purified water I.P. and water for Injection I.P. construction and working of the still used for the same.

Introduction to drying process-Study of Tray Dryers; Fluidized Bed Dryer, Vacuum Dryer and Freeze Dryer.

Sterilization-Concept of sterilization and its differences from disinfection-Thermal resistance of microorganisms. Detailed study of the following sterilization process.

Sterilization with moist heat, Dry heat sterilization, Sterilization by radiation, Sterilization by filtration and Gaseous sterilization.

Aseptic techniques-Applications of sterilization process in hospitals particularly with reference to surgical dressings and intravenous fluids. Precautions for safe and effective handling of sterilization equipment.

Processing of Tablets-Definition; different type of compressed tables and their properties. Processes involved in the production of tablets; Tablets excipients ; Defects in tablets; Evaluation of Tablets; Physical standards including Disintegration and Dissolution. Tablet coating-sugar coating; films coating, enteric coating and micro-encapsulation (Tablet coating may be de.. in an elementary manner).

Processing of Capsules-Hard and soft gelatin capsules; different sizes of capsules; filling of capsules; handling and storage of capsules. Special applications of capsules.

Study of immunological products like sera, vaccines, toxoids & their preparations.

Books recommended:(Latest editions)

1. Remington's Pharmaceutical
2. Indian Pharmacopoeia
3. Tutorial Pharmacy by Cooper Gunns

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Each question carry 16 marks answer any five out of eight
(question may contain subdivisions)

Exam Duration: 3 Hrs.

80 Marks

102T	PHARMACEUTICAL CHEMISTRY-I	L	T	P	Credits	Total Marks
		3	0	0	3	100

Scope: This subject deals with the monographs of inorganic drugs and pharmaceuticals.

Objectives: Upon completion of course student shall be able to

- know the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals
- understand the medicinal and pharmaceutical importance of inorganic compounds

Course Content

General discussion on the following inorganic compounds including important physical and chemical properties, medicinal and pharmaceutical uses, storage conditions and chemical incompatibility.

Acids, bases and buffers- Boric acid, Hydrochloric acid, Strong Ammonium hydroxide, Sodium hydroxide and official buffers.

Antioxidants- Hypophosphorous acid, Sulphur dioxide, Sodium bisulphite, Sodium meta-bisulphite, Sodium thiosulphate, Nitrogen and Sodium nitrite.

Gastrointestinal agents-

Acidifying agents- Dilute Hydrochloric acid.

Antacids- Sodium bicarbonate, Aluminum hydroxide gel, Aluminum phosphate, Calcium carbonate, Magnesium carbonate, Magnesium trisilicate, Magnesium oxide, Combinations of antacid preparations.

Protective and Adsorbents- Bismuth sub carbonate and Kaolin.

Saline cathartics- Sodium potassium tartrate and Magnesium sulphate.

Topical Agents-

Protective- Talc, Zinc Oxide, Calamine, Zinc stearate, Titanium dioxide, silicone polymers.

Antimicrobials and Astringents- Hydrogen peroxide*, Potassium permanganate, Chlorinated lime, Iodine, Solutions of Iodine, Povidone-iodine, Boric acid, Borax, Silver nitrate, Mild silver protein, Mercury yellow, Mercuric oxide, Ammoniated mercury.

Sulphur and its compounds- Sublimed sulphur, Percipitated sulphur, Selenium sulphide. Astringents- Alum and Zinc Sulphate.

Dental Products- Sodium fluoride, Stannous fluoride, Calcium carbonate, Sodium meta phosphate, Di- calcium phosphate, Strontium chloride, Zinc chloride.

Inhalants- Oxygen, Carbon dioxide, Nitrous oxide.

Respiratory stimulants- Ammonium carbonate.

Expectorants and Emetics- Ammonium chloride*, Potassium iodide, Antimony potassium tartrate.

Antidotes- Sodium nitrite.

Major Intra and Extra cellular electrolytes-

Electrolytes used for replacement therapy- Sodium chloride and its preparations, Potassium chloride and its preparations.

Physiological acid-base balance and electrolytes used- Sodium acetate, Potassium Acetate, Sodium bicarbonate Inj., Sodium citrate, Potassium citrate, Sodium lactate injection, Ammonium chloride and its injection.

Combination of oral electrolyte powders and solutions.

Inorganic official compounds of Iron, Iodine and Calcium, Ferrous Sulphate and Calcium Gluconate.

Radio pharmaceuticals and contrast media- Radio activity-Alpha; Beta and Gamma Radiations, Biological effects of radiations, Measurement of radio activity, G.M. Counter, Radio isotopes-their uses, Storage and precautions with special reference to the official preparations. Radio opaque contrast media- Barium sulfate.

Quality control of Drugs and pharmaceuticals-Importance of quality control, significant errors, methods used for quality control, sources of impurities in pharmaceuticals. Limit tests for Arsenic, Chloride, Sulfate, Iron and Heavy metals.

Identification tests for cations and anions as per Indian Pharmacopoeia.

Books recommended:(Latest editions)

1. Indian Pharmacopoeia
2. Text Book of Pharmaceutical Inorganic Chemistry by V.N.Rajasekaran
3. Text Book of Pharmaceutical Inorganic Chemistry by Gundu Rao

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Each question carry 16 marks answer any five out of eight may contain subdivisions)

Exam Duration: 3 Hrs.

80 Marks (question

103T	PHARMACOGNOSY	L	T	P	Credits	Total Marks
		3	0	0	3	100

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

1. Definition, history and scope of Pharmacogonosy including indigenous system of medicine.
2. Various systems of classification of drugs and natural origin.
3. Adulteration and drug evaluation; significance of pharmacopoeial standards.
4. Brief outline of occurrence, distribution, outline of isolation, identification tests, therapeutic effects and pharmaceutical application of alkaloids, terpenoids, glycosides, volatile oils, tannins and resins.
5. Occurrence, distribution, organoleptic evaluation, chemical constituents including tests

wherever applicable and therapeutic efficacy of following categories of drugs.

- (a) **Laxatives**- Aloes, Rhubarb, Castor oil, Ispaghula, Senna.
- (b) **Cardiotonics**- Digitalis, Arjuna.
- (c) **Carminatives & G.I. regulators**- Umbelliferous fruits, Coriander, Fennel, Ajowan, Cardamom, Ginger, Black pepper, Asafoetida, Nutmeg, Cinnamon, Clove.
- (d) **Astringents**- Catechu.
- (e) **Drugs acting on nervous system**- Hyoscyamus, Belladonna, Aconite, Ashwagandha, Ephedra, Opium, Cannabis, Nux-vomica.
- (f) **Antihypertensive**- Rauwolfia.
- (g) **Antitussives**- Vasaka, Tolu balsam, Tulsi.
- (h) **Antirheumatics**- Guggal, Colchicum.
- (i) **Antitumour**- Vinca.
- (j) **Antileprotics**- Chaulmoogra oil.
- (k) **Antidiabetics**- Pterocarpus, Gymnema sylvestre.
- (l) **Diuretics**- Gokhru, Punarnava.
- (m) **Antidysenterics**- Ipecacuanha.
- (n) **Antiseptics and disinfectants**- Benzoin, Myrrh, Neem, Curcuma.
- (o) **Antimalarials**- Cinchona.
- (p) **Oxytocics**- Ergot.
- (q) **Vitamins**- Shark liver oil and Amla.
- (r) **Enzymes**- Papaya, Diastase, Yeast.
- (s) **Perfumes and flavoring agents**- peppermint oil, Lemon oil, Orange oil, lemon grass oil, sandal wood.

Pharmaceutical aids-Honey, Arachis oil, starch, kaolin, pectin, olive oil. Lanolin, Beeswax, Acacia, Tragacanth, sodium Alginate, Agar, Guar gum, Gelatin.

Miscellaneous- Liquorice, Garlic, picrorhiza, Dirscoria, Linseed, shatavari, shankhpushpi, pyrethrum, Tobacco.

Collection and preparation of crude drugs for the market as exemplified by Ergot, opium, Rauwolfia, Digitalis, senna.

Study of source, preparation and identification of fibers used in sutures and surgical dressings- cotton, silk, wool and regenerated fibers.

Gross anatomical studies of-senna, Datura, cinnamon, cinchona, fennel, clove, Ginger, Nuxvomica & ipecacuanha.

Books recommended:(Latest editions)

1. Text book of Pharmacognosy by wallis
2. Text book of Pharmacognosy by kokate

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Each question carry 16 marks answer any five out of eight
(question may contain subdivisions)

Exam Duration: 3 Hrs.

80 Marks

104T	BIOCHEMISTRY AND CLINICAL PATHOLOGY	L	T	P	Credits	Total Marks
		2	0	0	2	100

Scope: Biochemistry deals with complete understanding of the molecular levels of the chemical process associated with living cells. The scope of the subject is providing biochemical facts and the principles to understand metabolism of nutrient molecules in physiological and pathological conditions. It is also emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA.

Objectives: Upon completion of course student shall able to

1. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.
2. Understand the metabolism of nutrient molecules in physiological and pathological conditions.
3. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

Course Content

Introduction to biochemistry. Brief chemistry and role of proteins, polypeptides and amino acids, classification, Qualitative tests, Biological value, Deficiency diseases.

Carbohydrates: Brief chemistry and role of carbohydrates, classification, qualitative tests, Diseases related to carbohydrate metabolism.

Lipids: Brief chemistry and role of lipids, classification and qualitative tests. Diseases related to lipids metabolism.

Vitamins: Brief chemistry and role of vitamins and coenzymes. Role of minerals and water in life processes.

Enzymes: Brief concept of enzymatic action. factors affecting it.

Therapeutics: Introduction to pathology of blood and urine. Lymphocytes and platelets, their role in health and disease. Erythrocytes-Abnormal cells and their significance. Abnormal constituents of urine and their significance in diseases.

Books recommended:(Latest editions)

1. Text book of Biochemistry by T.Sathyanarayana
2. Text book of Biochemistry by Ramarao

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Each question carry 16 marks answer any five out of eight
(question may contain subdivisions)

Exam Duration: 3 Hrs.

80 Marks

105T	HUMAN ANATOMY AND PHYSIOLOGY	L	T	P	Credits	Total Marks
		3	0	0	3	100

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.

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

- Explain the gross morphology, structure, and functions of various organs of the human body.
- Describe the various homeostatic mechanisms and their imbalances.
- Identify the various tissues and organs of different systems of human body.
- Perform the various experiments related to special senses and nervous system.
- Appreciate coordinated working pattern of different organs of each system

Course Content

Scope of Anatomy and physiology. Definition of various terms used in Anatomy. Structure of cell, function of its components with special reference to mitochondria and microsomes.

Elementary tissues: Elementary tissues of the body, i.e. epithelial tissue, muscular tissue, connective tissue and nervous tissue.

Skeletal System: Structure and function of Skelton .Classification of joints and their function. Joint disorders.

Cardiovascular System: Composition of blood, functions of blood elements. Blood group and coagulation of blood. Brief information regarding disorders of blood. Name and functions of lymph glands. Structure and functions of various parts of the heart .Arterial and venous system with special reference to the names and positions of main arteries and veins. Blood pressure and its recording. Brief information about cardiovascular disorders.

Respiratory system: Various parts of respiratory system and their functions, physiology of respiration.

Urinary System: Various parts of urinary system and their functions, structure and functions of kidney. Physiology of urine formation. Patho-physiology of renal diseases and edema.

Muscular System: Structure of skeletal muscle, physiology of muscle contraction. Names, positions, attachments and functions of various skeletal muscles. physiology of neuromuscular junction.

Central Nervous System: Various parts of central nervous system, brain and its parts, functions and reflex action. Anatomy and physiology of automatic nervous system.

Sensory Organs: Elementary knowledge of structure and functions of the organs of taste, smell, ear, eye and skin. Physiology of pain

Digestive System: names of various parts of digestive system and their functions. structure and functions of liver, physiology of digestion and absorption.

Endocrine System: Endocrine glands and Hormones. Location of glands, their hormones and functions. pituitary, thyroid. Adrenal and pancreas

Reproductive system: Physiology and Anatomy of Reproductive system.

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Each question carry 16 marks answer any five out of eight
(question may contain subdivisions)

Exam Duration: 3 Hrs.

80 Marks

106T	HEALTH EDUCATION AND COMMUNITY PHARMACY	L	T	P	Credits	Total Marks
		2	0	0	2	100

Concept of health: Definition of physical health, mental health, social health, spiritual health determinants

of health, indicatory of health, concept of disease, natural history of diseases, the disease agents, concept of prevention of diseases.

Nutrition and health: Classification of foods, requirements, diseases induced due to deficiency of proteins, vitamins and minerals-treatment and prevention.

Demography and family planning: Demography cycle, fertility, family planning, contraceptive methods, behavioral methods, natural family planning methods, chemical methods, mechanical methods, hormonal contraceptives, population problem of India.

First aid: Emergency treatment in shock, snake-bite, burns, poisoning, heart disease, fractures and resuscitation methods, Elements of minor surgery and dressings.

Environment and health: Source of water supply, water pollution, purification of water, health and air, noise, light-solid waste disposal and control-medical entomology, arthropod borne diseases and their control. rodents, animals and diseases.

Fundamental principles of microbiology: Classification of microbes, isolation, staining techniques of organisms of common diseases.

Communicable diseases: Causative agents, mode of transmission and prevention. Respiratory infections- chicken pox, measles, influenza, diphtheria, whooping cough and tuberculosis.

Intestinal infection-poliomyelitis, Hepatitis, cholera, Typhoid, food poisoning, Hookworm infection

Arthropod borne infections-plague, Malaria, filariases. **Surface infection-**Rabies, Trachoma, Tetanus, Leprosy. **Sexually transmitted diseases-**Syphilis, Gonorrhoea, AIDS

Non-communicable diseases: causative agents, prevention, care and control.

Epidemiology: Its scope, methods, uses, dynamics of disease transmission. Immunity and immunization: Immunological products and their dose schedule. Principles of disease control and prevention, hospital acquired infection, prevention and control. Disinfection, types of disinfection procedures, for-faces, urine, sputum, room linen, dead-bodies, instruments.

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

Each question carry 16 marks answer any five out of eight
(question may contain subdivisions)

80 Marks

107P	PHARMACEUTICS-I	L	T	P	Credits	Total Marks
		0	0	4	2	100

Preparation (minimum number stated against each of the following categories illustrating different techniques involved.

1. Aromatic waters³
2. Solutions ⁴
3. Spirits²
4. Tinctures⁴
5. Extracts²
6. Creams²
7. Cosmetic preparations³
8. Capsules²
9. Tablets²
10. Preparations involving²
11. Ophthalmic preparations²
12. Preparations involving aseptic techniques²

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

PART A : Synopsis

10 Marks

PART B : Experiments (major and Minor)

60 Marks

PART C: Viva voce & Record

10 Marks

108P	PHARMACEUTICAL CHEMISTRY-I	L	T	P	Credits	Total Marks
		0	0	3	1	100

1. Identification tests for inorganic compounds particularly drugs and pharmaceuticals.
2. Limit test for chloride, Sulfate, Arsenic, Iron and Heavy metals.
3. Assay of inorganic pharmaceuticals involving each of the following methods of compounds marked with (*) under theory.
 - i. Acid-Base titrations(at least 3)
 - ii. Redox titrations (one each of permanganometry and iodimetry).
 - iii. Precipitation titrations (at least 2)
 - iv. Complexometric titration (Calcium and Magnesium).

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

PART A : Synopsis

10 Marks

PART B : Experiments (major and Minor)

60 Marks

PART C: Viva voce & Record

10 Marks

109P	PHARMACOGNOSY	L	T	P	Credits	Total Marks
		0	0	3	1	100

1. Identification of drugs by morphological characters. Physical and chemical tests for evaluation of drugs wherever applicable.
2. Gross anatomical studies(t.s.)of the following drugs :Senna, Datura, cinnamon, cinchona, coriander, fennel , clove, Ginger, Nux-vomica, Ipecacuanha.
3. Identification of fibers and surgical dressing.

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

PART A : Synopsis

10 Marks

PART B : Experiments (major and Minor)

60 Marks

PART C: Viva voce & Record

10 Marks

110P	BIOCHEMISTRY & CLINICAL PATHOLOGY	L	T	P	Credits	Total Marks
		0	0	3	1	100

1. Detection and identification of proteins. Amino acids, carbohydrates and lipids.
2. Analysis of normal and abnormal constituents of Blood and Urine (Glucose, urea, creatine, creatinine, cholesterol, alkaline phosphatase acid phosphatase, Bilirubin, SGPT, SGOT, calcium, Diastase, Lipase).
3. Examination of sputum and faeces (microscopic & staining).
4. Practice in injecting drugs by intramuscular, subcutaneous and intravenous routes, withdrawal of blood samples.

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

PART A : Synopsis

10 Marks

PART B : Experiments (major and Minor)

60 Marks

PART C: Viva voce & Record

10 Marks

111P	HUMAN ANATOMY &PHYSIOLOGY	L	T	P	Credits	Total Marks
		0	0	2	1	100

1. Study of the human Skelton.
2. Study with the help of charts and models of the following system and organs: Digestive system Respiratory system Ear
Cardiovascular system Urinary system
Reproductive system Eye
3. Microscopic examination of epithelial tissue, cardiac muscle, smooth muscle, skeletal muscle. Connective tissue and nervous tissues.
4. Examination of blood films for TLC.DLC and malarial parasite.
5. Determination of RBCs, clotting time of blood, erythrocyte sedimentation rate and Hemoglobin value.
6. Recording of body temperature, pulse, heart-rate, blood pressure and ECG.

END EXAMINATION QUESTION PAPER PATTERN

Max. Marks: 80

Exam Duration: 3 Hrs.

PART A : Synopsis

10 Marks

PART B : Experiments (major and Minor)

60 Marks

PART C: Viva voce & Record

10 Marks

FIRST YEAR

PH 101	HUMAN ANATOMY AND PHYSIOLOGY	L	T	P	Total Marks
		3	1	3	100

Scope:

This course is designed to impart a fundamental knowledge on the structure and functions of the human body. It also helps in understanding both homeostasis mechanisms and homeostatic imbalances of various body systems. Since a medicament, which is produced by pharmacist, is used to correct the deviations in human body, it enhances the understanding of how the drugs act on the various body systems in correcting the disease state of the organs.

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

- describe the structure (gross and histology) and functions of various organs of the human body;
- describe the various homeostatic mechanisms and the imbalances of various systems;
- identify the various tissues and organs of the different systems of the human body;
- perform the hematological tests and also record blood pressure, heart rate, pulse and Respiratory volumes;
- appreciate coordinated working pattern of different organs of each system; and
- appreciate the interlinked mechanisms in the maintenance of normal functioning (homeostasis) of human body

UNIT: 1

- Scope of anatomy and physiology**, basic terminologies used in this subject (Description of the body as such planes and terminologies)
- Structure of cell** – its components and their functions. Elementary tissues of the human body: epithelial, connective, Muscular and nervous tissues-their sub-types and characteristics
 - Osseous system - structure, composition and functions of the Skeleton
 - Classification of joints, Types of movements of joints and disorders of joints (Definitions only)

UNIT: 2**i) Haemopoetic System**

- Composition and functions of blood
- Haemopoiesis and disorders of blood components
- Blood groups
- Clotting factors and mechanism
- Platelets and disorders of coagulation

ii) Lymph

- Lymph and lymphatic system, composition, formation and circulation.
- Spleen: structure and functions, Disorders
- Disorders of lymphatic system (definition only)

iii) Cardiovascular system

- Anatomy and functions of heart

- b) Blood vessels and circulation (Pulmonary, coronary and systemic circulation)
- c) Electrocardiogram (ECG)
- d) Cardiac cycle and heart sounds
- e) Blood pressure – its maintenance and regulation
- f) **Definition of the following disorders:** Hypertension, Hypotension, Arteriosclerosis, Atherosclerosis, Angina, Myocardial infarction, Congestive heart failure, Cardiac arrhythmias

UNIT-3**i) Respiratory system**

- a) Anatomy of respiratory organs and functions
- b) Mechanism / physiology of respiration and regulation of respiration
- c) Transport of respiratory gases
- d) Respiratory volumes and capacities, and Definition of: Hypoxia, Asphyxia, Dybarism, Oxygen therapy and resuscitation.

ii) Digestive system

- a) Anatomy and physiology of GIT
- b) Anatomy and functions of accessory glands of GIT
- c) Digestion and absorption
- d) Disorders of GIT (definitions only)

iii) Nervous system

- a) Definition and classification of nervous system
- b) Anatomy, physiology and functional areas of cerebrum
- c) Anatomy and physiology of cerebellum
- d) Anatomy and physiology of mid brain
- e) Thalamus, hypothalamus and Basal Ganglia
- f) Spinal cord: Structure & reflexes – mono-poly-planter
- g) Cranial nerves – names and functions
- h) ANS – Anatomy & functions of sympathetic & parasympathetic N.S.

UNIT: 4**i) Urinary system**

- a) Anatomy and physiology of urinary system
- b) Formation of urine
- c) Renin Angiotensin system – Juxtaglomerular apparatus - acid base Balance
- d) Clearance tests and micturition

ii) Endocrine system

- a) Pituitary gland
- b) Adrenal gland
- c) Thyroid and Parathyroid glands
- d) Pancreas and gonads

iii) Reproductive system

- a) Male and female reproductive system
- b) Their hormones – Physiology of menstruation
- c) Spermatogenesis & Oogenesis
- d) Sex determination (genetic basis)
- e) Pregnancy and maintenance and parturition
- f) Contraceptive devices

UNIT: 5**i) Sense organs**

- a) Eye
- b) Ear
- c) Skin
- d) Tongue & Nose

ii) Skeletal muscles

- a) Histology
- b) Physiology of Muscle contraction
- c) Physiological properties of skeletal muscle and their disorders (definitions)

iii) Sports physiology

- a) Muscles in exercise, Effect of athletic training on muscles and muscle performance,
- b) Respiration in exercise, CVS in exercise, Body heat in exercise, Body fluids and salts in exercise,
- c) Drugs and athletics

Text books

1. Tortora Gerard J. and Nicholas, P. Principles of anatomy and physiology Publisher Harpercollins College New York.
2. Wilson, K.J.W. Ross and Wilson's foundations of anatomy and physiology. Publisher: Churchill Livingstone, Edinburgh.

Reference books

1. Guyton Arthur, C. *Physiology of human body*. Publisher: Holt Saunders.
2. Chatterjee, C.C. *Human physiology*. Volume 1 & 11. Publisher: medical allied agency, Calcutta.
3. Peter L. Williams, Roger Warwick, Mary Dyson and Lawrence, H. *Gray's anatomy* Publisher: Churchill Livingstone, London

End Theory Examination Question Paper PatternMax. Marks: **70** marksExam Duration: **3 Hours**

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 101P	HUMAN ANATOMY AND PHYSIOLOGY-LAB	Total Marks
		100

General Requirements:

Dissection box, Laboratory Napkin, muslin cloth, record, Observation book(100pages), Stationary items, Blood lancet.

Course materials:**Text books**

Goyal, R. K, Natvar M.P, and Shah S.A, Practical anatomy, physiology and biochemistry, latest edition, Publisher: B.S Shah Prakashan, Ahmedabad.

Reference books

Ranade VG, Text book of practical physiology, Latest edition, Publisher: PVG, Pune Anderson Experimental Physiology, Latest edition, Publisher: NA

List of Experiments**1.Study of tissues of human body**

- a) Epithelial tissue.
- b) Muscular tissue.

2.Study of tissues of human body

- a) Connective tissue.
- b) Nervous tissue.

3.Study of appliances used in hematological experiments.**4.Determination of W.B.C. count of blood.****5.Determination of R.B.C. count of blood.****6.Determination of differential count of blood.****7.Determination of**

- a) Erythrocyte Sedimentation Rate.
- b) Hemoglobin content of Blood.
- c) Bleeding time & Clotting time.

8.Determination of

- a) Blood Pressure.
- b) Blood group.

9.Study of various systems with the help of charts, models & specimens

- a) Skeleton system part I-axial skeleton.
- b) Skeleton system part II- appendicular skeleton.
- c) Cardiovascular system.
- d) Respiratory system.
- 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:

Contents	Sessional	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).

PH 102	PHARMACEUTICS	L	T	P	Total Marks
		2	1	3	100

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.

Outcomes; 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.

UNIT: 1.

- a) Introduction to dosage forms - classification and definitions
- b) **Prescription:** definition, parts and handling
- c) **Posology:** Definition, Factors affecting dose selection. Calculation of children and infant doses.
- d) Historical back ground and development of profession of pharmacy and pharmaceutical industry in brief.

UNIT: 2

- a) Development of Indian Pharmacopoeia and introduction to other Pharmacopoeias such as BP, USP, European Pharmacopoeia, Extra pharmacopoeia and Indian national formulary.
- b) **Weights and measures,** Calculations involving percentage solutions, allegation, proof spirit, isotonic solutions etc.

UNIT: 3

- a) **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.
- b) **Monophasic Dosage forms:** Theoretical aspects of formulation including adjuvant like stabilizers, colorants, flavors with examples. Study of Monophasic liquids like gargles, mouth washes, Throat paint, Ear drops, Nasal drops, Liniments and lotions, Enemas and collodions.

UNIT: 4

- a) **Biphasic dosage forms:** Suspensions and emulsions, Definition, advantages and disadvantages, classification, test for the type of emulsion, formulation, stability and evaluation.
- b) **Suppositories and pessaries:** Definition, advantages and disadvantages, types of base, method of preparation, Displacement value and evaluation
- c) **Galenicals:** Definition, equipment for different extraction processes like infusion, Decoction, Maceration and Percolation, methods of preparation of spirits, tinctures and extracts.

UNIT: 5

- a) **Pharmaceutical calculations.**
- b) **Surgical aids:** Surgical dressings, absorbable gelatin sponge, sutures, ligatures and medicated bandages.
- c) **Incompatibilities:** Introduction, classification and methods to overcome the incompatibilities.

PH 102P	PHARMACEUTICS-LAB	Total Marks
		100

List of Experiments**1. Syrups**

- a) Simple Syrup I.P
- b) Syrup of Ephedrine Hcl NF
- c) Syrup Vasaka IP
- d) Syrup of ferrous Phosphate IP
- e) Orange Syrup

2. Elixir

- a) Piperizine citrate elixir BP
- b) Cascara elixir BPC
- c) Paracetamol elixir BPC

3. Linctus

- a) Simple Linctus BPC
- b) Pediatric simple Linctus BPC

4. Solutions

- a) Solution of cresol with soap IP
- b) Strong solution of ferric chloride BPC
- c) Aqueous Iodine Solution IP
- d) Strong solution of Iodine IP
- e) Strong solution of ammonium acetate IP

5. Liniments

- a) Liniment of turpentine IP*
- b) Liniment of camphor IP

6. Suspensions*

- a) Calamine lotion
- b) Magnesium Hydroxide mixture BP

7. Emulsions*

- a) Cod liver oil emulsion
- b) Liquid paraffin emulsion

8. Powders*

- a) Eutectic powder
- b) Explosive powder
- c) Dusting powder
- d) Insufflations

9. Suppositories*

- a) Boric acid suppositories
- b) Chloral suppositories

10. Incompatibilities

- a) Mixtures with Physical
- b) Chemical & Therapeutic incompatibilities

Colorless bottles required for dispensing ☐ Paper envelope (white), butter paper and white paper required for dispensing.

Scheme of Practical Examination:

Contents	Sessional	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).

PH 103	MEDICINAL BIOCHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope:

Applied biochemistry deals with complete understanding of the molecular level of the chemical process associated with living cells. Clinical chemistry deals with the study of chemical aspects of human life in health and illness and the application of chemical laboratory methods to diagnosis, control of treatment, and prevention of diseases

Objectives of the Subject (Know, do, appreciate):

The objective of the present course is providing biochemical facts and the principles to the students of pharmacy. *Upon completion of the subject student shall be able to –*

- understand the catalytic activity of enzymes and importance of isoenzymes in diagnosis of diseases;
- know the metabolic process of biomolecules in health and illness (metabolic disorders);
- understand the genetic organization of mammalian genome; protein synthesis; replication; mutation and repair mechanism;
- know the biochemical principles of organ function tests of kidney, liver and endocrine gland; and
- do the qualitative analysis and determination of biomolecules in the body fluids.

UNIT.1:

a. Introduction to biochemistry: Cell and its biochemical organization, transport process across the cell membranes. Energy rich compounds; ATP, Cyclic AMP and their biological significance.

b. Enzymes: Definition; Nomenclature; IUB classification; Factor affecting enzyme activity; Enzyme action; enzyme inhibition. Isoenzymes and their therapeutic and diagnostic applications; Coenzymes and their biochemical role and deficiency diseases.

UNIT.2:

i) Carbohydrate metabolism: Glycolysis, Citric acid cycle (TCA cycle), HMP shunt, Glycogenolysis, gluconeogenesis, glycogenesis. Metabolic disorders of carbohydrate metabolism (diabetes mellitus and glycogen storage diseases); Glucose, Galactose tolerance test and their significance; hormonal regulation of carbohydrate metabolism.

ii) Lipid metabolism: Oxidation of saturated (β -oxidation); Ketogenesis and ketolysis; biosynthesis of fatty acids, lipids; metabolism of cholesterol; Hormonal regulation of lipid metabolism. Defective metabolism of lipids (Atherosclerosis, fatty liver, hypercholesterolemia).

UNIT.3:

i) Biological oxidation: Coenzyme system involved in Biological oxidation. Electron transport chain (its mechanism in energy capture; regulation and inhibition); Uncouplers of ETC; Oxidative phosphorylation;

iii) Protein and amino acid metabolism: protein turn over; nitrogen balance; Catabolism of Amino acids (Transamination, deamination & decarboxylation). Urea cycle and its metabolic disorders; production of bile pigments; hyperbilirubinemia, porphoria, jaundice. Metabolic disorder of Amino acids.

iv) Nucleic acid metabolism: Metabolism of purine and pyrimidine nucleotides; Protein synthesis; Genetic code; inhibition of protein synthesis; mutation and repair mechanism; DNA replication (semiconservative /onion peel models) and DNA repair mechanism.

UNIT.4:

Introduction to clinical chemistry: Cell; composition; malfunction; Roll of the clinical chemistry laboratory.

The kidney function tests: Role of kidney; Laboratory tests for normal function includes-

- Urine analysis (macroscopic and physical examination, quantitative and semiquantitative tests.)
- Test for NPN constituents. (Creatinine /urea clearance, determination of blood and urine creatinine, urea and uric acid)
- Urine concentration test
- Urinary tract calculi. (stones)

Liver function tests: Physiological role of liver, metabolic, storage, excretory, protective, circulatory functions and function in blood coagulation.

- Test for hepatic dysfunction-Bile pigments metabolism.
- Test for hepatic function test- Serum bilirubin, urine bilirubin, and urine urobilinogen.
- Dye tests of excretory function.
- Tests based upon abnormalities of serum proteins. Selected enzyme tests.

UNIT.5:

i) Lipid profile tests: Lipoproteins, composition, functions. Determination of serum lipids, total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides.

ii) Immunochemical techniques for determination of hormone levels and protein levels in serum for endocrine diseases and infectious diseases.

Radio immuno assay (RIA) and Enzyme Linked Immuno Sorbent Assay (ELISA)

iii) Electrolytes: Body water, compartments, water balance, and electrolyte distribution. Determination of sodium, calcium potassium, chlorides, bicarbonates in the body fluids.

Text books (Theory)

- Harpers review of biochemistry - Martin
- Text book of biochemistry – D.Satyanarayana
- Text book of clinical chemistry- Alex kaplan&LaverneL.Szabo

Reference books (Theory)

- Principles of biochemistry -- Lehninger
- Text book of biochemistry -- Ramarao
- Practical Biochemistry-David T.Plummer.

End Theory Examination Question Paper Pattern

Max. Marks: 70 marks

Exam Duration: 3 Hours

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 103P	MEDICINAL BIOCHEMISTRY -LAB	Total Marks
		100

Title of the Experiment:

1. Qualitative analysis of normal constituents of urine.*
2. Qualitative analysis of abnormal constituents of urine.*
3. Quantitative estimation of urine sugar by Benedict's reagent method.**
4. Quantitative estimation of urine chlorides by Volhard's method.**
5. Quantitative estimation of urine creatinine by Jaffe's method.**
6. Quantitative estimation of urine calcium by precipitation method.**
7. Quantitative estimation of serum cholesterol by LibermannBurchard's method.**
8. Preparation of Folin Wu filtrate from blood.*
9. Quantitative estimation of blood creatinine.**
10. Quantitative estimation of blood sugar Folin- Wu tube method.**
11. Estimation of SGOT in serum.**
12. Estimation of SGPT in serum.**
13. Estimation of Urea in Serum.**
14. Estimation of Proteins in Serum.**
15. Determination of serum bilirubin**
16. Determination of Glucose by means of Glucoseoxidase.**
17. Enzymatic hydrolysis of Glycogen/Starch by Amylases.**
18. Study of factors affecting Enzyme activity. (pH& Temp.)**
19. Preparation of standard buffer solutions and its pH measurements (any two)*
20. Experiment on lipid profile tests**
21. Determination of sodium,calcium and potassium in serum.**

** indicate major experiments & * indicate minor experiments

Assignments: Format of the assignment

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

Scheme of Practical Examination:

Contents	Sessional	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).

PH 104	PHARMACEUTICAL ORGANIC CHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This course is designed to impart a very good knowledge about

- IUPAC/Common system of nomenclature of simple organic compounds belonging to different classes of organic compounds;
- Some important physical properties of organic compounds;
- Free radical/ nucleophilic [alkyl/ acyl/ aryl] /electrophilic substitution, free radical/ nucleophilic / electrophilic addition, elimination, oxidation and reduction reactions with mechanism, orientation of the reaction, order of reactivity, stability of compounds;
- Some named organic reactions with mechanisms; and
- Methods of preparation, test for purity, principle involved in the assay, important medicinal uses of some important organic compounds.

UNIT.1:

i) Structures and Physical properties:

- Polarity of bonds, polarity of molecules, M.P, Inter molecular forces, B.P, Solubility, non ionic solutes and ionic solutes, protic and aprotic Solvents, ion pairs,
- Acids and bases, Lowry bronsted and Lewis theories
- Isomerism

ii) Nomenclature of organic compound belonging to the following classes Alkanes, Alkenes, Dienes, Alkynes, Alcohols, Aldehydes, Ketones, Amides, Amines, Phenols, Alkyl Halides, Carboxylic Acid, Esters, Acid Chlorides And Cycloalkanes.

iii) Free radicals chain reactions of alkane : Mechanism, relative reactivity and stability

iv) Alicyclic compounds : Preparations of cyclo alkanes, Bayer strain theory and orbital picture of angle strain.

UNIT.2:

i) Nucleophilic aliphatic substitution mechanism: Nucleophiles and leaving groups, kinetics of second and first order reaction, mechanism and kinetics of SN 2 reactions. Stereochemistry and steric hindrance, role of solvents, phase transfer catalysis, mechanism and kinetics of SN1 reactions, stereochemistry, carbocation and their stability, rearrangement of carbocation, role of solvents in SN1 reaction, Ion dipole bonds, SN2 versus SN1 solvolyses, nucleophilic assistance by the solvents.

ii) Dehydro halogenation of alkyl halides: 1,2 elimination, kinetics, E2 and E1 mechanism, elimination via carbocation, evidence for E2 mechanism, absence of rearrangement isotope effect, absence hydrogen exchange, the element effect, orientation and reactivity, E2 versus E1, elimination versus substitution, dehydration of alcohol, ease of dehydration, acid catalysis, reversibility, orientation.

iii) Electrophilic and free radicals addition: Reactions at carbon-carbon, double bond, electrophile, hydrogenation, heat of hydrogenation and stability of alkenes, markownikoff rule, addition of hydrogen halides, addition of hydrogen bromides, peroxide effect, electrophilic addition, mechanism, rearrangement, absence of hydrogen exchange, orientation and reactivity, addition of halogen, mechanism, halohydrin formation, mechanism of free radicals addition, mechanism of peroxide

initiated addition of hydrogen bromide, orientation of free addition, additions of carbene to alkene, cyclo addition reactions.

iv) Carbon-carbon double bond as substituents: Free radical halogenations of alkenes, comparison of free radical substitution with free radical addition, free radical substitution in alkenes, orientation and reactivity, allylic rearrangements.

UNIT.3:

i) Theory of resonance: Allyl radical as a resonance hybrid, stability, orbital picture, resonance stabilisation of allyl radicals, hyper conjugation, allylcation as a resonance hybrid, nucleophilic substitution in allylic substrate, SN1 reactivity, allylic rearrangement, resonance stabilisation of allylcation, hyper conjugation, nucleophilic substitution in allylic substrate, SN2 nucleophilic substitution in vinylic substrate, vinylic addition, stability of conjugated dienes, resonance in alkenes, hyper conjugation, ease of formation of conjugated dienes, orientation of elimination, electrophilic addition to conjugated dienes, 1,4- addition, 1,2-versus 1,4-addition, rate versus equilibrium, orientation and reactivity of free radical addition to conjugated dienes.

ii) Electrophilic aromatic substitution: Effect of substituent groups, determination of orientation, determination of relative reactivity, classification of substituent group, mechanism of nitration, sulphonation, halogenation, Friedel-Craft alkylation, Friedel-Craft acylation, reactivity and orientation, activating and deactivating O,P,M directing groups, electron release via resonance, effect of halogen on electrophilic aromatic substitution in alkyl benzene, side chain halogenation of alkyl benzene, resonance stabilization of benzyl radical.

UNIT.4:

i) Nucleophilic addition reaction: Mechanism, ionisation of carboxylic acids, acidity constants, acidity of acids, structure of carboxylate ions, effect of substituent on acidity, nucleophilic acyl substitution reaction, conversion of acid to acid chloride, esters, amide and anhydride. Role of carboxyl group, comparison of alkyl nucleophilic substitution with acyl nucleophilic substitution.

ii) Mechanism of aldol condensation, Claisen condensation, Cannizzaro reaction, crossed aldol condensation, crossed Cannizzaro reaction, benzoin condensation, Perkin condensation. Knoevenagel, Reformatsky reaction, Wittig reaction, Michael addition.

iii) Hoffman rearrangement: Migration to electron deficient nitrogen, Sandmeyer's reaction, basicity of amines, diazotisation and coupling, acidity of phenols, Williamson synthesis, Fries rearrangement, Kolbe reaction, Reimer-Tiemann's reactions.

UNIT.5:

i) Nucleophilic aromatic substitution: Bimolecular displacement mechanisms, orientation, comparison of aliphatic nucleophilic substitution with that of aromatic.

ii) Oxidation reduction reaction.

iii) Study of the following official compounds- preparation, test for purity, assay and medicinal uses of Chlorbutol, Dimercaprol, Glyceryl trinitrate, Urea, Ethylene diamine dihydrate, Vanillin, Paraldehyde,

Ethylene chloride, Lactic acid, Tartaric acid, citric acid, salicylic acid, aspirin, methyl salicylate, ethyl benzoate, benzylbenzoate, dimethyl phthalate, sodium lauryl sulphate, saccharin sodium, mephensin.

REFERENCES

- a. T.R.Morrison and R. Boyd - Organic chemistry,
- b. Bentley and Driver-Text book of Pharmaceutical chemistry
- c. I.L.Finer- Organic chemistry, the fundamentals of chemistry
- d. Organic chemistry – J.M.Cram and D.J.Cram
- e. Organic chemistry- Brown
- f. Advanced organic chemistry- Jerry March, Wiley
- g. Organic chemistry- Cram and Hammered, Pine Hendrickson

End Theory Examination Question Paper Pattern

Max. Marks: **70** marks

Exam Duration: **3 Hours**

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 104P	PHARMACEUTICAL ORGANIC CHEMISTRY -LAB	Total Marks
		100

I. Introduction to the various laboratory techniques through demonstration involving synthesis of the following compounds (at least 8 compounds to be synthesised):

1. Benzanilide / Phenyl benzoate (Benzoylation)
2. Acetanilide / aspirin (Acetylation)
3. P-bromo acetanilide / 2,4,6 – tribromo aniline (Bromination)
4. Dibenzylidene acetone (Condensation)
5. 1-Phenylazo-2-naphthol (Diazotisation and coupling)
6. Benzoic acid / salicylic acid (Hydrolysis of ester)
7. M-dinitro benzene (Nitration)
8. Anthraquinone (Oxidation of anthracene) / preparation of benzoic acid from toluene or benzaldehyde
9. M-phenylene diamine (Reduction of M-dinitrobenzene) / Aniline from nitrobenzene
10. Benzophenoneoxime
11. Nitration of salicylic acid
12. Preparation of picric acid
13. Preparation of O-chlorobenzoic acid from O-chlorotoluene
14. Preparation of cyclohexanone from cyclohexanol

II. Identification of organic compounds belonging to the following classes by :

Systematic qualitative organic analysis including preparation of derivatives Phenols, amides, carbohydrates, amines, carboxylic acids, aldehyde and ketones, Alcohols, esters, hydrocarbons, anilides, nitrocompounds.

III. Introduction to the use of stereo models:

Methane, Ethane, Ethylene, Acetylene, Cis alkene, Trans alkene, inversion of configuration.

Scheme of Practical Examination:

Contents	Sessional	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).

PH 105	PHARMACEUTICAL INORGANIC CHEMISTRY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This course mainly deals with fundamentals of Analytical chemistry and also the study of inorganic pharmaceuticals regarding their monographs and also the course deals with basic knowledge of analysis of various pharmaceuticals.

Upon completion of the course student shall be able to:

- understand the principles and procedures of analysis of drugs and also regarding the application of inorganic pharmaceuticals;
- know the analysis of the inorganic pharmaceuticals their applications; and
- appreciate the importance of inorganic pharmaceuticals in preventing and curing the disease.

UNIT.1:

- Errors
- Volumetric analysis
- Acid-base titrations
- Redox titrations

UNIT.2:

- Non aqueous titrations
- Precipitation titrations
- Complexometric titrations
- Theory of indicators

UNIT.3:

- Gravimetry
- Limit tests
- Medicinal gases

D. Acidifiers

UNIT.4:

A. Antacids

B. Cathartics

C. Electrolyte replenishers

D. Essential Trace elements

UNIT.5:

A. Antimicrobials

B. Pharmaceutical aids

C. Dental Products

D. Miscellaneous compounds

E. Radio Pharmaceuticals

REFERENCES

- A text book Inorganic medicinal chemistry by Surendra N. Pandeya
- A. H. Beckett and J. B. Stanlake's Practical Pharmaceutical chemistry Vol-I & Vol-II
- Inorganic Pharmaceutical Chemistry III-Edition P.Gundu Rao
- Inorganic Pharmaceutical Chemistry by Anand&Chetwal
- Pharmaceutical Inorganic chemistry by Dr.B.G.Nagavi
- Analytical chemistry principles by John H. Kennedy d. I.P.1985 and 1996, Govt. of India, Ministry of health

End Theory Examination Question Paper PatternMax. Marks: **70** marksExam Duration: **3 Hours**

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 105P	PHARMACEUTICAL INORGANIC CHEMISTRY -LAB	Total Marks
		100

1. Limit test (6 exercises)

- Limit test for chlorides
- Limit test for sulphates
- Limit test for iron
- Limit test for heavy metals
- Limit test for arsenic
- Modified limit tests for chlorides and sulphates

2. Assays (10 exercises)

- Ammonium chloride- Acid-base titration
- b.Ferrous sulphate- Cerimetry
- c.Coppersulphahte- Iodometry

- d) d.Calcilugluconate- Complexometry
- e) e.Hydrogen peroxide – Permanganometry
- f) f.Sodium benzoate – Nonaqueous titration
- g) g.Sodium chloride – Modified volhard's method
- h) h.Assay of KI – KIO₃ titration
- i) i.Gravimetric estimation of barium as barium sulphate
- j) j.Sodium antimony gluconate or antimony potassium tartarate

3. Estimation of mixture (Any two exercises)

- a) Sodium hydroxide and sodium carbonate
- b) Boric acid and Borax
- c) Oxalic acid and sodium oxalate

4. Test for identity (Any three exercises)

- a) Sodium bicarbonate
- b) Barium sulphate
- c) Ferrous sulphate
- d) Potassium chloride

5. Test for purity (Any two exercises)

- a) Swelling power in Bentonite
- b) Acid neutralising capacity in aluminium hydroxide gel
- c) Ammonium salts in potash alum
- d) Adsorption power heavy Kaolin
- e) Presence of Iodates in KI

6. Preparations (Any two exercises)

- a) Boric acids
- b) Potash alum
- c) Calcium lactate
- d) Magnesium sulphate

Scheme of Practical Examination:

Contents	Sessional	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).

PH 106RM	REMEDIAL MATHEMATICS	L	T	P	Total Marks
		3	1	0	100

Scope and objectives: This is an introductory course in mathematics. This subjects deals with the introduction to matrices, determinants, trigonometry, analytical geometry, differential calculus, integral calculus, differential equations, laplace transform.

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

- Know Trignometry, Analytical geometry, Matrices, Determinant, Integration, Differential equation, Laplace transform and their applications;
- solve the problems of different types by applying theory; and
- appreciate the important applications of mathematics in pharmacy.

UNIT.1:

- Algebra: Determinants, Matrices
- Trigonometry:** Sides and angles of a triangle, solution of triangles

UNIT.2:

Differential calculus: Limit of a function, Differential calculus, Differentiation of a sum, Product, Quotient Composite, Parametric, exponential, trigonometric and Logarithmic function. Successive differentiation, Leibnitz's theorem, Partial differentiation, Euler's theorem on homogeneous functions of two variables

UNIT.3:

Integral Calculus: Definite integrals, integration by substitution and by parts, Properties of definite integrals.

UNIT.4:

Differential equations: Definition, order, degree, variable separable, homogeneous, Linear, heterogeneous, linear, differential equation with constant coefficient, simultaneous linear equation of second order.

UNIT.5:

- Analytical Geometry:** Points, Straight line, circle, parabola
- Laplace transform:** Definition, Laplace transform of elementary functions, Properties of linearity and shifting.

REFERENCES

- Differential calculus By Shantinakaran
- Text book of Mathematics for second year pre- university by Prof.B.M.Sreenivas
- Integral calculus By Shanthinakaran
- Engineering mathematics By B.S.Grewal
- Trigonometry Part-I By S.L.Loney

End Theory Examination Question Paper Pattern

Max. Marks: **70** marks

Exam Duration: **3 Hours**

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 106RB	REMEDIAL BIOLOGY	L	T	P	Total Marks
		3	1	3	100

Scope and objectives: This is an introductory course in Biology, which gives detailed study of natural sources such as plant and animal origin. This subject has been introduced to the pharmacy course in order to make the student aware of various naturally occurring drugs and its history, sources, classification, distribution and the characters of the plants and animals. This subject gives basic foundation to Pharmacognosy.

PART – A

UNIT.1:

- Introduction
- General organization of plants and its inclusions
- Plant tissues
- Plant kingdom and its classification
- Morphology of plants
- Root, Stem, Leaf and Its modifications

UNIT.2:

- Inflorescence and Pollination of flowers
- Morphology of fruits and seeds
- Plant physiology

UNIT.3:

- Taxonomy of Leguminosae, umbelliferae, Solanaceae, Liliaceae, Zinziberaceae, Rubiaceae
- Study of Fungi, Yeast, Penicillin and Bacteria

PART-B

UNIT.4:

- Study of Animal cell
- Study animal tissues
- Detailed study of frog

UNIT.5:

- Study of Pisces, Raptiles, Aves
- General organization of mammals
- Study of poisonous animals

REFERENCES

- Text book of Biology by S.B.Gokhale
- A Text book of Biology by Dr.Thulajappa and Dr.Seetaram.
- A Text book of Biology by B.V.Sreenivasa Naidu
- A Text book of Biology by Naidu and Murthy
- Botany for Degree students By A.C.Dutta.
- Outlines of Zoology by M.Ekambaranathaayyer and T.N.Ananthakrishnan.
- A manual for pharmaceutical biology practical by S.B.Gokhale and C.K.Kokate.

End Theory Examination Question Paper PatternMax. Marks: **70** marksExam Duration: **3 Hours**

Part-A	Long Answer Question carries 10 Marks , Answer any 2 out of 3	20 Marks
Part-B	Short Answer question each carries 5 marks, Answer any 6 out of 7	30 Marks
Part-C	10 Very Short answer Questions, carries 2 marks each	20 Marks

PH 106RBP	REMEDIAL BIOLOGY -LAB	Total Marks
		100

1. Introduction of biology experiments
2. Study of cell wall constituents and cell inclusions
3. Study of Stem modifications
4. Study of Root modifications
5. Study of Leaf modifications
6. Identification of Fruits and seeds
7. Preparation of Permanent slides
8. T.S. of Senna, Cassia, Ephedra, Podophyllum.
9. Simple plant physiological experiments
10. Identification of animals
11. Detailed study of Frog
12. Computer based tutorials

Scheme of Practical Examination:

Contents	Sessional	Annual
Identification	04	10
Synopsis	04	10
Major Experiment	07	20
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03	01

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

M. Pharm (Pharmaceutics)- Semester-I

MPH101T	Modern Pharmaceutical Analytical Techniques (Theory)	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope:

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Course Objectives: After completion of course student is able to know,

- Chemicals and Excipients
- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

60 Hours**Unit: I****11 hrs**

a. **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV Visible spectroscopy.

b. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

c. **Spectrofluorimetry:** Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

Unit: II**11 hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and ¹³C NMR. Applications of NMR spectroscopy.

Unit: III**11 Hours**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI. Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

Unit: IV**12 Hours**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:

- Paper chromatography
- Thin Layer chromatography
- Ion exchange chromatography
- Column chromatography
- Gas chromatography
- High Performance Liquid chromatography
- Affinity chromatography

Unit: V**15 Hours**

a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

- a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis
d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X ray diffraction methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X ray diffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs**

PART-A Long Answer Question carry 20 Marks answer all (2 × 20 = 40)

40 Marks

PART-B Short Answer Question each carry 5 Marks answer all 7

35 Marks

MPH102T	DRUG DELIVERY SYSTEMS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

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

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of delivering system
- The formulation and evaluation of Novel drug delivery systems.

THEORY**60 Hours****Unit: I****11 Hrs**

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basic Concepts, advantages/disadvantages, factors influencing, Physicochemical & biological approaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application Dosage Forms for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bio electronic Medicines, 3D printing of pharmaceuticals, Tele pharmacy.

Unit: II**11 Hrs**

Rate Controlled Drug Delivery Systems: Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems; Principles & Fundamentals.

Unit: III**11 Hrs**

Gastro-Retentive Drug Delivery Systems: Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of mucoadhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations.

Unit: IV**12 Hrs**

a) Ocular Drug Delivery Systems: Barriers of drug permeation, Methods to overcome barriers.

b) Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation.

Unit: V**15 Hrs**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules. Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal and transdermal delivery of vaccines.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker, Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Inter science Publication, John Wiley and Sons, Inc, New York! Chichester / Weinheim
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.

JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release (Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH103T	MODERN PHARMACEUTICS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries

Objectives

- Upon completion of the course, student shall be able to understand
- The elements of Preformulation studies.
- The Active Pharmaceutical Ingredients and Generic drug Product development
- Industrial Management and GMP Considerations.
- Optimization Techniques & Pilot Plant Scale Up Techniques
- Stability Testing, sterilization process & packaging of dosage forms.

THEORY**60 Hours****Unit: I****12 Hrs**

a) Preformulation Concepts – Drug Excipient interactions -different methods, kinetics of stability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsion and Suspension, SMEDDS) preparation and stability Large and small volume parental – physiological and formulation consideration, Manufacturing and evaluation.

b). Optimization techniques in Pharmaceutical Formulation: Concept and parameters of optimization, Optimization techniques in pharmaceutical formulation and processing. Statistical design, Response surface method, Contour designs, Factorial designs and application in formulation.

Unit: II**12 Hrs**

Validation: Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH& WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, Types of validation. Government regulation, Manufacturing Process Model, URS, DQ, IQ, OQ & P.Q. of facilities.

Unit: III**12 Hrs**

C GMP & Industrial Management: Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance Production management: Production organization, , materials management, handling and transportation, inventory management and control, production and planning control, Sales forecasting, budget and cost control, industrial and personal relationship. Concept of Total Quality Management.

Unit: IV**12 Hrs**

Compression and compaction: Physics of tablet compression, compression, consolidation, effect of friction, distribution of forces, compaction profiles. Solubility.

Unit: V**12 Hrs**

Study of consolidation parameters; Diffusion parameters, Dissolution parameters and Pharmacokinetic parameters, Heckle plots, Similarity factors – f₂ and f₁, Higuchi and Peppas plot, Linearity Concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test.

REFERENCES

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol. 1-2; By Leon Lachmann.
5. Modern Pharmaceutics; By Gillbert and S. Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred Martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Second edition; By Sidney H. Willig.
11. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
12. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
13. How to practice GMPs; By P.P. Sharma. Vandhana Publications, Agra.
14. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash.
15. Pharmaceutical Preformulations; By J.J. Wells.
16. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
17. Encyclopaedia of Pharmaceutical technology, Vol I – III.

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH104T	REGULATORY AFFAIRS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings indifferent 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

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 indifferent countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ e CTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilance and process of monitoring in clinical trials.

THEORY**60Hours****Unit: I****12 Hrs**

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 FEDERALREGULATION), drug product performance, in-vitro, AND A 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.

Unit: II**12 Hrs**

Regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs

Unit: III**12 Hrs**

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.

Unit: IV**12 Hrs**

Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Unit: V

12 Hrs

Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, Pharmacovigilance safety monitoring in clinical trials.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and IsaderKaufer, Marcel Dekker series, Vol.143
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R.Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations By Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol. 190.
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley&Sons.Inc.
5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A.Rozovsky and Rodney K. Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. <https://www.tga.gov.au/tga-basics>

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH105P	PHARMACEUTICS PRACTICALS-I	L	T	P	Credits	Total Marks
		0	0	12	6	150

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometer
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. To perform In-vitro dissolution profile of CR/ SR marketed formulation
8. Formulation and evaluation of sustained release matrix tablets
9. Formulation and evaluation osmotically controlled DDS
10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
11. Formulation and evaluation of Muco adhesive tablets.
12. Formulation and evaluation of trans dermal patches.
13. To carry out Preformulation studies of tablets.
14. To study the effect of compressional force on tablets disintegration time.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of a tablet.
17. To study the effect of binders on dissolution of a tablet.
18. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

MPH106S	SEMINAR / ASSIGNMENT	L	T	P	Credits	Total Marks
		0	7	0	4	100

M. Pharm – I year II Sem. (Pharmaceutics)

MPH201T	Molecular Pharmaceutics (Nano Technology & Targeted DDS) (NTDS)	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge on the area of advances in novel drug delivery systems.

Objectives

Upon completion of the course student shall be able to understand

- The various approaches for development of novel drug delivery systems.
- The criteria for selection of drugs and polymers for the development of NTDS
- The formulation and evaluation of novel drug delivery systems.

THEORY**60 Hours****Unit: I****12 Hrs**

Targeted Drug Delivery Systems: Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery.

Unit: II**12 Hrs**

Targeting Methods: introduction preparation and evaluation. Nano Particles & Liposome's: Types, preparation and evaluation.

Unit: III**12 Hrs**

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes, Electrosomes.

Unit: IV**12 Hrs**

Pulmonary Drug Delivery Systems: Aerosols, propellants, Containers Types, preparation and evaluation, Intra Nasal Route Delivery systems; Types, preparation and evaluation.

Unit: V**12 Hrs**

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non viral gene transfer). Liposomal gene delivery systems. Bio distribution and Pharmacokinetics. Knowledge of therapeutic anti sense molecules and aptamers as drugs of future.

REFERENCES

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery- concepts and advances, VallabhPrakashan, New Delhi, First edition 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH202T	Advanced Biopharmaceutics & Pharmacokinetics	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.

Objectives

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.
- The design and evaluation of dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application of basics of pharmacokinetic

THEORY**60 Hours****Unit: I****12 Hrs**

Drug Absorption from the Gastrointestinal Tract: Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes-Whitney equation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of In vivo data with in vitro dissolution data. Transport model: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pH Micro climate Intracellular pH Environment, Tight-Junction Complex.

Unit: II**12 Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance: Introduction, biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution Testing performance of drug products. In vitro-in vivo correlation, dissolution profile comparisons, drug product stability, considerations in the design of a drug product.

Unit: III**12 Hour**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model: two compartment - model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimation of k_{max} and v_{max} . Drug interactions: introduction, the effect of protein binding interactions, the effect of tissue-binding interactions, cytochrome p450-based drug interactions, drug interactions linked to transporters.

Unit: IV**12 Hrs**

Drug Product Performance, In Vivo: Bioavailability and Bioequivalence: drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover study designs, evaluation of the data, bioequivalence example, study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (bio similar drug products), clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, generic substitution.

Unit: V**12 Hrs**

Application of Pharmacokinetics: Modified-Release Drug Products, Targeted Drug Delivery Systems and Biotechnological Products. Introduction to Pharmacokinetics and pharmacodynamic, drug interactions. Pharmacokinetics and pharmacodynamics of biotechnology drugs. Introduction, Proteins and peptides, Monoclonal antibodies, oligonucleotides, Vaccines (immunotherapy), Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmkar and Sunil B. Jaiswal., VallabPrakashan, Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book
5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, Marcel Dekker Inc., New York, 1982
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970
7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition by Malcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia, 1995
8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pamarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge State, Alex Avdeef, John Wiley & Sons, Inc, 2003.

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH203T	COMPUTER AIDED DRUG DEVELOPMENT	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary for computer Applications in pharmaceutical research and development who want to understand the application of computers across the entire drug research and development process. Basic theoretical discussions of the principles of more integrated and coherent use of computerized information (informatics) in the drug development process are provided to help the students to clarify the concepts.

Objectives

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

- History of Computers in Pharmaceutical Research and Development
- Computational Modeling of Drug Disposition
- Computers in Preclinical Development
- Optimization Techniques in Pharmaceutical Formulation
- Computers in Market Analysis
- Computers in Clinical Development
- Artificial Intelligence (AI) and Robotics
- Computational fluid dynamics(CFD)

THEORY**60 Hours****Unit: I****12 Hrs**

a. Computers in Pharmaceutical Research and Development: A General Overview: History of Computers in Pharmaceutical Research and Development. Statistical modeling in Pharmaceutical research and development: Descriptive versus Mechanistic Modeling, Statistical Parameters, Estimation, Confidence Regions, Nonlinearity at the Optimum, Sensitivity Analysis, Optimal Design, Population Modeling

b. Quality-by-Design In Pharmaceutical Development: Introduction, ICH Q8 guideline, Regulatory and industry views on QbD, Scientifically based QbD - examples of application.

Unit: II**12 Hrs**

Computational Modeling Of Drug Disposition: Introduction, Modeling Techniques: Drug Absorption, Solubility, Intestinal Permeation, Drug Distribution, Drug Excretion, Active Transport; P-gp, BCRP, Nucleoside Transporters, hPEPT1, ASBT, OCT, OATP, BBB-Choline Transporter.

Unit: III**12 Hrs**

Computer-aided formulation development: Concept of optimization, Optimization parameters, Factorial design, Optimization technology & Screening design. Computers in Pharmaceutical Formulation: Development of pharmaceutical emulsions, micro emulsion drug carriers Legal Protection of Innovative Uses of Computers in R&D, The Ethics of Computing in Pharmaceutical Research, Computers in Market analysis

Unit: IV**12 Hrs**

A) Computer-aided biopharmaceutical characterization: Gastrointestinal absorption simulation. Introduction, Theoretical background, Model construction, Parameter sensitivity analysis, Virtual trial, Fed vs. fasted state, In vitro dissolution and in vitro- in vivo correlation, Biowaiver considerations.

B) Computer Simulations in Pharmacokinetics and Pharmacodynamics: Introduction, Computer Simulation: Whole Organism, Isolated Tissues, Organs, Cell, Proteins and Genes.

C) Computers in Clinical Development: Clinical Data Collection and Management, Regulation of Computer Systems

Unit: V**12 Hrs**

Artificial Intelligence (AI), Robotics and Computational fluid dynamics: General overview, Pharmaceutical Automation, Pharmaceutical applications, Advantages and Disadvantages. Current Challenges and Future Directions.

REFERENCES

1. Computer Applications in Pharmaceutical Research and Development, SeanEkins, 2006, John Wiley & Sons.
2. Computer-Aided Applications in Pharmaceutical Technology, 1st Edition, JelenaDjuris, Woodhead Publishing
3. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G.Boylan, Marcel Dekker Inc, New York, 1996.

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH204T	COSMETICS AND COSMECEUTICALS	L	T	P	Credits	Total Marks
		4	0	0	4	100

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals with desired Safety, stability, and efficacy.

THEORY**60 Hours****Unit: I****12 Hrs**

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics Regulatory provisions relating to import of cosmetics, Misbranded and spurious cosmetics. Regulatory provisions relating to manufacture of cosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.

Unit: II**12 Hrs**

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne, pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm.

Unit: III**12 Hrs**

Formulation Building blocks: Building blocks for different product formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. Soaps and syndic bars. Perfumes; Classification of perfumes. Perfume ingredients listed as allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

Unit: IV**12 Hrs**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, and body odor, and dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

Unit: V**12 Hrs**

Herbal Cosmetics: Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.
2. Poucher's perfumecosmeticsandSoaps, 10th edition.
3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4th edition
4. Handbook of cosmetic science and Technology A.O.Barel, M.PayeeandH.I. Maibach. 3rd edition
5. Cosmetic and Toiletries recent suppliers' catalogue.
6. CTFA directory.

END SEMESTER EXAMINATION QUESTION PAPER PATTERN**Max Marks 75****Exam Duration 3 Hrs****PART-A** Long Answer Question carry 20 Marks answer all (2 ×20=40)**40 Marks****PART-B** Short Answer Question each carry 5 Marks answer all 7**35 Marks**

MPH205P	PHARMACEUTICS PRACTICALS-II	L	T	P	Credits	Total Marks
		0	0	12	6	150

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes /niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by Winnoline R software
11. In vitro cell studies for permeability and metabolism
12. DoE Using Design Expert® Software
13. Formulation data analysis Using Design Expert® Software
14. Quality-by-Design in Pharmaceutical Development
15. Computer Simulations in Pharmacokinetics and Pharmacodynamics
16. Computational Modeling Of Drug Disposition
17. To develop Clinical Data Collection manual
18. To carry out Sensitivity Analysis, and Population Modeling.
19. Development and evaluation of Creams
20. Development and evaluation of Shampoo and Toothpaste base
21. To incorporate herbal and chemical actives to develop products
22. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

MPH206S	SEMINAR/ASSIGNMENT	L	T	P	Credits	Total Marks
		0	7	0	4	100