



Syllabus of the Program
Bachelor of Pharmacy (B.-Pharm)
Semester I, II, III, IV, V, VI, VII & VIII

ARKA JAIN UNIVERSITY, JHARKHAND
SCHOOL OF PHARMACY
PROGRAM OUTCOMES AND PROGRAM SPECIFIC OUTCOMES
BACHELOR OF PHARMACY

PROGRAM OUTCOMES:

[PO 1]: Disciplinary knowledge: Capable of demonstrating comprehensive knowledge and understanding the programme of study.

[PO 2]: Critical Thinking: Take informed actions after identifying the assumptions that frame thinking and actions, checking out the degree to which these assumptions are accurate and valid, and look at our ideas and decisions (drug development its adversity and benefits) from different perspectives.

[PO 3]: Effective Communication: Speak, read, write and listen clearly in person and through electronic media in English and in one Indian language, and make meaning of the world by connecting people, ideas, books, media and technology.

[PO 4]: Social Interaction: Elicit views of others, mediate disagreements and help reach conclusions in group settings. Shall acquire the knowledge related to medicine and their effectively for the healthy society.

[PO 5]: Effective Citizenship: Demonstrate empathetic social concern and equity centred national development, and the ability to act with an informed awareness of issues and participate in civic life through volunteering.

[PO 6]: Ethics: Recognize different value systems including your own, understand the moral dimensions of your decisions, and accept responsibility for them with regard to how they should conduct in relation to the job, trade, fellow professionals, and general public.

[PO 7]: Environment and Sustainability: Understand the issues of environmental contexts and sustainable development.

[PO 8]: Self-directed and Life-long Learning: Acquire the ability to engage in independent and life-long learning in the broadest context of socio-technological changes.

[PO 9]: Research-related skills: A sense of inquiry and capability for asking relevant/appropriate questions, problematising, synthesising and articulating; Ability to recognise cause-and-effect, define problems, formulate hypotheses, test hypotheses, analyse, interpret and draw conclusions from data, establish hypotheses, predict cause-and-effect relationships; ability to plan, execute and report the results of an experiment or investigation.

[PO 10]: Scientific interpretation: Ability to analyse, interpret and draw conclusions from quantitative/qualitative data; and critically evaluate ideas, evidence and experiences from an open-minded and interpreted perspective.

[PO 11]: Information and digital literacy: Capability to use information and communications technology in a variety of learning situations, demonstrate ability to access, evaluate, and use a variety of relevant information sources; and use appropriate software for analysis of data.

PROGRAM SPECIFIC OUTCOMES:

[PSO 1]: Detail understanding of theoretical and practical knowledge of all the subjects of pharmaceutical sciences.

[PSO 2]: Focus on Drug Discovery and Design, Drug Delivery, Drug Action and Clinical Sciences, Drug Analysis, Cost Effectiveness of Medicines, Drug Regulatory Affairs etc.

[PSO 3]: Exposure to current work practices as opposed to theoretical knowledge being taught in the classrooms.

[PSO 4]: Provide a real-time, supervised experience related to the professional tasks emphasised in course of study.

[PSO 5]: Develop knowledge of ethical and management principles to work as well as to lead teams.

[PSO 6]: Educate to contribute towards the promotion of National Health Policies (NRHM, NHM, RBSK etc.).

Scheme of Study-1st Semester

| Sl. No | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-----------------------|------------------------------------------------|-------------------------------------|-------------------------------------|----------|----------------------------------------|----------------------------------------|----------------------------------------|-------------------------------------|-------------------------------------|
| 1 | PHM21001 | Human Anatomy and Physiology I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM21002 | Pharmaceutical Analysis I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM21003 | Pharmaceutics I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM21004 | Pharmaceutical Inorganic Chemistry – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM21005 | Communication skills – Theory * | 2 | 2 | - | 50 | 35 | 10 | 3 | 2 |
| 6 | PHM21013/ PHM21006 | Remedial Biology/ Mathematics – Theory* | 2 | 2 | - | 50 | 35 | 10 | 3 | 2 |
| 7 | PHM21007 | Human Anatomy and Physiology I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM21008 | Pharmaceutical Analysis I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 9 | PHM21009 | Pharmaceutics I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 10 | PHM21010 | Pharmaceutical Inorganic Chemistry – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 11 | PHM21011 | Communication skills – Practical* | 1 | 2 | - | 25 | 15 | 5 | 3 | 2 |
| 12 | PHM21012 | Remedial Biology – Practical* | 1 | 2 | - | 25 | 15 | 5 | 3 | 2 |
| Total | | | 27/29 [§] /30 [#] | 32/34 [§] /36 [#] | 4 | 675/725 [§] /750 [#] | 490/525 [§] /540 [#] | 115/125 [§] /130 [#] | 42/45 [§] /48 [#] | 28/30 [§] /32 [#] |

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

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

* Non University Examination (NUE)

CM-Continuous Mode evaluation for Theory subjects. Based on Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar) and Student – Teacher interaction, CM-Continuous Mode evaluation for Practical subjects. Based on Practical Records, Regular viva voce, etc

SEMESTER - I
Subject: Human Anatomy and Physiology I - Theory
Code: PHM21001
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

CO1. Explains the gross morphology, structure and functions of various organs of the human body

CO2. Describe the various homeostatic mechanisms and their imbalances.

CO3. Identify the various tissues and organs of different systems of human body.

CO4. Perform the various experiments related to special senses and nervous system.

CO5. Appreciate coordinated working pattern of different organs of each system.

| MODULE – I | Topics to be covered | 10 lectures |
|---------------------------------------|------------------------------------------------------------------------------------------------|-------------|
| Introduction to human body | Definition and scope of anatomy and physiology | 1 |
| | Levels of structural organization and body systems | 1 |
| | Basic life processes, homeostasis, basic anatomical terminology | 1 |
| Cellular level of organization | Structure and functions of cell, transport across cell membrane, cell division, cell junctions | 1 |
| | General principles of cell communication | 1 |
| | Intracellular signaling pathway activation by extracellular signal molecule | 1 |
| | Forms of intracellular signaling. a) Contact-dependent b) Paracrine c) Synaptic d) Endocrine | 1 |
| Tissue level of organization | Classification of tissues Structure, location and functions of epithelial tissues | 1 |
| | Structure, location and functions of Muscular and nervous tissues | 1 |
| | Structure, location and functions of Connective tissues | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|-----------------------------|-----------------------------------------------------------------------------------|--------------------|
| Integumentary system | Integumentary system | 1 |
| | Structure and functions of skin | 1 |
| Skeletal system | Divisions of skeletal system | 1 |
| | Types of bone | 1 |
| | Salient features and functions of bones of axial and appendicular skeletal system | 1 |
| | Organization of skeletal muscle | 1 |
| | Physiology of muscle contraction, neuromuscular junction | 1 |
| Joints | Structural and functional classification | 1 |
| | Types of joints movements | 1 |
| | Types of joints articulation | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|------------------------------|-----------------------------------------------------|--------------------|
| Body fluids and blood | Body fluids, composition and functions of blood | 1 |
| | Hemopoiesis | 1 |
| | Formation of hemoglobin, anemia | 1 |
| | Mechanisms of coagulation, blood grouping | 1 |
| | Rh factors, transfusion, its significance | 1 |
| | Disorders of blood | 1 |
| | Reticulo endothelial system | 1 |
| Lymphatic system | Lymphatic organs and tissues | 1 |
| | Lymphatic vessels | 1 |
| | Lymph circulation and functions of lymphatic system | 1 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-----------------------------------|----------------------------------------------------------------------------------------------------|--------------------|
| Peripheral nervous system. | Classification of peripheral nervous system. Structure and functions of sympathetic nervous system | 1 |
| | Structure and functions of parasympathetic nervous system | 1 |
| | Origin and functions of spinal nerves | 1 |
| | Origin and functions of cranial nerves | 1 |
| Special senses | Structure and functions of eye and their disorders | 1 |
| | Structure and functions of ear and their disorders | 1 |
| | Structure and functions of nose and their disorders | 1 |

| | | |
|--|-------------------------------------------------------|---|
| | Structure and functions of tongue and their disorders | 1 |
|--|-------------------------------------------------------|---|

| MODULE –V | Topics to be covered | 07 lectures |
|------------------------------|---------------------------------------------------------------------------------------------------|--------------------|
| Cardiovascular system | Heart – anatomy of heart, blood circulation, blood vessels | 1 |
| | Structure and functions of artery, vein and capillaries, | 1 |
| | Elements of conduction system of heart and heart beat, its regulation by autonomic nervous system | 1 |
| | Cardiac output | 1 |
| | Cardiac cycle | 1 |
| | Regulation of blood pressure, pulse, electrocardiogram | 1 |
| | Disorders of heart | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER - I
Subject: Human Anatomy and Physiology I - Practical
Code: PHM21007
2 Credits

Total Practicals Required – 4 Hours / week

Course Outcome: Upon completion of the experiments the student should be able to

CO1. Understand human body histology & microscopic process

CO2. Understanding both physiological/anatomical homeostatic mechanisms.

CO3. Learn about human skeleton

CO4. Learn about vital sign measurements

| Sl. No. | Experiment |
|---------|-------------------------------------------------------|
| 1 | Study of compound microscope. |
| 2 | Microscopic study of epithelial and connective tissue |
| 3 | Microscopic study of muscular and nervous tissue |
| 4 | Identification of axial bones |
| 5 | Identification of appendicular bones |
| 6 | Introduction to hemocytometry. |
| 7 | Enumeration of white blood cell (WBC) count |
| 8 | Enumeration of total red blood corpuscles (RBC) count |
| 9 | Determination of bleeding time |
| 10 | Determination of clotting time |
| 11 | Estimation of hemoglobin content |
| 12 | Determination of blood group. |
| 13 | Determination of erythrocyte sedimentation rate (ESR) |
| 14 | Determination of heart rate and pulse rate. |
| 15 | Recording of blood pressure. |

Recommended Books.

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

SEMESTER-I
Subject: Pharmaceutical Analysis I - Theory
Code: PHM21002
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This course deals with the fundamentals of analytical chemistry and principles of electrochemical analysis of drugs.

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

CO01. Develop the ideas with the fundamental of analytical chemistry

CO02. Know the sources of mistakes and errors in analysis and their minimizing techniques

CO03. Develop the fundamentals of volumetric analytical skills.

CO04. Understand the fundamentals and mechanism of precipitation, and complexometric titration

CO05. Understand the fundamentals and types of redox titration.

CO06. Acquire the basic knowledge in the principles of electrochemical analytical techniques

| Module – I | Topics to be covered | 10 lectures |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------|
| Pharmaceutical analysis | Definition and scope, Different techniques of analysis | 1 |
| | Methods of expressing concentration, Primary and secondary standards. | 1 |
| | Preparation and standardization of various molar and normal solutions. Oxalic acid, sodium hydroxide, hydrochloric acid | 1 |
| | Sodium thiosulphate, sulphuric acid, potassium permanganate and ceric ammonium sulphate | 1 |
| Errors | Sources of errors, types of errors, | 1 |
| | Methods of minimizing errors, accuracy, precision | 1 |
| | Significant figures | 1 |
| | Pharmacopoeia, | 1 |
| | Sources of impurities in medicinal agents | 1 |
| | Limit tests | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------|--------------------------------------------------------------------------|-------------|
| Acid base titration | Theories of acid base indicators, classification of acid base titrations | 1 |
| | theory involved in titrations of strong, weak, very weak acids and bases | 3 |
| | neutralization curves | 1 |
| Non aqueous titration | Theory of non-aqueous titration | 1 |
| | Solvents, acidimetry | 1 |
| | Alkalimetry titration | 1 |
| | Estimation of Sodium benzoate | 1 |
| | Ephedrine HCl | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|----------------------------------|----------------------------------------------------------------------|-------------|
| Precipitation titrations. | Mohr's method, Volhard's Modified Volhard's | 1 |
| | Fajans method, estimation of sodium chloride. | 1 |
| Complexometric titration | Classification, metal ion indicators | 1 |
| | Masking and demasking reagents, | 1 |
| | Estimation of Magnesium sulphate, and calcium gluconate | 1 |
| Gravimetry | Principle and steps involved in gravimetric analysis | 1 |
| | Purity of the precipitate, co-precipitation and post precipitation | 1 |
| | Estimation of barium sulphate | 1 |
| | Basic Principles, methods and application of diazotisation titration | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|----------------------------------------------------------------|----------------------------------------------|-------------|
| Redox titrations | Concepts of oxidation and reduction | 2 |
| Types of redox titrations (Principles and applications) | Cerimetry, Iodimetry | 2 |
| | Iodometry, Bromatometry, | 2 |
| | Dichrometry, Titration with potassium iodate | 2 |

| MODULE –V | Topics to be covered | 07 lectures |
|--------------------------------------------|---------------------------------------------------------------------------|-------------|
| Electrochemical methods of analysis | Conductometry- | 2 |
| | Introduction, Conductivity cell, Conductometric titrations, applications. | |
| | Potentiometry - | 2 |
| | Electrochemical cell, construction and working | |

| | | |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | of reference (Standard hydrogen, silver chloride electrode and calomel electrode) and indicator electrodes (metal electrodes and glass electrode) | |
| | methods to determine end point of potentiometric titration and applications. | 1 |
| | Polarography - | 1 |
| | Principle, Ilkovic equation, construction and working of dropping mercury electrode and rotating platinum electrode, applications | 1 |

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|-----------------|-----------------------------|--------------------|
| MODULE | Topics to be covered | 15 lectures |
| Tutorial | | |

SEMESTER - I
Subject: Pharmaceutical Analysis I - Practical
Code: PHM21008
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiments student shall be able to

CO1. Learn the fundamental methodology to prepare different strength of standard solutions.

CO2. Perform different types of titrations (neutralization, non-aqueous, precipitation, complexometry and redox titrations)

CO3. Standardize different standard solutions

CO4. Perform assay of different drugs by titrimetric method

| Sl. No. | Experiment |
|---------|-----------------------------------------------------------------------------------------------|
| 1 | 1- Limit Test of Chloride |
| | 2- Limit Test of Sulphate |
| 2 | 3-Limit Test of Iron |
| | 4- Limit Test of Arsenic |
| 3 | 5- Preparation and standardization of Sodium hydroxide |
| | 6-Preparation and standardization of Sulphuric acid |
| 4 | 7-Preparation and standardization of Sodium thiosulfate |
| | 8- Preparation and standardization of Potassium permanganate |
| 5 | 9- Preparation and standardization of Ceric ammonium sulphate |
| 6 | 10- Assay of Ammonium chloride by acid base titration |
| 7 | 11- Assay of ferrous sulphate by Cerimetry |
| 8 | 12- Assay of Copper sulphate by Iodometry |
| 9 | 13- Assay of Calcium gluconate by complexometry |
| 10 | 14- Assay of Hydrogen peroxide by Permanganometry |
| 11 | 15- Assay of Sodium benzoate by non-aqueous titration |
| 12 | 16- Assay of Sodium Chloride by precipitation titration |
| 13 | 17- Determination of Normality by Conductometric titration of strong acid against strong base |
| 14 | 18- Determination of Normality by Conductometric titration of strong acid against strong base |
| 15 | 19- Determination of Normality by Potentiometric titration of strong acid against strong base |

Recommended Books.

1. A.I. Vogel, Text Book of Quantitative Inorganic analysis
2. P. Gundu Rao, Inorganic Pharmaceutical Chemistry
3. Bentley and Driver's Textbook of Pharmaceutical Chemistry
4. John H. Kennedy, Analytical chemistry principles
5. Indian Pharmacopoeia.
6. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlon Press of University of London

SEMESTER-I
Subject: Pharmaceutics I - Theory
Code: PHM21003
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Know the history of profession of pharmacy.

CO2. Understand the basics of different dosage forms, pharmaceutical incompatibilities and pharmaceutical calculations.

CO3. Understand the professional way of handling the prescription.

CO4. Preparation of various conventional dosage forms.

| MODULE – I | Topics to be covered | 12 lectures |
|-------------------------------|------------------------------------------------------------------|--------------------|
| Historical background. | Historical background and development of profession of pharmacy. | 1 |
| | Pharmacy as a career | 1 |
| | Introduction to IP, BP, USP and Extra Pharmacopoeia. | 2 |
| Dosage forms. | Introduction to dosage forms, classification and definitions | 1 |
| | Introduction to dosage forms, classification and definitions | 1 |
| Prescription | Introduction to dosage forms, classification and definitions | 1 |
| | Definition, Parts of prescription, | 1 |
| | handling of Prescription Errors in prescription. | 1 |
| Posology | Definition, Factors affecting posology. | 1 |
| | Paediatric dose calculations based on age, body weight | 2 |

| MODULE – II | Topics to be covered | 09 lectures |
|-------------------------------------|----------------------------------------------------------------------------------------------|--------------------|
| Pharmaceutical calculations. | Weights and measures – Imperial & Metric system, Calculations involving percentage solutions | 1 |
| | Calculation by alligation, proof spirit | 1 |
| | isotonic solutions based on freezing point and molecular weight. | 1 |
| Powders. | Definition, classification, advantages and disadvantages, Simple & compound powders | 1 |
| | official preparations, dusting powders, effervescent, | 1 |
| | official preparations of efflorescent & hygroscopic powders, eutectic mixtures | 1 |
| | Geometric dilutions | 1 |
| Liquid dosage forms | Advantages and disadvantages of liquid dosage forms. | 1 |
| | Excipients used in formulation of liquid dosage forms. Solubility enhancement techniques | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|----------------------------|---------------------------------------------------------------------------------------------------|--------------------|
| Monophasic liquids. | Definitions and preparations of Gargles, Mouthwashes, Throat Paint, Eardrops, Nasal drops, Enemas | 1 |
| | Definitions and preparations of Syrups, Elixirs, Liniments and Lotions. | 1 |
| Biphasic liquids. | Definition, advantages and disadvantages, of Suspension | 1 |
| Suspensions. | Classifications, Preparation of suspensions Flocculated and Deflocculated suspension | 1 |
| | stability problems in suspension and | 1 |
| | methods to overcome instability problems in suspension | 1 |
| Emulsions | Definition, classification, emulsifying agent, | 1 |
| | test for the identification of type of Emulsion, | 1 |
| | Methods of preparation of Emulsion, | 1 |
| | stability problems in Emulsion & methods to overcome in instability in Emulsion | 1 |

| MODULE – IV | Topics to be covered | 07 lectures |
|---------------------|-------------------------------------------------------------------------------------------------------|--------------------|
| Suppository. | Definition, types, methods of preparations of suppository & advantages and disadvantages. suppository | 1 |
| | types of bases, in suppository | 1 |
| | Displacement value & its calculations, | 1 |
| | evaluation of suppositories | 1 |

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|---------------------------|-------------------------------------------------------------------------|---|
| Incompatibilities. | Definition, classification, physical incompatibilities with examples | 1 |
| | Definition, classification, chemical incompatibilities with examples | 1 |
| | Definition, classification, therapeutic incompatibilities with examples | 1 |

| MODULE – V | Topics to be covered | 11 lectures |
|--------------------------------|--------------------------------------------------|--------------------|
| Semisolid dosage forms. | Definitions, classification, mechanisms | 2 |
| | factors influencing dermal penetration of drugs | 2 |
| | Preparation of ointments, pastes, creams & gels. | 3 |
| | Excipients used in semi solid dosage forms. | 2 |
| | Evaluation of semi solid dosages forms | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-I
Subject: Pharmaceutics I- Practical
Code: PHM21009
2 Credits

Total Practical Required – 4 Hours / week

Course Outcomes: Upon completion of the experiments the student should be able to

CO1. Gain required hands-on experience to prepare simple monophasic oral liquid dosage forms

CO2. Understand basic methods to formulate conventional powder dosage forms

CO3. Perform experiments on bi-phasic oral liquid dosage forms

CO4. Learn the techniques to formulate conventional semisolid dosage forms

| Sl. No. | Category | Experiment |
|---------|-------------------------|-----------------------------------------------------|
| 1 | Syrups | Syrup IP'66 |
| | | Compound syrup of Ferrous Phosphate BPC'68 |
| 2 | Elixirs | Piperazine citrate elixir |
| | | Paracetamol pediatric elixir |
| 3 | Linctus | Terpin Hydrate Linctus IP'66 |
| | | Iodine Throat Paint (Mandles Paint) |
| 4 | Solutions | Strong solution of ammonium acetate |
| | | Cresol with soap solution |
| | | Lugol's solution |
| 5 | Suspensions | Calamine lotion |
| | | Magnesium Hydroxide mixture |
| | | Aluminium Hydroxide gel |
| 6 | Emulsions | Turpentine Liniment |
| | | Liquid paraffin emulsion |
| 7 | Powders and Granules | ORS powder (WHO) |
| | | Effervescent granules |
| | | Dusting powder |
| | | Divided powders |
| 8 | Suppositories | Glycero gelatin suppository |
| | | Cocoa butter suppository |
| | | Zinc Oxide suppository |
| 9 | Semisolids | Sulphur ointment |
| | | Non staining-iodine ointment with methyl salicylate |
| | | Carbopol gel |
| 10 | Gargles and Mouthwashes | Iodine gargle |
| | | Chlorhexidine mouthwash |

Recommended Books.

1. H.C. Ansel et al., Pharmaceutical Dosage Form and Drug Delivery System, Lippincott Williams and Walkins, New Delhi.
2. Carter S.J., Cooper and Gunn's-Dispensing for Pharmaceutical Students, CBS publishers, New Delhi.
3. M.E. Aulton, Pharmaceutics, The Science & Dosage Form Design, Churchill Livingstone, Edinburgh.
4. Indian pharmacopoeia.
5. British pharmacopoeia.
6. Lachmann. Theory and Practice of Industrial Pharmacy, Lea & Febiger Publisher, The University of Michigan.
7. Alfonso R. Gennaro Remington. The Science and Practice of Pharmacy, Lippincott Williams, New Delhi.
8. Carter S.J., Cooper and Gunn's. Tutorial Pharmacy, CBS Publications, New Delhi.
9. E.A. Rawlins, Bentley's Text Book of Pharmaceutics, English Language Book Society, Elsevier Health Sciences, USA.
10. Isaac Ghebre Sellassie... Pharmaceutical Pelletization Technology, Marcel Dekker, INC, New York.
11. Dilip M. Parikh... Handbook of Pharmaceutical Granulation Technology, Marcel Dekker, INC, New York.
12. Francoise Nieloud and Gilberte Marti-Mestres. Pharmaceutical Emulsions and Suspensions, Marcel Dekker, INC, New York.

SEMESTER-I
Subject: Pharmaceutical Inorganic Chemistry - Theory
Code: PHM21004
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

Course Outcome: Upon completion of course student shall be able to

CO1. Know the principles of limit tests.

CO2. Understand different classes of inorganic pharmaceuticals and their analysis

CO3. Know about identification and test for purity of different inorganic pharmaceuticals.

CO4. Acquire knowledge about the sources of impurities and methods to determine the impurities in inorganic drugs and pharmaceuticals

CO5. Understand the medicinal and radiopharmaceutical importance of inorganic compounds

CO6. Introduced to a variety of inorganic drug classes.

| MODULE – I | Topics to be covered | 10 lectures |
|-------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Impurities in pharmaceutical substances: | History of Pharmacopoeia, Sources and types of impurities, | 1 |
| | principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals, modified limit test for Chloride and Sulphate | 3 |
| General methods of preparation | assay for the compounds superscripted with asterisk (*) , properties and medicinal uses of inorganic compounds belonging to the following classes | 6 |

| MODULE – II | Topics to be covered | 10 lectures |
|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Acids, Bases and Buffers | Buffer equations and buffer capacity in general, buffers in pharmaceutical systems, preparation, stability, buffered isotonic solutions, measurements of tonicity, calculations and methods of adjusting isotonicity. | 2 |
| Major extra and intracellular electrolytes | Functions of major physiological ions, Electrolytes used in the replacement therapy: Sodium chloride*, Potassium chloride, Calcium | 4 |

| | | |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | gluconate* and Oral Rehydration Salt (ORS), Physiological acid base balance. | |
| Dental products | Dentifrices, role of fluoride in the treatment of dental caries, Desensitizing agents, Calcium carbonate, Sodium fluoride, and Zinc eugenol cement. | 4 |

| MODULE – III | | Topics to be covered | 10 lectures |
|--------------------------------|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Gastrointestinal agents | Acidifiers | Ammonium chloride* and Dil. HCl | 1 |
| | Antacid | Ideal properties of antacids, combinations of antacids, Sodium Bicarbonate*, Aluminum hydroxide gel, Magnesium hydroxide mixture | 3 |
| | Cathartics | Magnesium sulphate, Sodium orthophosphate, Kaolin and Bentonite | 3 |
| | Antimicrobials | Mechanism, classification, Potassium permanganate, Boric acid, Hydrogen peroxide*, Chlorinated lime*, Iodine and its preparations | 3 |

| MODULE – IV | | Topics to be covered | 8 lectures |
|----------------------------|--|-------------------------------------------------------------------------|-------------------|
| Expectorants | | Potassium iodide, Ammonium chloride*. | 1 |
| Emetics | | Copper sulphate*, Sodium potassium tartarate | 2 |
| Haematinics | | Ferrous sulphate*, Ferrous gluconate | 2 |
| Poison and Antidote | | Sodium thiosulphate*, Activated charcoal, Sodium nitrite ³³³ | 1 |
| Astringents | | Zinc Sulphate, Potash Alum | 1 |

| MODULE – V | | Topics to be covered | 7 lectures |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------------|
| Radiopharmaceuticals | Radio activity, Measurement of radioactivity | | 2 |
| | Properties of α , β , γ radiations, Half life, radio isotopes and study of radio isotopes - Sodium iodide I131, | | 2 |
| | Storage conditions, precautions & pharmaceutical application of radioactive substances | | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-I
Subject: Pharmaceutical Inorganic Chemistry - Practical
Code: PHM21010
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiments student shall be able to

CO1. Design and execute detection of likely impurities in sample compounds.

CO2. Know about different function and role of major extracellular and intracellular electrolytes and buffer solutions

CO3. Prepare different types gastrointestinal agents and its category

CO4. Carry out the preparation and study of important inorganic pharmaceuticals

| Sl. No. | Experiment |
|---------|----------------------------------------------------------------------------------|
| 1 | Limit test for Chlorides and Sulphates |
| | Modified limit test for Chlorides and Sulphates |
| 2 | Limit test for Iron |
| | Limit test for Heavy metals |
| 3 | Limit test for Lead |
| | Limit test for Arsenic |
| 4 | Identification test of Magnesium hydroxide |
| | Identification test of Ferrous sulphate |
| 5 | Identification test of Sodium bicarbonate |
| | Identification test of Calcium gluconate |
| 6 | Identification test of Copper sulphate |
| | Test for purity Swelling power of Bentonite |
| 7 | Test for purity Neutralizing capacity of aluminum hydroxide gel |
| | Test for purity Determination of potassium iodate and iodine in potassium Iodide |
| 8 | Preparation of inorganic pharmaceuticals Boric acid |
| 9 | Preparation of inorganic pharmaceuticals Potash alum |
| 10 | Preparation of inorganic pharmaceuticals Ferrous sulphate |

Recommended Books.

1. A.H. Beckett & J.B. Stenlake's, Practical Pharmaceutical Chemistry Vol I & II, Stahlone Press of University of London, 4th edition.
2. A.I. Vogel, Text Book of Quantitative Inorganic analysis
3. P. Gundu Rao, Inorganic Pharmaceutical Chemistry, 3rd Edition
4. M.L Schroff, Inorganic Pharmaceutical Chemistry
5. Bentley and Driver's Textbook of Pharmaceutical Chemistry
6. Anand & Chatwal, Inorganic Pharmaceutical Chemistry
7. Indian Pharmacopoeia

SEMESTER-I
Subject: Communication Skills - Theory
Code: PHM21005
2 Credits

Total Lectures Required –30 hrs

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

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

CO1. Understand the behavioral needs for a Pharmacist to function effectively in the areas of pharmaceutical operation

CO2. Communicate effectively (Verbal and Non Verbal)

CO3. Effectively manage the team as a team player

CO4. Develop interview skills

CO5. Develop Leadership qualities and essentials

| MODULE – I | Topics to be covered | 07 lectures |
|---------------------------------------|-------------------------------------------------------------------------------------|-------------|
| Communication Skills. | Introduction, Definition, The Importance of Communication | 1 |
| | The Communication Process – Source, Message, | 1 |
| | Encoding, Channel, Decoding, Receiver, Feedback, Context | 1 |
| Barriers to communication. | Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers | 1 |
| | Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers | 1 |
| Perspectives in Communication. | Introduction, Visual Perception, Language, Other factors affecting our perspective | 1 |
| | Past Experiences, Prejudices, Feelings, Environment | 1 |

| MODULE – II | Topics to be covered | 07 lectures |
|-----------------------------------|----------------------------------------------------------|-------------|
| Elements of Communication. | Introduction, Face to Face Communication | 1 |
| | Tone of Voice, Body Language (Non-verbal communication), | 1 |
| | Verbal Communication, Physical | 1 |

| | | |
|------------------------------|-----------------------------------------------------------------------------------------------------|---|
| | Communication | |
| Communication Styles. | Introduction, The Communication Styles Matrix with example for each -Direct Communication Style | 1 |
| | Introduction, The Communication Styles Matrix with example for each Spirited Communication Style | 1 |
| | Introduction, The Communication Styles Matrix with example for each Systematic Communication Style | 1 |
| | Introduction, The Communication Styles Matrix with example for each Considerate Communication Style | 1 |

| MODULE – III | Topics to be covered | 07 lectures |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|--------------------|
| Basic Listening Skills. Effective Written Communication. | Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations | 1 |
| | Introduction, When and When Not to Use Written Communication - | 1 |
| | Complexity of the Topic, Amount of Discussion Required, Shades of Meaning, Formal Communication | 1 |
| Writing Effectively. | Subject Lines, Put the Main Point First | 2 |
| | Know Your Audience, Organization of the Message | 2 |

| MODULE – IV | Topics to be covered | 07 lectures |
|------------------------------|-------------------------------------------------|--------------------|
| Interview Skills. | Purpose of an interview | 1 |
| | Do's and Dont's of an interview | 1 |
| Giving Presentations. | Dealing with Fears, Planning your Presentation, | 2 |
| | Structuring Your Presentation, | 1 |
| | Delivering Your Presentation | 1 |
| | Techniques of Delivery | 1 |

| MODULE – V | Topics to be covered | 04 lectures |
|--------------------------|---------------------------------------------------------|--------------------|
| Group Discussion. | Introduction, Communication skills in group discussion, | 2 |
| | Do's and Dont's of group discussion | 2 |

SEMESTER-I
Subject: Communication Skills - Practical
Code: PHM21011
1 Credits

Total Practical Required – 2 Hours / Week

Course Outcome: Upon completion of the experiments the student shall be able to

CO1. Communicate effectively without grammar mistake.

CO2. Develop the ability to speak English by developing vocabulary, and understanding phonetics

CO3. Develop the ability to write letter, essay, reports, curriculum vitae etc. in English.

CO4. Develop the ability to listen and understand media, audio, video, speeches and the likes

The following learning modules are to be conducted using wordsworth® English language lab software.

| Sl. No. | Category | Experiment |
|---------|----------------------------------------------------------|------------------------------------------------------|
| 1 | Basic communication covering the following topics | Meeting People |
| | | Asking Questions |
| | | Making Friends |
| | | What did you do? |
| | | Do's and Dont's |
| 2 | Pronunciations covering the following topics | Pronunciation (Consonant Sounds) |
| | | Pronunciation and Nouns |
| | | Pronunciation (Vowel Sounds) |
| 3 | Advanced Learning | Listening Comprehension / Direct and Indirect Speech |
| | | Figures of Speech |
| | | Effective Communication |
| | | Writing Skills |
| | | Effective Writing |
| | | Interview Handling Skills |
| | | E-Mail etiquette Presentation Skills |

Recommended Books.

1. Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
2. Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
3. Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
4. Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
5. The Ace of Soft Skills... Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
6. Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
7. Communication skills for professionals, Konar nira, 2nd Edition, New arrivals –PHI, 2011
8. Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
9. Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
10. Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
11. Effective communication, John Adair, 4th Edition, Pan Mac Millan, 2009
12. Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999.

SEMESTER-I
Subject: Remedial Biology - Theory
Code: PHM21013
2 Credits

Total Lectures Required –30 hrs

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

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

CO1. Understand classification system of the living world.

CO2. Know the morphology and anatomy of plants and animals

CO3. Understand the organ system in plant and there physiology

CO4. Know the organ system in animals and there physiology

CO5. Know about the nutrition and growth regulators of plant

CO6. Understand cell biology (Basic Nature of Plant cell and Animal cell)

| MODULE – I | Topics to be covered | 07 lectures |
|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-------------|
| Living world. | Definition and characters of living organisms | 1 |
| | Diversity in the living world | 1 |
| | Binomial nomenclature | 1 |
| | Five kingdoms of life and basis of classification. Salient features of Monera, Potista, Fungi, Animalia and Plantae, Virus | 1 |
| Morphology of Flowering plants | Morphology of different parts of flowering plants – Root, stem, inflorescence, | 1 |
| | flower, leaf, fruit, seed. General Anatomy of Root, stem, leaf of monocotyledons & Dicotylidones | 2 |

| MODULE – II | Topics to be covered | 07 lectures |
|------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------|
| Body fluids and circulation | Composition of blood, blood groups, coagulation of blood | 1 |
| | Composition and functions of lymph | 1 |
| | Human circulatory system Structure of human heart and blood vessels; Cardiac cycle, cardiac output and ECG | 1 |

| | | |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------|---|
| Digestion and Absorption | Human alimentary canal and digestive glands; Role of digestive enzymes, Digestion, absorption and assimilation of digested food | 2 |
| Breathing and respiration | Human respiratory system Mechanism of breathing and its regulation | 1 |
| | Exchange of gases, transport of gases and regulation of respiration; Respiratory volumes | 1 |

| MODULE – III | Topics to be covered | 07 lectures |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|--------------------|
| Excretory products and their elimination | Modes of excretion, Human excretory system- structure and function | 1 |
| | Urine formation, Rennin angiotensin system | 1 |
| Neural control and coordination | Definition and classification of nervous system Structure of a neuron, Generation and conduction of nerve impulse | 1 |
| | Structure of brain and spinal cord, Functions of cerebrum, cerebellum, hypothalamus and medulla oblongata | 1 |
| Chemical coordination and regulation | Endocrine glands and their secretions, Functions of hormones secreted by endocrine glands | 1 |
| Human reproduction | Parts of female reproductive system, Parts of male reproductive system | 1 |
| | Spermatogenesis and Oogenesis, Menstrual cycle | 1 |

| MODULE – IV | Topics to be covered | 05 lectures |
|-------------------------------------|---------------------------------------------------------------------|--------------------|
| Plants and mineral nutrition | Essential mineral, macro and micronutrients Nitrogen metabolism, | 1 |
| | Nitrogen cycle, biological nitrogen fixation | 1 |
| Photosynthesis | Autotrophic nutrition, photosynthesis. | 1 |
| | Photosynthetic pigments, | 1 |
| | Factors affecting photosynthesis | 1 |

| MODULE – V | Topics to be covered | 04 lectures |
|-------------------------------------|-----------------------------------------------------------------------------------------------|--------------------|
| Plant respiration. | Respiration, glycolysis, fermentation (anaerobic). | 1 |
| Plant growth and development | Phases and rate of plant growth, Condition of growth, Introduction to plant growth regulators | 1 |
| Cell - The unit of life | Structure and functions of cell and cell organelles. Cell division | 1 |
| Tissues | Definition, types of tissues, location and functions. | 1 |

SEMESTER-I
Subject: Remedial Biology – Practical
Code: PHM21012
1 Credits

Total Practical Required – 2 Hours / Week

Course Outcomes: Upon completion of the experiments, the student shall be able to

CO1. Understand about the handling of microscopes and preparation of slides

CO2. Know about the parts of plants and their microscopic characteristics

CO3. Estimate different hematological parameters

CO4. Know about the skeletal systems and bones

| Sl. No. | Experiment |
|-------------------------------------------|------------------------------------------------------------------------------------------------------|
| 1. Introduction to experiments in biology | a) Study of Microscope |
| | b) Section cutting techniques |
| | c) Mounting and staining |
| | d) Permanent slide preparation |
| 2. | Study of cell and its inclusions |
| | Study of Stem, Root, Leaf, seed, fruit, flower and their modifications |
| 3 | Detailed study of frog by using computer models |
| 4 | Microscopic study and identification of tissues pertinent to Stem, Root Leaf, seed, fruit and flower |
| 5 | Identification of bones |
| 6 | Determination of blood group |
| 7 | Determination of blood pressure |
| 8 | Determination of tidal volume |

Reference Books

1. Practical human anatomy and physiology. by S.R.Kale and R.R.Kale.
2. A Manual of pharmaceutical biology practical by S.B.Gokhale, C.K.Kokate and S.P.Shriwastava.
3. Biology practical manual according to National core curriculum .Biology forum of Karnataka. Prof .M.J.H.Shafi
4. Text book of Biology by S. B. Gokhale
5. A Text book of Biology by Dr. Thulajappa and Dr. Seetaram.
6. A Text book of Biology by B.V. Sreenivasa Naidu
7. A Text book of Biology by Naidu and Murthy
8. Botany for Degree students By A.C.Dutta.
9. Outlines of Zoology byM. Ekambaranatha ayyer and T. N. Ananthakrishnan.
10. A manual for pharmaceutical biology practical by S.B. Gokhale and C. K. Kokate

SEMESTER-I
Subject: Remedial Mathematics - Theory
 Code: PHM21006
 2 Credits

Total Lectures Required –30 hrs

Title: This is an introductory course in mathematics. This subject deals with the Introduction to Partial fraction, Logarithm, matrices and Determinant, Analytical geometry, Calculus, differential equation and Laplace transform.

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

CO1. Evaluate and demonstrate the partial fraction, logarithms, functions and limits and continuity.

CO2. Explain matrices and determination.

CO3. Explain simple equations using graphs.

CO4. Evaluate relationship and functions; fundamentals of trigonometry and geometry.

CO5. Analyze sequences and binomial series.

CO6. Evaluate calculus and integral calculus.

| MODULE – I | Topics to be covered | 06 lectures |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Partial fraction. | Introduction, Polynomial, Rational fractions, Proper and Improper fractions, Partial fraction, Resolving into Partial fraction, Application of Partial Fraction in Chemical Kinetics and Pharmacokinetics | 2 |
| Logarithms | Introduction, Definition, Theorems/Properties of logarithms, Common logarithms, Characteristic and Mantissa, worked examples, application of logarithm to solve pharmaceutical problems | 2 |
| Limits and continuity. | Introduction, Limit of a function, Definition of limit of a function ($\lim_{n \rightarrow \infty} x_n = a$ definition), $\lim_{n \rightarrow \infty} \sin \frac{1}{n} = 0$, $\lim_{x \rightarrow a} x = a$ | 2 |

| MODULE – II | Topics to be covered | 06 lectures |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Matrices and Determinant. | Introduction matrices, Types of matrices, Operation on matrices, | 2 |
| | Transpose of a matrix, Matrix Multiplication, Determinants, Properties of determinants , Product of determinants, Minors and co-Factors, Adjoint or adjugate of a square matrix Singular and non-singular matrices, | 2 |
| | Inverse of a matrix, Solution of system of linear of equations using matrix method, Cramer’s rule, Characteristic equation and roots of a square matrix, Cayley–Hamilton theorem, Application of Matrices in solving Pharmacokinetic equations | 2 |

| MODULE – III | Topics to be covered | 06 lectures |
|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Calculus Differentiation Without Proof | Introductions, Derivative of a function, Derivative of a constant, Derivative of a product of a constant and a function , Derivative of the sum or difference of two functions, Derivative of the product of two functions (product formula), Derivative of the quotient of two functions (Quotient formula) | 2 |
| | Derivative of x^n w.r.t x , where n is any rational number, Derivative of e^x , Derivative of $\log_e x$, Derivative of a^x , Derivative of trigonometric functions from first principles | 2 |
| | Successive Differentiation, Conditions for a function to be a maximum or a minimum at a point. Application | 2 |

| MODULE – IV | Topics to be covered | 06 lectures |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Analytical Geometry Introduction. | Signs of the Coordinates, Distance formula, | 2 |
| Straight Line | Slope or gradient of a straight line, Conditions for parallelism and perpendicularity of two lines, Slope of a line joining two points, Slope – intercept form of a straight line | 2 |
| Integration | Introduction, Definition, Standard formulae, Rules of integration , Method of substitution, Method of Partial fractions, Integration by parts, definite integrals, application | 2 |

| MODULE –V | Topics to be covered | 06 lectures |
|-----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Differential Equations... Application in solving Pharmacokinetic equations | Some basic definitions, Order and degree, Equations in separable form , Homogeneous equations, Linear Differential equations, Exact equations, | 3 |
| Laplace Transform... | Introduction, Definition, Properties of Laplace transform, Laplace Transforms of elementary functions, Inverse Laplace transforms, Laplace transform of derivatives, Application to solve Linear differential equations Application in solving Chemical kinetics and Pharmacokinetics equations | 3 |

Recommended Books

1. Differential Calculus by Shanthinarayan
2. Pharmaceutical Mathematics with application to Pharmacy by Panchaksharappa Gowda D.H.
3. Integral Calculus by Shanthinarayan
4. Higher Engineering Mathematics by Dr.B.S.Grewal

Scheme of Study-Semester II

| Sl. No. | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|-------------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|------------|
| 1 | PHM22014 | Human Anatomy and Physiology II– Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM22015 | Pharmaceutical Organic Chemistry I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM22016 | Biochemistry – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM22017 | Pathophysiology – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM22018 | Computer Applications in Pharmacy – Theory * | 3 | 3 | - | 75 | 50 | 15 | 8 | 2 |
| 6 | PHM22019 | Environmental sciences – Theory* | 3 | 3 | - | 75 | 50 | 15 | 8 | 2 |
| 7 | PHM22020 | Human Anatomy and Physiology II– Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM22021 | Pharmaceutical Organic Chemistry I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 9 | PHM22022 | Biochemistry – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 10 | PHM22023 | Computer Applications in Pharmacy – Practical * | 1 | 2 | - | 25 | 15 | 5 | 3 | 2 |
| Total | | | 29 | 32 | 4 | 725 | 520 | 125 | 50 | 30 |

*NonUniversity Subject

SEMESTER-II
Subject: Human Anatomy and Physiology II - Theory
Code: PHM22014
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: 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 Outcome: Upon completion of this course the student should be able to.

CO1. Understand the gross morphology, structure and functions of various organs of the human body.

CO2. Describe the various homeostatic mechanisms and their imbalances.

CO3. Identify the various tissues and organs of different systems of human body.

CO4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.

CO5. Appreciate coordinated working pattern of different organs of each system

CO6. Appreciate the interlinked mechanisms in the maintenance of normal functioning (Homeostasis) of human body.

| MODULE – I | Topics to be covered | 10 lectures |
|----------------|--------------------------------------------------------------------------------------------------|-------------|
| Nervous system | Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, | 2 |
| | electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. | 2 |
| | Central nervous system. Meninges, ventricles of brain and | 2 |
| | cerebrospinal fluid. structure and functions of brain (cerebrum, brain stem, cerebellum) | 2 |
| | spinal cord (gross structure, functions of afferent and efferent nerve tracts, reflex activity) | 2 |

| MODULE – II | Topics to be covered | 06 lectures |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Digestive system | Anatomy of GI Tract with special reference to anatomy and functions of stomach, | 1 |
| Energetics | Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine | 1 |
| | anatomy and functions of salivary glands, pancreas and liver, | 1 |
| | movements of GIT, digestion and absorption of nutrients and disorders of GIT. | 1 |
| | Formation and role of ATP, Creatinine Phosphate and BMR. | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Respiratory system | Anatomy of respiratory system with special reference to anatomy of lungs, | 2 |
| Urinary system | mechanism of respiration, regulation of respiration | 2 |
| | Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods | 2 |
| | Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, | 2 |
| | micturition reflex and role of kidneys in acid base balance, role of RAS in kidney and disorders of kidney | 2 |

| MODULE – IV | Topics to be covered | 10 lectures |
|-------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------|
| Endocrine system | Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland | 2 |
| | Classification of hormones, mechanism of hormone action, structure and functions of, parathyroid gland, adrenal gland | 2 |
| | Classification of hormones, mechanism of hormone action, | 2 |

| | | |
|--|--------------------------------------------------------------------------------|---|
| | structure and functions of of pancreas, pineal gland, thymus | |
| | Disorders of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, | 2 |
| | Disorders of pituitary gland, thyroid gland, pancreas, pineal gland, thymus | 2 |

| MODULE –V | Topics to be covered | 09 lectures |
|---------------------------------|--------------------------------------------------------------------------------------------------|-------------|
| Reproductive system | Anatomy of male and female reproductive system, | 2 |
| | Functions of male and female reproductive system, sex hormones, | 2 |
| | physiology of menstruation, fertilization, spermatogenesis, oogenesis, pregnancy and parturition | 2 |
| Introduction to genetics | Chromosomes, genes and DNA | 2 |
| | protein synthesis, genetic pattern of inheritance | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|----------------------|-------------|
| Tutorial | | |

SEMESTER-II
Subject: Human Anatomy and Physiology II - Practical
Code: PHM22020
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment the student should be able to.

CO1. Understand the gross morphology, structure and functions of various organs of the human body.

CO2. Describe the various homeostatic mechanisms and their imbalances.

CO3. Identify the various tissues and organs of different systems of human body.

CO4. Perform the hematological tests like blood cell counts, haemoglobin estimation, bleeding/clotting time etc and also record blood pressure, heart rate, pulse and respiratory volume.

| Sl. No. | Experiment |
|---------|------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | To study the integumentary and special senses using specimen, models, etc. |
| 2 | To study the nervous system using specimen, models, etc., |
| 3 | To study the endocrine system using specimen, models, etc |
| 4 | To demonstrate the general neurological examination |
| 5 | To demonstrate the function of olfactory nerve |
| 6 | To examine the different types of taste. |
| 7 | To demonstrate the visual acuity |
| 8 | To demonstrate the reflex activity |
| 9 | Recording of body temperature |
| 10 | To demonstrate positive and negative feedback mechanism. |
| 11 | Determination of tidal volume and vital capacity. |
| 12 | Study of digestive, respiratory, cardiovascular systems, urinary and reproductive systems with the help of models, charts and specimens. |
| 13 | Recording of basal mass index |
| 14 | Study of family planning devices and pregnancy diagnosis test |
| 15 | Demonstration of total blood count by cell analyser |
| 16 | Permanent slides of vital organs and gonads. |

Recommended Books.

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

SEMESTER-II
Subject: Pharmaceutical Organic Chemistry I - Theory
 Code: PHM22015
 4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject deals with classification and nomenclature of simple organic compounds, structural isomerism, intermediates forming in reactions, important physical properties, reactions and methods of preparation of these compounds. The syllabus also emphasizes on mechanisms and orientation of reactions.

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

CO1. Elucidate the structure, name and the type of isomerism of the organic compound

CO2. Understand the reaction, name the reaction and orientation of reactions

CO3. Understand the Account for reactivity/stability of compounds,

CO4. Identify/confirm the identification of organic compound

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained. To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

| MODULE – I | Topics to be covered | 07 lectures |
|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Classification, nomenclature and isomerism | Classification of Organic Compounds Common and IUPAC systems of nomenclature of organic compounds (up to 10 Carbons open chain and carbocyclic compounds) Structural isomerisms in organic compounds | 07 |

| MODULE – II | Topics to be covered | 10 lectures |
|--------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Alkanes*, Alkenes* and Conjugated dienes* | SP ³ hybridization in alkanes, Halogenation of alkanes, uses of paraffins. Stabilities of alkenes, SP ² hybridization in alkenes | 2 |
| | E1 and E2 reactions – kinetics, order of reactivity of alkyl halides, rearrangement of carbocations, Saytzeffs orientation and evidences. E1 verses E2 reactions, Factors affecting E1 and E2 reactions. | 2 |

| | | |
|--|----------------------------------------------------------------------------------------------------------------------------------|---|
| | Ozonolysis, electrophilic addition reactions of alkenes, Markownikoff's orientation, free radical addition reactions of alkenes, | 2 |
| | Anti Markownikoff's orientation. Stability of conjugated dienes, | 2 |
| | Diel-Alder, electrophilic addition, free radical addition reactions of conjugated dienes, allylic rearrangement | 2 |

| MODULE –III | Topics to be covered | 10 lectures |
|-----------------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Alkyl halides* | SN1 and SN2 reactions - kinetics, order of reactivity of alkyl halides, stereochemistry and rearrangement of carbocations. | 2 |
| | SN1 versus SN2 reactions, Factors affecting SN1 and SN2 reactions | 2 |
| | Structure and uses of ethylchloride, Chloroform, trichloroethylene, tetrachloroethylene, dichloromethane, tetrachloromethane and iodoform. | 2 |
| Alcohols* | Qualitative tests, Structure and uses of Ethyl alcohol, Methyl alcohol, | 2 |
| | Qualitative tests, Structure and uses of chlorobutanol, Cetosteryl alcohol, Benzyl alcohol, Glycerol, Propylene glycol | 2 |

| MODULE –IV | Topics to be covered | 10 lectures |
|--------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------|
| Carbonyl compounds* (Aldehydes and ketones) | Nucleophilic addition, Electromeric effect, aldol condensation, Crossed Aldol condensation | 2 |
| | Cannizzaro reaction, Crossed Cannizzaro reaction, Benzoin condensation | 2 |
| | Perkin condensation, qualitative tests, Structure and | 2 |

| | | |
|--|------------------------------------------------------------------------------------------------------|---|
| | uses of Formaldehyde, Paraldehyde, Acetone, | |
| | Perkin condensation, qualitative tests, Structure and uses of Chloral hydrate, Hexamine, | 2 |
| | Perkin condensation, qualitative tests, Structure and uses of Benzaldehyde, Vanilin, Cinnamaldehyde. | 2 |

| MODULE –V | Topics to be covered | 08 lectures |
|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Carboxylic acids* | Acidity of carboxylic acids, effect of substituents on acidity, inductive effect | 1 |
| | qualitative tests for carboxylic acids ,amide and ester | 1 |
| | Structure and Uses of Acetic acid, Lactic acid, Tartaric acid, Citric acid, Succinic acid. Oxalic acid, Salicylic acid, Benzoic acid, Benzyl benzoate, Dimethyl phthalate, Methyl salicylate and Acetyl salicylic acid | 2 |
| Aliphatic amines* | Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethanolamine | 2 |
| | Basicity, effect of substituent on Basicity. Qualitative test, Structure and uses of Ethylenediamine, Amphetamine | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|----------------------|-------------|
| Tutorial | | |

SEMESTER-II
Subject: Pharmaceutical Organic Chemistry I - Practical
Code: PHM22021
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment the student shall be able to

CO1. Carry out preparation of suitable solid derivatives from organic compounds

CO2. Demonstrate and understand Construction of molecular models

CO3. Understand Classification of Organic Compounds and its Preliminary test, Solubility test etc

CO4. Execute Melting point/Boiling point of various organic compounds

| Sl. No. | Experiment |
|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Systematic qualitative analysis of unknown organic compounds like | |
| 1 | Preliminary test: Color, odour, aliphatic/aromatic compounds, saturation and unsaturation, etc. |
| 2 | Detection of elements like Nitrogen, Sulphur and Halogen by Lassaigne's test |
| 3 | Solubility test |
| 4 | Functional group test like Phenols, Amides/ Urea, Carbohydrates, Amines, Carboxylic acids, Aldehydes and Ketones, Alcohols, Esters, Aromatic and Halogenated Hydrocarbons, Nitro compounds and Anilides. |
| 5 | Melting point/Boiling point of organic compounds |
| 6 | Identification of the unknown compound from the literature using melting point/ boiling point. |
| 7 | Preparation of the derivatives and confirmation of the unknown compound by melting point/ boiling point. |
| 8 | Minimum 5 unknown organic compounds to be analysed systematically. |
| 9 | Preparation of suitable solid derivatives from organic compounds |
| 10 | Construction of molecular models |

Recommended Books

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.
8. Introduction to Organic Laboratory techniques by Pavia, Lampman and Kriz.
9. Reaction and reaction mechanism by Ahluwalia/Chatwal.

SEMESTER-II
Subject: Biochemistry – Theory
Code: PHM22016
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: 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.

Course Outcome: Upon completion of course student shall be able to

CO1. Acquire knowledge about chemistry and biological importance of biological macromolecules and biochemical energetics.

CO2. Understand the metabolism of carbohydrate in physiological and pathological conditions and biological oxidation of nutrient molecules.

CO3. Understand the metabolism of lipids in physiological and pathological conditions.

CO4. Understand the metabolism of proteins in physiological and pathological conditions

CO5. Understand the genetic organization of mammalian genome and functions of DNA in the synthesis of RNAs and proteins.

CO6. Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes.

| MODULE – I | Topics to be covered | 08 lectures |
|----------------------|-------------------------------------------------------------------------------------------------------------------|-------------|
| Biomolecules | Introduction, classification, chemical nature and biological role of carbohydrate, lipids | 2 |
| | Introduction, classification, chemical nature and biological role of nucleic acids, amino acids and proteins. | 2 |
| Bioenergetics | Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy | 2 |

| | | |
|--|--------------------------------------------------------------------------------------------------------------------|---|
| | Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP | 2 |
|--|--------------------------------------------------------------------------------------------------------------------|---|

| MODULE – II | Topics to be covered | 10 lectures |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Carbohydrate metabolism | Glycolysis – Pathway, energetics and significance Citric acid cycle- Pathway, energetics and significance HMP shunt and its significance | 2 |
| | Glucose-6-Phosphate dehydrogenase(G6PD) deficiency Glycogen metabolism Pathways and glycogen storage diseases (GSD) | 2 |
| | Gluconeogenesis- Pathway and its significance Hormonal regulation of blood glucose level and Diabetes mellitus | 2 |
| Biological oxidation | Electron transport chain (ETC) and its mechanism. Oxidative phosphorylation & its mechanism and substrate phosphorylation | 2 |
| | Inhibitors ETC and oxidative phosphorylation/Uncouplers | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Lipid metabolism | β -Oxidation of saturated fatty acid (Palmitic acid) Formation and utilization of ketone bodies; ketoacidosis De novo synthesis of fatty acids (Palmitic acid) | 2 |
| | Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D | 2 |
| | Disorders of lipid metabolism... Hypercholesterolemia, atherosclerosis, fatty liver and | 2 |

| | | |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | obesity. | |
| Amino acid metabolism | General reactions of amino acid metabolism... Transamination, deamination & decarboxylation, urea cycle and its disorders Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenylketonuria, Albinism, alcaptonuria, tyrosinemia) | 2 |
| | Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline Catabolism of heme; hyperbilirubinemia and jaundice | 2 |

| MODULE – IV | Topics to be covered | 10 lectures |
|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------|
| Nucleic acid metabolism and genetic information transfer | Biosynthesis of purine and pyrimidine nucleotides Catabolism of purine nucleotides and Hyperuricemia and Gout disease | 2 |
| | Organization of mammalian genome Structure of DNA and RNA and their functions | 2 |
| | DNA replication (semi conservative model) | 2 |
| | Transcription or RNA synthesis Genetic code, | 2 |
| | Translation or Protein synthesis and inhibitors | 2 |

| MODULE – V | Topics to be covered | 07 lectures |
|-------------------|--------------------------------------------------------------------------|--------------------|
| Enzymes | Introduction, properties, nomenclature and IUB classification of enzymes | 1 |
| | Enzyme kinetics (Michaelis plot, Line Weaver Burke plot) | 2 |
| | Enzyme inhibitors with examples | 1 |

| | | |
|--|-------------------------------------------------------------------------------------------------------------------------------|---|
| | Regulation of enzymes... enzyme induction and repression, allosteric enzymes regulation | 1 |
| | Therapeutic and diagnostic applications of enzymes and isoenzymes Coenzymes – Structure and biochemical functions | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-II
Subject: Biochemistry – Practical
Code: PHM22021
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment student shall able to

CO1. Understand the basic principles of protein and polysaccharide structure

CO2. Acquire knowledge in qualitative and quantitative estimation of the biological macromolecules.

CO3. Know the interpretation of data emanating from a clinical test lab

CO4. Know how physiological conditions influence the structures and re-activities of biomolecules.

| Sl. No. | Experiment |
|---------|-------------------------------------------------------------------------------------------------|
| 1 | Qualitative analysis of carbohydrates (Glucose, Fructose, Lactose, Maltose, Sucrose and starch) |
| 2 | Identification tests for Proteins (albumin and Casein |
| 3 | Quantitative analysis of reducing sugars (DNSA method) and Proteins (Biuret method) |
| 4 | Qualitative analysis of urine for abnormal constituents |
| 5 | Determination of blood creatinine |
| 6 | Determination of blood sugar |
| 7 | Determination of serum total cholesterol |
| 8 | Preparation of buffer solution and measurement of pH |
| 9 | Study of enzymatic hydrolysis of starch |
| 10 | Determination of Salivary amylase activity |
| 11 | Study the effect of Temperature on Salivary amylase activity |
| 12 | Study the effect of substrate concentration on salivary amylase activity |

Recommended Books

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

SEMESTER-II
Subject: Pathophysiology – Theory
Code: PHM22017
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

Course Outcome: Upon completion of course student shall be able to

CO1. Describe the etiology and basics of pathophysiology

CO2. Acquire knowledge of signs and symptoms of the diseases

CO3. Identify the complications of the diseases.

CO4. Know about most commonly encountered pathophysiological state(s) and/or disease mechanism(s), as well as any clinical testing requirements

| MODULE – I | Topics to be covered | 10 lectures |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Basic principles of Cell injury and Adaptation. | Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), | 2 |
| | Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), | 2 |
| | Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance | 2 |

| | | |
|----------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| Basic mechanism involved in the process of inflammation and repair. | Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation | 2 |
| | Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Cardiovascular System. | Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis and arteriosclerosis) | 4 |
| Respiratory system. | Asthma Chronic obstructive airways diseases. | 3 |
| Renal system | Acute and chronic renal failure | 3 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Haematological Diseases | Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia | 3 |
| Endocrine system | Diabetes, thyroid diseases, disorders of sex hormones | 2 |
| Nervous system | Epilepsy, Parkinson's disease, stroke, psychiatric disorders... depression, schizophrenia and Alzheimer's disease. | 3 |
| Gastro Intestinal system | Peptic Ulcer | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-------------------------------------|-----------------------------------------------------------------------------------------|--------------------|
| | Inflammatory bowel diseases, jaundice, hepatitis (A,B,C,D,E,F) alcoholic liver disease. | 4 |
| Disease of bones and joints. | Rheumatoid arthritis, osteoporosis and gout | 2 |

| | | |
|------------------------------|-----------------------------------------------------|---|
| Principles of cancer. | classification, etiology and pathogenesis of cancer | 2 |
|------------------------------|-----------------------------------------------------|---|

| | | |
|--------------------------------------|---------------------------------------------------------------------|--------------------|
| MODULE – V | Topics to be covered | 07 lectures |
| Infectious diseases. | Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections | 4 |
| Sexually transmitted diseases | AIDS, Syphilis, Gonorrhea | 3 |

| | | |
|-----------------|-----------------------------|--------------------|
| MODULE | Topics to be covered | 15 lectures |
| Tutorial | | |

Recommended Books

1. Vinay Kumar, Abul K. Abas, Jon C. Aster; Robbins & Cotran Pathologic Basis of Disease; South Asia edition; India; Elsevier; 2014.
2. Harsh Mohan; Text book of Pathology; 6th edition; India; Jaypee Publications; 2010.
3. Laurence B, Bruce C, Bjorn K. ; Goodman Gilman's The Pharmacological Basis of Therapeutics; 12th edition; New York; McGraw-Hill; 2011.
4. Best, Charles Herbert 1899-1978; Taylor, Norman Burke 1885-1972; West, John B (John Burnard); Best and Taylor's Physiological basis of medical practice; 12th ed; united states;
5. William and Wilkins, Baltimore; 1991 [1990 printing].
6. Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston; Davidson's Principles and Practice of Medicine; 21st edition; London; ELBS/Churchill Livingstone; 2010.
7. Guyton A, John .E Hall; Textbook of Medical Physiology; 12th edition; WB Saunders Company; 2010.
8. Joseph DiPiro, Robert L. Talbert, Gary Yee, Barbara Wells, L. Michael Posey; Pharmacotherapy... A Pathophysiological Approach; 9th edition; London; McGraw-Hill Medical; 2014.
9. V. Kumar, R. S. Cotran and S. L. Robbins; Basic Pathology; 6th edition; Philadelphia; WB Saunders Company; 1997.
10. Roger Walker, Clive Edwards; Clinical Pharmacy and Therapeutics; 3rd edition; London; Churchill Livingstone publication; 2003.

SEMESTER-II
Subject: Computer Applications in Pharmacy – Theory
Code: PHM22018
3 Credits

Total Lectures Required – 45 hrs

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

Course Outcome: Upon completion of course student shall able to

CO01. Apply the knowledge of mathematics and computing fundamentals to pharmaceutical applications for any given requirement

CO02. Discuss about computers (I/O devices), binary conversion, applications of computers in pharmacy.

CO03. Describe Concept of common languages in computers, algorithm flow chart, solution of problems based on biostatistics and other simple problems of pharmaceutical interest.

CO04. Explain MS Word, MS Excel, MS Power Point.

CO05. Explain Concept of ISIS, RASMOL, CHEMSKETCH.

CO06. Know the web-based tools for pharmacy practice. Apply the knowledge to design and develop digital tools for pharmaceutical applications.

| MODULE – I | Topics to be covered | 08 lectures |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Number system | Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement, Two's complement method, binary multiplication, binary division | 4 |
| Concept of Information Systems and Software | Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life | 4 |

| | | |
|--|------------------------------------------|--|
| | cycle, planning and managing the project | |
|--|------------------------------------------|--|

| MODULE – II | Topics to be covered | 08 lectures |
|-------------------------|-----------------------------------------------------------------------------------------------------------|--------------------|
| Web technologies | Introduction to HTML, XML, CSS and Programming languages, introduction to web servers and Server Products | 4 |
| | Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database | 4 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Application of computers in Pharmacy | Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, | 5 |
| | barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System | 5 |

| MODULE – IV | Topics to be covered | 09 lectures |
|-----------------------|-------------------------------------------------------------------------------------|--------------------|
| Bioinformatics | Introduction, Objective of Bioinformatics, Bioinformatics | 4 |
| | Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery | 5 |

| MODULE –V | Topics to be covered | 10 lectures |
|--------------------------------------------------------------|-----------------------------------------------------------------------|--------------------|
| Computers as data analysis in Preclinical development | Chromatographic data analysis(CDS), Laboratory Information management | 5 |
| | System (LIMS) and Text Information Management System(TIMs) | 5 |

SEMESTER-II
Subject: Computer Applications in Pharmacy – Practical
Code: PHM22023
1 Credits

Total Practical Required - 2 Hrs/Week

Course Outcome: Upon completion of the experiment student shall able to

CO1. Understand different types of software for structural drawings and prepare tables and charts for presentations of chemical and biological data.

CO2. Apply their knowledge by the access of various search engines, scientific journals, and databases, & various pharmaceutical websites for scientific information.

CO3. Understand the use of Computers in pharmacy for the information of drug data, records, and files, drug management.

CO4. Know the role of computer in Receiving the details, storing it and processing it and its dissemination and this continuous flow of information shows effective functioning of any system.

| Sl. No. | Experiment |
|---------|----------------------------------------------------------------------------------------------------------|
| 1 | Design a questionnaire using a word processing package to gather information about a particular disease. |
| 2 | Create a HTML web page to show personal information. |
| 3 | Retrieve the information of a drug and its adverse effects using online tools |
| 4 | Creating mailing labels Using Label Wizard , generating label in MS WORD |
| 5 | Create a database in MS Access to store the patient information with the required fields Using access |
| 6 | Design a form in MS Access to view, add, delete and modify the patient record in the database |
| 7 | Generating report and printing the report from patient database |
| 8 | Creating invoice table using – MS Access |
| 9 | Drug information storage and retrieval using MS Access |
| 10 | Creating and working with queries in MS Access |
| 11 | Exporting Tables, Queries, Forms and Reports to web pages |
| 12 | Exporting Tables, Queries, Forms and Reports to XML pages |

Recommended books.

1. Computer Application in Pharmacy – William E.Fassett –Lea and Febiger, 600 South Washington Square, USA, (215) 922-1330.
2. Computer Application in Pharmaceutical Research and Development –Sean Ekins –Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
3. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
4. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi – 110002

SEMESTER-II
Subject: Environmental Sciences – Theory
Code: PHM22019
3 Credits

Total Lectures Required – 45 hrs

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

Course Outcome: Upon completion of course student shall able to

CO1. Create the awareness about environmental problems among learners.

CO2. Impart basic knowledge about the environment and its allied problems.

CO3. Develop an attitude of concern for the environment.

CO4. Motivate learner to participate in environment protection and environment improvement.

CO5. Acquire skills to help the concerned individuals in identifying and solving environmental problems.

CO6. Strive to attain harmony with Nature.

| MODULE – I | Topics to be covered | 15 lectures |
|-------------------|----------------------------------------------------------------------------------------------------------------|--------------------|
| Resources | The Multidisciplinary nature of environmental studies Natural Resources Renewable and non-renewable resources. | 3 |
| | Natural resources and associated problems a) Forest resources; b) Water resources; c) Mineral resources | 4 |
| | d) Food resources; e) Energy resources | 4 |
| | Land resources... Role of an individual in conservation of natural resources. | 4 |

| MODULE – II | Topics to be covered | 15 lectures |
|--------------------|-----------------------------------------------------------------------------|--------------------|
| Ecosystems | Ecosystems Concept of an ecosystem. Structure and function of an ecosystem. | 4 |

| | | |
|--|----------------------------------------------------------------------------------------|---|
| | Introduction, types, characteristic features, structure and function of the ecosystems | 3 |
| | Forest ecosystem; Grassland ecosystem; Desert ecosystem | 4 |
| | Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries) | 4 |

| MODULE – III | Topics to be covered | 15 lectures |
|--------------------------------|-----------------------------|--------------------|
| Environmental Pollution | Air pollution | 5 |
| | Water pollution | 5 |
| | Soil pollution | 5 |

Recommended Books

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

Scheme of Study-Semester- III

| Sl. No. | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|------------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|------------|
| 1 | PHM23024 | Pharmaceutical Organic Chemistry II –Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM23025 | Physical Pharmaceutics-I Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM23026 | Pharmaceutical Microbiology-Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM23027 | Pharmaceutical Engineering-Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM23028 | Pharmaceutical Organic Chemistry II –Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 6 | PHM23029 | Physical Pharmaceutics I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 7 | PHM23030 | Pharmaceutical Microbiology – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM23031 | Pharmaceutical Engineering – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| Total | | | 24 | 28 | 4 | 600 | 440 | 100 | 36 | 24 |

SEMESTER-III
Subject: Pharmaceutical Organic Chemistry II – Theory
Code: PHM23024
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject deals with general methods of preparation and reactions of some organic compounds. Reactivity of organic compounds are also studied here. The syllabus emphasizes on mechanisms and orientation of reactions. Chemistry of fats and oils are also included in the syllabus.

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

CO1. Elucidate the structure, name and the type of isomerism of the organic compound

CO2. Understand the reaction, name the reaction and orientation of reactions

CO3. Account for reactivity/stability of compounds,

CO4. Identify/confirm the identification of organic compound

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

| MODULE – I | Topics to be covered | 10 lectures |
|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Benzene and its derivatives | Analytical, synthetic and other evidences in the derivation of structure of benzene, Orbital picture, resonance in benzene, aromatic characters, Huckel's rule | 2 |
| | Reactions of benzene - nitration, sulphonation, halogenation reactivity, Friedelcrafts alkylation- reactivity, limitations, Friedelcrafts acylation. | 3 |
| | Substituents, effect of substituents on reactivity and orientation of mono substituted benzene compounds towards electrophilic substitution reaction | 3 |
| | Structure and uses of DDT, Saccharin, BHC and Chloramine | 2 |

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

| MODULE – II | Topics to be covered | 10 lectures |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Phenols | Acidity of phenols, effect of substituents on acidity, qualitative tests, Structure and uses of phenol, cresols, resorcinol, naphthols | 2 |
| Aromatic Amines* | Basicity of amines, effect of substituents on basicity, and synthetic uses of aryl diazonium salts | 3 |
| Aromatic Acids* | Acidity, effect of substituents on acidity and important reactions of benzoic acid. | 3 |

| MODULE – III | Topics to be covered | 10 lectures |
|----------------------|--------------------------------------------------------------------------------------------------|--------------------|
| Fats and Oils | Fatty acids – reactions. | 2 |
| | Hydrolysis, Hydrogenation, Saponification and Rancidity of oils, Drying oils. | 2 |
| | Analytical constants – Acid value, Saponification value, Ester value, Iodine value, Acetyl value | 4 |
| | Reichert Meissl (RM) value – significance and principle involved in their determination. | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|----------------------------------|------------------------------------------------------------------------|--------------------|
| Polynuclear hydrocarbons. | Synthesis, reactions | 2 |
| | Structure and medicinal uses of Naphthalene and Phenanthrene | 2 |
| | Structure and medicinal uses of, Anthracene and Diphenylmethane, | 2 |
| | Structure and medicinal uses of Triphenylmethane and their derivatives | 2 |

General methods of preparation and reactions of compounds superscripted with asterisk (*) to be explained To emphasize on definition, types, classification, principles/mechanisms, applications, examples and differences

| MODULE –V | Topics to be covered | 07 lectures |
|-----------------------|--------------------------------------------------------------------------------------|--------------------|
| Cyclo alkanes* | Stabilities – Baeyer’s strain theory, limitation of Baeyer’s strain theory | 2 |
| | Coulson and Moffitt’s modification, Sachse Mohr’s theory (Theory of strainless rings | 3 |
| | reactions of cyclopropane and cyclobutane only | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-III
Subject: Pharmaceutical Organic Chemistry II – Practical
Code: PHM23028
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment student shall be able to

CO1. Elucidate the structure, name and the type of isomerism of the organic compound

CO2. Understand the reaction, name the reaction and orientation of reactions

CO3. Account for reactivity/stability of compounds,

CO4. Identify/confirm the identification of organic compound

| Sl. No. | Experiment |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Experiments involving laboratory techniques <input type="checkbox"/> <input type="checkbox"/> Recrystallization <input type="checkbox"/> <input type="checkbox"/> Steam distillation |
| 2 | Determination of following oil values (including standardization of reagents) <input type="checkbox"/> <input type="checkbox"/> Acid value <input type="checkbox"/> <input type="checkbox"/> Saponification value |
| 3 | Preparation of compounds Benzanilide/Phenyl benzoate/Acetanilide from Aniline/ Phenol /Aniline by acylation reaction. |
| 4 | Preparation of compounds 2,4,6-Tribromo aniline/Para bromo acetanilide from Aniline. |
| 5 | Preparation of compounds Acetanilide by halogenation (Bromination) reaction |
| 6 | Preparation of compounds 5-Nitro salicylic acid/Meta di nitro benzene from Salicylic acid / Nitro benzene by nitration reaction. |
| 7 | Preparation of compounds Benzoic acid from Benzyl chloride by oxidation reaction. |
| 8 | Preparation of compounds Benzoic acid/ Salicylic acid from alkyl benzoate/ alkyl salicylate by hydrolysis reaction. |
| 9 | Preparation of compounds 1-Phenyl azo-2-naphthol from Aniline by diazotization and coupling reactions. |

| | |
|----|-------------------------------------------------------------------------------------------------|
| 10 | Preparation of compounds Benzil from Benzoin by oxidation reaction. |
| 11 | Preparation of compounds Dibenzal acetone from Benzaldehyde by Claisen Schmidt reaction. |
| 12 | Preparation of compounds Cinnamic acid from Benzaldehyde by Perkin reaction. |
| 13 | Preparation of compounds <i>P</i> -Iodo benzoic acid from <i>P</i> -amino benzoic acid |

Recommended books.

1. Organic Chemistry by Morrison and Boyd
2. Organic Chemistry by I.L. Finar , Volume-I
3. Textbook of Organic Chemistry by B.S. Bahl & Arun Bahl.
4. Organic Chemistry by P.L.Soni
5. Practical Organic Chemistry by Mann and Saunders.
6. Vogel's text book of Practical Organic Chemistry
7. Advanced Practical organic chemistry by N.K.Vishnoi.

SEMESTER-III
Subject: Physical Pharmaceutics I - Theory
Code: PHM23025
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

CO1. Acquire knowledge about solubility phenomena and its application in pharmaceutical practice.

CO2. Acquire knowledge about physical principles of states of matter

CO3. Understanding various physicochemical properties of drug molecules and its application.

CO4. Illustrate the knowledge and concept of surface tension and interfacial tension and its importance in dispersion stability

CO5. Acquire knowledge about drug complexes, protein binding in pharmacy.

CO6. Acquire knowledge about the pH, buffers, isotonicity and its application in biological and pharmaceutical field.

| MODULE – I | Topics to be covered | 10 lectures |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| .Solubility of drugs | Solubility expressions, mechanisms of solute solvent interactions, | 2 |
| | ideal solubility parameters, solvation & association, quantitative approach to the factors influencing solubility of drugs, diffusion principles in biological systems. | 2 |
| | Solubility of gas in liquids, solubility of liquids in liquids, (Binary solutions, ideal solutions) | 2 |
| | Raoult's law, real solutions. | 2 |

| | | |
|--|----------------------------------------------------------------------------|---|
| | Partially miscible liquids, Critical solution temperature and applications | |
| | Distribution law, its limitations and applications | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|
| States of Matter and properties of matter. | State of matter, changes in the state of matter, latent heats, vapour pressure, sublimation critical point | 2 |
| | eutectic mixtures, gases, aerosols – inhalers, relative humidity | 2 |
| | liquid complexes, liquid crystals, glassy states solid crystalline, amorphous & polymorphism | 2 |
| Physicochemical properties of drug molecules. | Refractive index, optical rotation, dielectric constant, | 2 |
| | dipole moment, dissociation constant, determinations and applications | 2 |

| MODULE – III | Topics to be covered | 08 lectures |
|--------------------------------------------|-------------------------------------------------------------------------------|--------------------|
| Surface and interfacial phenomenon. | Liquid interface, surface & interfacial tensions | 2 |
| | surface free energy, measurement of surface & interfacial tensions | 2 |
| | spreading coefficient, adsorption at liquid interfaces, surface active agents | 2 |
| | HLB Scale, solubilisation, detergency, adsorption at solid interface. | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------------------------|----------------------------------------------------------------------------------------|--------------------|
| Complexation and protein binding. | Introduction, Classification of Complexation, | 2 |
| | Applications, methods of analysis, protein binding, | 2 |
| | Complexation and drug action | 2 |
| | crystalline structures of complexes and thermodynamic treatment of stability constants | 2 |

| MODULE – V | Topics to be covered | 07 lectures |
|----------------------------------------------|------------------------------------------------------------------------|--------------------|
| pH, buffers and Isotonic solutions... | Sorensen's pH scale, pH determination (electrometric and calorimetric) | 2 |
| | applications of buffers, buffer equation, buffer capacity | 2 |
| | buffers in pharmaceutical and biological systems | 2 |
| | buffered isotonic solutions | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-III
Subject: Physical Pharmaceutics I - Practical
Code: PHM23029
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Handle of different pharmaceutical instruments used in determining various physical properties such as surface tension and interfacial tension etc.

CO2. Skill of calculating physical parameters such as effect of surfactant and critical micellar concentration.

CO3. Calculate of critical solution temperature of phenol water system.

CO4. Demonstrate of the solubility of drug and its calculation.

| Sl. No. | Experiment |
|---------|--------------------------------------------------------------------------------------------------------------|
| 1 | Determination the solubility of drug at room temperature |
| 2 | Determination of pKa value by Half neutralization/ Henderson Hasselbalchequation. |
| 3 | Determination of Partition co- efficient of benzoic acid in benzene and water |
| 4 | Determination of Partition co- efficient of Iodine in CCl ₄ and water |
| 5 | Determination of % composition of NaCl in a solution using phenol-water system byCST method |
| 6 | Determination of surface tension of given liquids by drop count and drop weightmethod |
| 7 | Determination of HLB number of a surfactant by saponification method |
| 8 | Determination of Freundlich and Langmuir constants using activated char coal |
| 9 | Determination of critical micellar concentration of surfactants |
| 10 | Determination of stability constant and donor acceptor ratio of PABA-Caffeinecomplex by solubilitymethod |
| 11 | Determination of stability constant and donor acceptor ratio of Cupric-Glycinecomplex by pH titration method |

Recommended Books.

1. Physical Pharmacy by Alfred Martin
2. Experimental Pharmaceutics by Eugene, Parott.
3. Tutorial Pharmacy by Cooper and Gunn.
4. Stocklosam J. Pharmaceutical Calculations, Lea &Febiger, Philadelphia.
5. Liberman H.A, Lachman C., Pharmaceutical Dosage forms, Tablets, Volume-1 to MarcelDekkar Inc.
6. Liberman H.A, Lachman C, Pharmaceutical Dosage forms. Disperse systems, volume 1, 2, 3. Marcel Dekkar Inc.
7. Physical Pharmaceutics by Ramasamy C and ManavalanR.
8. LaboratoryManual of Physical Pharmaceutics, C.V.S. Subramanyam, J. Thimma settee
9. Physical Pharmaceutics by C.V.S. Subramanyam
10. Test book of Physical Phramacy, by Gaurav Jain & Roop K. Khar

SEMESTER-III
Subject: Pharmaceutical Microbiology - Theory
Code: PHM23026
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: Study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.

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

CO1. Understand methods of identification, cultivation and preservation of various microorganisms

CO2. Understand the importance and implementation of sterilization in pharmaceutical processing and industry

CO3. Learn sterility testing of pharmaceutical products.

CO4. Carry out microbiological standardization of Pharmaceuticals.

CO5. Understand the cell culture technology and its applications in pharmaceutical industries.

| MODULE I | TOPICS | 10Lectures |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Introduction microbiology | Introduction, history of microbiology, its branches, scope and its importance | 2 |
| | Introduction to Prokaryotes and Eukaryotes Study of ultra-structure and morphological classification of bacteria, | 2 |
| | nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, | 2 |
| | isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count). | 2 |
| | Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy | 2 |

| MODULE II | TOPICS | 10Lectures |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| | Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC) | 2 |
| | Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization. | 2 |
| | Evaluation of the efficiency of sterilization | 2 |

| | | |
|--|---------------------------------------------------------------------------|---|
| | methods. | |
| | Equipments employed in large scale sterilization. Sterility indicators | 4 |

| MODULE III | TOPICS | 10Lectures |
|-------------------|---------------------------------------------------------------------------------------------------------------------|-------------------|
| | Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses | 2 |
| | Classification and mode of action of disinfectants | 2 |
| | Factors influencing disinfection, antiseptics and their evaluation | 2 |
| | For bacteriostatic and bactericidal actions Evaluation of bactericidal & Bacteriostatic | 2 |
| | Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP. | 2 |

| MODULE IV | TOPICS | 08 Lectures |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| | Designing of aseptic area, laminar flow equipments, study of different sources of contamination in an aseptic area and methods of prevention | 2 |
| | Clean area classification, Principles and methods of different microbiological assay. | 2 |
| | Methods for standardization of antibiotics, vitamins and amino acids | 2 |
| | Methods for Assessment of a new antibiotic | 2 |

| MODULE V | TOPICS | 07Lectures |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| | Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. | 2 |
| | Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations. | 2 |
| | Growth of animal cells in culture, general procedure for cell culture. Primary, established and transformed cell cultures. | 2 |
| | Application of cell cultures in pharmaceutical industry and research. | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-III
Subject: Pharmaceutical Microbiology - Practical
Code: PHM23030
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Understand methods of identification, cultivation and preservation of various microorganisms

CO2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry

CO3. Learn sterility testing of pharmaceutical products.

CO4. Carry out microbiological standardization of Pharmaceuticals.

CO5. Understand the cell culture technology and its applications in pharmaceutical industries

| Sl. No. | Experiment |
|---------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology. |
| 2 | Sterilization of glassware, preparation and sterilization of media. |
| 3 | Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations. |
| 4 | Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical). |
| 5 | Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques. |
| 6 | Microbiological assay of antibiotics by cup plate method and other methods |
| 7 | Motility determination by Hanging drop method. |
| 8 | Sterility testing of pharmaceuticals. |
| 9 | Bacteriological analysis of water |
| 10 | Biochemical test. |

Recommended Books.

1. W.B. Hugo and A.D. Russel... Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox... Pharmaceutical Microbiology.
5. Rose... Industrial Microbiology.
6. Probisher, Hinsdill et al... Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's... Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler... Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan ... Text Book of Microbiology, Orient-Longman, Chennai
11. Edward... Fundamentals of Microbiology.
12. N.K.Jain... Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company.

SEMESTER-III
Subject: Pharmaceutical Engineering - Theory
Code: PHM23027
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Know various unit operations used in Pharmaceutical industries.

CO2. Understand the material handling techniques.

CO3. Perform various processes involved in pharmaceutical manufacturing process.

CO4. Carry out various test to prevent environmental pollution.

CO5. Appreciate and comprehend significance of plant lay out design for optimum use of resources.

CO6. Appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

| MODULE I | TOPICS | 10Lectures |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Flow of fluids | Types of manometers, Reynolds number and its significance, Bernoulli's theorem and its applications, Energy losses, Orifice meter, Venturimeter, Pitot tube and Rotameter. | 3 |
| Size Reduction | Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill, fluid energy mill, Edge runner mill & endrunner mill. | 3 |
| Size Separation | Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator, Airseparator, Bag filter & elutriation tank. | 4 |

| MODULE II | TOPICS | 10Lectures |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Heat Transfer. | Objectives, applications & Heat transfer mechanisms. Fourier's law, Heat transfer by conduction, convection & radiation. Heat interchangers & heat exchangers. | 3 |
| Evaporation... | Objectives, applications and factors influencing | 4 |

| | | |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| □ □ | evaporation,differences between evaporation and other heat process. principles, construction,working, uses, merits and demerits of Steam jacketed kettle, horizontal tubeevaporator, climbing film evaporator, forced circulation evaporator, multipleeffect evaporator& Economy of multiple effect evaporator. | |
| Distillation. | Basic Principles and methodology of simple distillation,flashdistillation, fractional distillation, distillation under reduced pressure, steamdistillation & molecular distillation | 3 |

| MODULE III | TOPICS | 8 Lectures |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Drying | Objectives, applications & mechanism of drying process, measurements& applications of Equilibrium Moisture content, rate of drying curve. principles, construction, working, uses, merits and demerits of Tray dryer, drum dryer spray dryer, fluidized bed dryer, vacuum dryer, freeze dryer | 4 |
| Mixing | Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, twin shell blender, ribbon blender, Sigma blade mixer, planetarymixers, Propellers, Turbines, Paddles & Silverson Emulsifier. | 4 |

| MODULE IV | TOPICS | 8 Lectures |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Filtration. | Objectives, applications, Theories & Factors influencing filtration,filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, filter leaf, rotary drum filter, Meta filter &Cartridge filter, membrane filters and Seidtz filter. | 4 |
| Centrifugation | Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basketcentrifuge, Non-perforated basket centrifuge, semi continuous centrifuge & supercentrifuge. | 4 |

| MODULE V | TOPICS | 8 Lectures |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Materials of pharmaceutical plant construction, Corrosion and its prevention | Factors affecting during materials selected for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. | 4 |
| | Ferrous and nonferrous metals, inorganic and organic non metals, basic of material handling systems. | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-III
Subject: Pharmaceutical Engineering - Practical
Code: PHM23031
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Know about various unit operations used in Pharmaceutical industries.

CO2. Understand about the material handling techniques.

CO3. Perform various processes involved in pharmaceutical manufacturing process.

CO4. Carry out various test to prevent environmental pollution.

CO5. Appreciate and comprehend significance of plant lay out design for optimum use of resources.

CO6. Appreciate the various preventive methods used for corrosion control in Pharmaceutical industries.

| Sl. No. | Experiment |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Determination of radiation constant of brass, iron, unpainted and painted glass. |
| 2 | Steam distillation – To calculate the efficiency of steam distillation. |
| 3 | To determine the overall heat transfer coefficient by heat exchanger. |
| 4 | Construction of drying curves (for calcium carbonate and starch). |
| 5 | Determination of moisture content and loss on drying. |
| 6 | Determination of humidity of air – i) From wet and dry bulb temperatures –use of Dew point method. |
| 7 | Description of Construction working and application of Pharmaceutical Machinery such as rotary tablet machine, fluidized bed coater, fluid energy mill, de humidifier. |
| 8 | Size analysis by sieving – To evaluate size distribution of tablet granulations –Construction of various size frequency curves including arithmetic and logarithmic probability plots. |
| 9 | Size reduction. To verify the laws of size reduction using ball mill and determining Kicks, Rittinger's, Bond's coefficients, power requirement and critical speed of Ball Mill. |
| 10 | Demonstration of colloid mill, planetary mixer, fluidized bed dryer, freeze dryer and such other major equipment. |
| 11 | To study the effect of time on the Rate of Crystallization. |
| 12 | To calculate the uniformity Index for given sample by using Double Cone Blender. |

Recommended Books.

1. Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
2. Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson-Latest edition.
3. Unit operation of chemical engineering – McCabe Smith, Latest edition.
4. Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
5. Remington practice of pharmacy- Martin, Latest edition.
6. Theory and practice of industrial pharmacy by Lachmann., Latest edition.
7. Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
8. Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

Scheme of Study-Semester- Semester- IV

| Sl. No. | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance* |
|--------------|-------------|----------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|-------------|
| 1 | PHM24032 | Pharmaceutical Organic Chemistry III –Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM24033 | Medicinal Chemistry I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM24034 | Physical Pharmaceutics II – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM24035 | Pharmacology I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM24036 | Pharmacognosy I – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 6 | PHM24037 | Medicinal Chemistry I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 7 | PHM24038 | Physical Pharmaceutics II – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM24039 | Pharmacology I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 9 | PHM24040 | Pharmacognosy I – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| Total | | | 28 | 31 | 5 | 700 | 515 | 115 | 42 | 28 |

SEMESTER-IV
Subject: Pharmaceutical Organic Chemistry III – Theory
 Code: PHM24032
 4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject imparts knowledge on stereo-chemical aspects of organic compounds and organic reactions, important named reactions, chemistry of important hetero cyclic compounds. It also emphasizes on medicinal and other uses of organic compounds.

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

CO1. Understand the methods of preparation and properties of organic compounds

CO2. Explain the stereo chemical aspects of organic compounds and stereo chemical reactions

CO3. Know the medicinal uses and other applications of organic compounds

CO4. Emphasize on definition, types, mechanisms, examples, uses/applications

| MODULE I | TOPICS | 10 Lectures |
|-------------------------|--------------------------------------------------------------------------------------------------------------------|-------------|
| Stereo isomerism | Optical isomerism – Optical activity, enantiomerism, diastereoisomerism, meso compounds | 2 |
| | Elements of symmetry, chiral and achiral molecules DL system of nomenclature of optical isomers, sequence rules | 2 |
| | RS system of nomenclature of optical isomers | 2 |
| | Reactions of chiral molecules Racemic modification and resolution of racemic mixture | 2 |
| | Asymmetric synthesis... partial and absolute | 2 |

| MODULE II | TOPICS | 10 Lectures |
|-----------|----------------------------------------------------------------------------------------------|-------------|
| | Geometrical isomerism Nomenclature of geometrical isomers (Cis Trans, EZ, Syn Anti systems) | 2 |
| | Methods of determination of configuration of geometrical isomers. | 2 |
| | Conformational isomerism in Ethane, n-Butane and Cyclohexane. | 2 |
| | Stereo isomerism in biphenyl compounds (Atropisomerism) and conditions for optical activity. | 2 |
| | Stereospecific and stereoselective reactions | 2 |

| MODULE III | TOPICS | 10Lectures |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Heterocyclic compounds. | Nomenclature and classification Synthesis, reactions and medicinal uses of following compounds/derivatives Pyrrole, Furan, and Thiophene | 5 |
| | Relative aromaticity and reactivity of Pyrrole, Furan and Thiophene | 5 |

| MODULE IV | TOPICS | 08Lectures |
|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-------------------|
| Synthesis, reactions and medicinal uses of given compounds/derivatives | Pyrazole, Imidazole, Oxazole and Thiazole. | 2 |
| | Pyridine, Quinoline, Isoquinoline, Acridine and Indole. | 2 |
| | Basicity of pyridine Synthesis and medicinal uses of Pyrimidine, Purine, azepines and their derivatives | 4 |

| MODULE V | TOPICS | 07 Lectures |
|------------------------------------------|---------------------------------------------------------------------|--------------------|
| Reactions of synthetic importance | Metal hydride reduction (NaBH ₄ and LiAlH ₄) | 1 |
| | Clemmensen reduction, Birch Reduction, Wolff Kishner reduction | 1 |
| | Oppenauer-oxidation and Dakin reaction | 1 |
| | Beckmanns rearrangement and Schmidt rearrangement | 2 |
| | Claisen-Schmidt condensation | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books

1. Organic chemistry by I.L. Finar, Volume-I & II.
2. A text book of organic chemistry – Arun Bahl, B.S. Bahl.
3. Heterocyclic Chemistry by Raj K. Bansal
4. Organic Chemistry by Morrison and Boyd
5. Heterocyclic Chemistry by T.L. Gilchrist

SEMESTER-IV
Subject: Medicinal Chemistry I – Theory
 Code: PHM24033
 4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

- CO1. Understand the chemistry of drugs with respect to their pharmacological activity
- CO2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- CO3. Know the Structural Activity Relationship (SAR) of different class of drugs
- CO4. Write the chemical synthesis of some drugs

| MODULE I | TOPICS | 10 Lectures |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Introduction to Medicinal Chemistry | Ionization, Solubility, Partition Coefficient, Hydrogen bonding, Proteinbinding, Chelation, Bioisosterism, Optical and Geometrical isomerism. | 5 |
| History and development of medicinal chemistry Physicochemical properties in relation to biological action Drug metabolism | Drug metabolism principles- Phase I and Phase II. Factors affecting drug metabolism including stereo chemical aspects. | 5 |

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

| MODULE II | TOPICS | 10 Lectures |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|-------------|
| Drugs acting on Autonomic Nervous System Adrenergic Neurotransmitters. | Biosynthesis and catabolism of catecholamine. Adrenergic receptors (Alpha & Beta) and their distribution | 2 |
| Sympathomimetic agents. | Direct acting... Nor-epinephrine, Epinephrine, | 2 |

| | | |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| SAR of Sympathomimetic agents | Phenylephrine*, Dopamine, Methyldopa, Clonidine, Dobutamine, Isoproterenol, Terbutaline, Salbutamol*, Bitolterol, Naphazoline, Oxymetazoline and Xylometazoline. □□ Indirect acting agents... Hydroxyamphetamine, Pseudoephedrine, Propylhexedrine. □□ Agents with mixed mechanism... Ephedrine, Metaraminol | |
| Adrenergic Antagonists. Alpha adrenergic blockers. | Tolazoline*, Phentolamine, Phenoxybenzamine, Prazosin, Dihydroergotamine, Methysergide | 2 |
| Beta adrenergic blockers. | SAR of beta blockers, Propranolol*, Metibranolol, Atenolol, Betazolol, Bisoprolol, Esmolol, Metoprolol, Labetolol, Carvedilol. | 2 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*) | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| MODULE III | TOPICS | 10 Lectures |
| Cholinergic neurotransmitters. | Biosynthesis and catabolism of acetylcholine. Cholinergic receptors (Muscarinic & Nicotinic) and their distribution. | 2 |
| Parasympathomimetic agents. SAR of Parasympathomimetic agents Direct acting agents. | Acetylcholine, Carbachol*, Bethanechol, Methacholine, Pilocarpine | 2 |
| Indirect acting/ Cholinesterase inhibitors (Reversible & Irreversible). | Physostigmine, Neostigmine*, Pyridostigmine, Edrophonium chloride, Tacrine hydrochloride, Ambenonium chloride, Isofluorophate, Echothiophate iodide, Parathion, Malathion | 2 |
| Cholinesterase reactivator. Cholinergic Blocking agents. SAR of cholinolytic agents Solanaceous alkaloids and analogues. | Pralidoxime chloride; Atropine sulphate, Hyoscyamine sulphate, Scopolamine hydrobromide, Homatropine hydrobromide, Ipratropium bromide* | 2 |
| Synthetic cholinergic blocking agents. | Tropicamide, Cyclopentolate hydrochloride, Clidinium bromide, Dicyclomine hydrochloride*, Glycopyrrolate, Methantheline bromide, Propantheline bromide, Benztropine mesylate, Orphenadrine citrate, Biperidine hydrochloride, Procyclidine hydrochloride*, Tridihexethyl chloride, Isopropamide iodide, Ethopropazine hydrochloride. | 2 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*) | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| MODULE IV | TOPICS | 08 Lectures |
| Drugs acting on Central Nervous System A. Sedatives and Hypnotics. | Benzodiazepines... SAR of Benzodiazepines, Chlordiazepoxide, Diazepam*, Oxazepam, Chlorazepate, Lorazepam, Alprazolam, Zolpidem Barbiturtes... SAR of barbiturates, Barbitol*, Phenobarbital, Mephobarbital, Amobarbital, Butobarbital, Pentobarbital, Secobarbital Miscellaneous... Amides & imides... Glutethimide. Alcohol & their carbamate derivatives... Meprobamate, Ethchlorvynol. Aldehyde & their derivatives... Triclofos sodium, Paraldehyde. | 2 |
| B. Antipsychotics. | Phenothiazines... SAR of Phenothiazines Promazine hydrochloride, Chlorpromazine hydrochloride*, Triflupromazine, Thioridazine hydrochloride, Piperacetazine hydrochloride, Prochlorperazine maleate, Trifluoperazine hydrochloride. Ring Analogues of Phenothiazines... Chlorprothixene, Thiothixene, Loxapine succinate, Clozapine. Fluorobutero-phenones... Haloperidol, Droperidol, Risperidone. Beta amino ketones... Molindone hydrochloride. Benzamides... Sulpiride. | 2 |
| C. Anticonvulsants. | SAR of Anticonvulsants, mechanism of anticonvulsant action Barbiturates... Phenobarbitone, Methobarbital. Hydantoins... Phenytoin*, Mephenytoin, Ethotoin Oxazolindiones... Trimethadione, Paramethadione Succinimides... Phensuximide, Methsuximide, Ethosuximide* Urea and monoacylureas... Phenacemide, Carbamazepine* Benzodiazepines... Clonazepam Miscellaneous... Primidone, Valproic acid, Gabapentin, Felbamate | 4 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*) | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|-------------|
| MODULE V | TOPICS | 07 Lectures |
| Drugs acting on Central Nervous System General anesthetics. | Halothane*, Methoxyflurane, Enflurane, Sevoflurane, Isoflurane, Desflurane. | 1 |

| | | |
|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | | |
| Inhalation anesthetics... Ultra short acting barbiturates. | Methohexital sodium*, Thiamylal sodium, Thiopental sodium | 1 |
| Dissociative anesthetics... Narcotic and non-narcotic analgesics Morphine and related drugs. | Ketamine hydrochloride.*; SAR of Morphine analogues, Morphine sulphate, Codeine, Meperidine hydrochloride, Anilerdine hydrochloride, Diphenoxylate hydrochloride, Loperamide hydrochloride, Fentanyl citrate*, Methadone hydrochloride*, Propoxyphene hydrochloride, Pentazocine, Levorphanol tartarate. | 3 |
| Narcotic antagonists. | Nalorphine hydrochloride, Levallorphan tartarate, Naloxone hydrochloride. | 1 |
| Anti-inflammatory agents. | Sodium salicylate, Aspirin, Mefenamic acid*, Meclofenamate, Indomethacin, Sulindac, Tolmetin, Zomepirac, Diclofenac, Ketorolac, Ibuprofen*, Naproxen, Piroxicam, Phenacetin, Acetaminophen, Antipyrine, Phenylbutazone | 1 |

| | | |
|-----------------|-----------------------------|--------------------|
| MODULE | Topics to be covered | 15 lectures |
| Tutorial | | |

SEMESTER-IV
Subject: Medicinal Chemistry I – Practical
Code: PHM24037
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the Experiment the student shall be able to

CO1. Understand the chemistry of drugs with respect to their pharmacological activity

CO2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

CO3. Know the Structural Activity Relationship (SAR) of different class of drugs

CO4. Write the chemical synthesis of some drugs

| Sl. No. | Experiment |
|---------|----------------------------------------------------------|
| | Preparation of drugs/ intermediates |
| 1 | 1,3-pyrazole |
| 2 | 1,3-oxazole |
| 3 | Benzimidazole |
| 4 | Benzotriazole |
| 5 | 2,3- diphenyl quinoxaline |
| 6 | Benzocaine |
| 7 | Phenytoin |
| 8 | Phenothiazine |
| 9 | Barbiturate |
| | Assay of drugs |
| 10 | Chlorpromazine |
| 11 | Phenobarbitone |
| 12 | Atropine |
| 13 | Ibuprofen |
| 14 | Aspirin |
| 15 | Furosemide |
| 16 | Determination of Partition coefficient for any two drugs |

Recommended Books

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

SEMESTER-IV
Subject: Physical Pharmaceutics II – Theory
Code: PHM24034
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: The course deals with the various physical and physicochemical properties, and principles involved in dosage forms/formulations. Theory and practical components of the subject help the student to get a better insight into various areas of formulation research and development, and stability studies of pharmaceutical dosage forms.

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

CO1. Understand the concept of colloidal dispersion systems.

CO2. Illustrate fundamentals and pharmaceutical applications of rheology and deformation of solids.

CO3. Understand the concept of formulation and stabilization of suspension

CO4. Understand the concept of formulation and stabilization of emulsions

CO5. Have basic understanding of micromeritics and its application in pharmacy.

CO6. Analyze the reaction kinetics and chemical stability of various drug products

| MODULE I | TOPICS | 05 Lectures |
|-------------------------------|-----------------------------------------------------------------------------------------------------------|-------------|
| Colloidal dispersions. | Classification of dispersed systems & their general characteristics, size & shapes of colloidal particles | 2 |
| | classification of colloids & comparative account of their general properties | 1 |
| | Optical, kinetic & electrical properties. | 1 |
| | Effect of electrolytes, coacervation, peptization & protective action. | 2 |

| MODULE II | TOPICS | 10 Lectures |
|------------------------------|----------------------------------------------------------------------------------------------|-------------|
| Rheology | Newtonian systems, law of flow, kinematic viscosity, effect of temperature, | 2 |
| | non-Newtonian systems, pseudoplastic, dilatant, plastic, thixotropy, thixotropy formulation, | 2 |
| | determination of viscosity, capillary, falling Sphere, rotational viscometers | 2 |
| Deformation of solids | Plastic and elastic deformation, Heckel equation, | 2 |
| | Stress, Strain, Elastic Modulus | 2 |

| MODULE III | TOPICS | 10 Lectures |
|---------------------------|------------------------------------------------------------------------------------|--------------------|
| Coarse dispersion: | Suspension, interfacial properties of suspended articles, settling in suspensions, | 2 |
| | formulation of flocculated and deflocculated suspensions | 2 |
| | Emulsions and theories of emulsification, microemulsion and multiple emulsions | 2 |
| | Stability of emulsions, preservation of emulsions | 2 |
| | rheological properties of emulsions and emulsion formulation by HLB method | 2 |

| MODULE IV | TOPICS | 10 Lectures |
|-----------------------|---------------------------------------------------------------------------------------------------------|--------------------|
| Micromeretics: | Particle size and distribution, mean particle size, number and weight distribution, particle number, | 2 |
| | methods for determining particle size by different methods, | 2 |
| | counting and separation method, particle shape, specific surface, methods for determining surface area, | 2 |
| | permeability, adsorption, derived properties of powders | 2 |
| | porosity, packing arrangement, densities, bulkiness & flow properties | 2 |

| MODULE V | TOPICS | 10 Lectures |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Drug stability: | Reaction kinetics: zero, pseudo-zero, first & second order, units of basic rate constants, determination of reaction order | 2 |
| | Physical and chemical factors influencing the chemical degradation of pharmaceutical product temperature, solvent, ionic strength, dielectric constant, specific & general acid base catalysis, Simple numerical problems | 2 |
| | Stabilization of medicinal agents against common reactions like hydrolysis & oxidation | 2 |
| | Accelerated stability testing in expiration dating of pharmaceutical dosage forms | 2 |
| | Photolytic degradation and its prevention | 2 |
| | | |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-IV
Subject: Physical Pharmaceutics II – Practical
Code: PHM24038
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Demonstration of effect of micromeritic parameters for pharmaceutical formulation.

CO2. Demonstration of effect of flow characteristics of fluid for pharmaceuticals

CO3. Analyse the stability of dispersions.

CO4. Perform accelerated stability studies

| Sl. No. | Experiment |
|---------|------------------------------------------------------------------------------------------------------|
| 1 | Determination of particle size, particle size distribution using sieving method |
| 2 | Determination of particle size, particle size distribution using Microscopic method |
| 3 | Determination of bulk density, true density and porosity |
| 4 | Determine the angle of repose and influence of lubricant on angle of repose |
| 5 | Determination of viscosity of liquid using Ostwald's viscometer |
| 6 | Determination sedimentation volume with effect of different suspending agent |
| 7 | Determination sedimentation volume with effect of different concentration of single suspending agent |
| 8 | Determination of viscosity of semisolid by using Brookfield viscometer |
| 9 | Determination of reaction rate constant first order |
| | Determination of reaction rate constant second order |
| 10 | Accelerated stability studies |

Recommended Books:

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

SEMESTER-IV
Subject: Pharmacology I – Theory
Code: PHM24035
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications and routes of administration of different classes of drugs.

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

CO1. Explain the general principles of pharmacology

CO2. Describe the pharmacokinetic, pharmacodynamic, adverse drug reactions and drug interactions

CO3. Explain drug discovery and clinical evaluation of new drugs

CO4. Explain the drugs acting on the peripheral nervous system

CO5. Describe the drugs acting on the central nervous system

CO6. Strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases.

| MODULE I | TOPICS | 08Lectures |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| General Pharmacology | Introduction to Pharmacology- Definition, historical landmarks and scope of pharmacology, nature and source of drugs, essential drugs concept and routes of drug administration, Agonists, antagonists(competitive and non competitive), spare receptors, addiction, tolerance, dependence, tachyphylaxis, idiosyncrasy, allergy | 4 |
| | Pharmacokinetics- Membrane transport, absorption, distribution, metabolism and excretion of drugs .Enzyme induction, enzyme inhibition, kinetics of elimination | 4 |

| MODULE II | TOPICS | 12 Lectures |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| General Pharmacology | Pharmacodynamics- Principles and mechanisms of drug action. Receptor theories and classification of receptors, regulation of receptors. drug receptors interactions signal transduction mechanisms, G-protein–coupled receptors, ion channel receptor, transmembrane enzyme linked receptors, transmembrane JAK-STAT binding receptor and receptors that regulate transcription factors, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action. | 3 |
| | Adverse drug reactions. | 3 |
| | Drug interactions (pharmacokinetic and pharmacodynamic) | 3 |
| | Drug discovery and clinical evaluation of new drugs -Drug discovery phase, preclinical evaluation phase, clinical trial phase, phases of clinical trials and pharmacovigilance. | 3 |

| MODULE III | TOPICS | 10 Lectures |
|------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------|
| Pharmacology of drugs acting on peripheral nervous system | Organization and function of ANS. | 2 |
| | Neurohumoral transmission, co-transmission and classification of neurotransmitters | 2 |
| | Parasympathomimetics, Parasympatholytics, Sympathomimetics, sympatholytics | 2 |
| | Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). | 2 |
| | Local anesthetic agents. Drugs used in myasthenia gravis and glaucoma | 2 |

| MODULE IV | TOPICS | 08 Lectures |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Pharmacology of drugs acting on central nervous system | Neurohumoral transmission in the C.N.S. special emphasis on importance of various neurotransmitters like with GABA, Glutamate, Glycine, serotonin, dopamine. | 2 |
| | General anesthetics and pre-anesthetics. | 2 |
| | Sedatives, hypnotics and centrally acting muscle relaxants. | 2 |
| | Anti-epileptics | 1 |
| | Alcohols and disulfiram | 1 |

| MODULE V | TOPICS | 07Lectures |
|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-------------------|
| Pharmacology of drugs acting on central nervous system | Psychopharmacological agents: Antipsychotics, antidepressants, anti-anxiety agents, anti-manics and hallucinogens | 2 |
| | Drugs used in Parkinsons disease and Alzheimer's disease. | 2 |
| | CNS stimulants and nootropics | 1 |
| | Opioid analgesics and antagonists | 1 |
| | Drug addiction, drug abuse, tolerance and dependence | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-IV
Subject: Pharmacology I – Practical
Code: PHM24039
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Explain the commonly used instruments, laboratory animals used in experimental pharmacology

CO2. Describe the maintenance of laboratory animals as per CPCSEA guidelines

CO3. Explain the common laboratory techniques, blood withdrawal, serum and plasma separation, anesthetics, and euthanasia used for animal studies

CO4. Understand the administration of the drug in mice/rats

| Sl. No. | Experiment |
|---------|---------------------------------------------------------------------------------------------------------------------------------|
| 1 | Introduction to experimental pharmacology. |
| 2 | Commonly used instruments in experimental pharmacology. |
| 3 | Study of common laboratory animals. |
| 4 | Maintenance of laboratory animals as per CPCSEA guidelines. |
| 5 | Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies |
| 6 | Study of different routes of drugs administration in mice/rats. |
| 7 | Study of effect of hepatic microsomal enzyme inducers on the phenobarbitone sleepingtime in mice. |
| 8 | Effect of drugs on ciliary motility of frog oesophagus |
| 9 | Effect of drugs on rabbit eye. |
| | Effects of skeletal muscle relaxants using rota-rod apparatus. |
| 10 | Effect of drugs on locomotor activity using actophotometer.. |
| 11 | Anticonvulsant effect of drugs byMES and PTZ method |
| 12 | Study of stereotype and anti-catatonic activity of drugs on rats/mice. |
| 13 | Study of anxiolytic activity of drugs using rats/mice. |
| 14 | Study of local anesthetics by different methods |

Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos

Recommended Books:

1. H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata McGraw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A.K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews-Pharmacology 100
6. K.D.Tripathi. Essentials of Medical Pharmacology, JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R. Craig & Robert,
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan.

SEMESTER-IV
Subject: Pharmacognosy and Phytochemistry I - Theory
 Code: PHM24036
 4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: 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.

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

CO1.Know the techniques in the cultivation and production of crude drugs

CO2.Know the crude drugs, their uses and chemical nature

CO3. Know the evaluation techniques for the herbal drugs

CO4. Carry out the microscopic and morphological evaluation of crude drugs

| MODULE I | TOPICS | 10 Lectures |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Introduction to Pharmacognosy: | Definition, history, scope and development of Pharmacognosy | 2 |
| |) Sources of Drugs – Plants, Animals, Marine & Tissue culture | 2 |
| | Organized drugs, unorganized drugs (dried latex, dried juices, dried extracts, gums and mucilages, oleoresins and oleo- gum -resins) | 2 |
| Classification of drugs: | Alphabetical, morphological, taxonomical, chemical, pharmacological, chemo and sero-taxonomical classification of drugs | 2 |
| Quality control of Drugs of Natural Origin: | Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties. Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida. | 2 |

| MODULE II | TOPICS | 10 Lectures |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-------------|
| Cultivation, Collection, Processing and storage of drugs of natural origin: | Cultivation and Collection of drugs of natural origin | 2 |
| | Factors influencing cultivation of medicinal plants | 3 |
| | Plant hormones and their applications | 3 |
| | Polyploidy, mutation and hybridization with reference to medicinal plants | 2 |
| | Conservation of medicinal plants | 2 |

| MODULE III | TOPICS | 07Lectures |
|------------------------------|-------------------------------------------------------------------|------------|
| Plant tissue culture: | Historical development of plant tissue culture, types of cultures | 2 |
| | Nutritional requirements, growth and their maintenance | 2 |
| | Applications of plant tissue culture in pharmacognosy | 2 |
| | Edible vaccines | 1 |

| MODULE IV | TOPICS | 10 Lectures |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Pharmacognosy in various systems of medicine: | Role of Pharmacognosy in allopathy and traditional systems of medicine namely, Ayurveda, Unani, Siddha, Homeopathy and Chinese systems of medicine. | 5 |
| Introduction to secondary metabolites: | Definition, classification, properties and test for identification of Alkaloids, Glycosides, Flavonoids, Tannins, Volatile oil and Resins | 5 |

| MODULE V | TOPICS | 10 Lectures |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Study of biological source, chemical nature and uses of drugs of natural origin containing following drugs | | |
| Plant Products: | Fibers - Cotton, Jute, Hemp, Hallucinogens, Teratogens, Natural allergens | |
| Primary metabolites: | General introduction, detailed study with respect to chemistry, sources, preparation, evaluation, preservation, storage, therapeutic used and commercial utility as Pharmaceutical Aids and/or Medicines for the following Primarymetabolites | |
| | Carbohydrates: Acacia, Agar, Tragacanth, Honey | |
| | Proteins and Enzymes : Gelatin, casein, proteolytic enzymes (Papain, bromelain, serratiopeptidase, urokinase, streptokinase, pepsin) | |
| | Lipids(Waxes, fats, fixed oils) : Castor oil, Chaulmoogra oil, Wool Fat, Bees Wax | |
| Marine Drugs: | Novel medicinal agents from marine sources | |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|----------------------|-------------|
| Tutorial | | |

SEMESTER-IV
Subject: Pharmacognosy and Phytochemistry I - Practical
Code: PHM24040
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon the completion of the experiment student shall be able to

CO1. Know the techniques in the cultivation and production of crude drugs

CO2. Know the crude drugs, their uses and chemical nature

CO3. Know the evaluation techniques for the herbal drugs

CO4. Carry out the microscopic and morphological evaluation of crude drugs

| Sl. No. | Experiment |
|---------|--------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Analysis of crude drugs by chemical tests: (i) Tragacanth (ii) Acacia (iii) Agar (iv) Gelatin (v) starch (vi) Honey (vii) Castor oil |
| 2 | . Determination of stomatal number and index |
| 3 | Determination of vein islet number, vein islet termination and palisade ratio. |
| 4 | Determination of size of starch grains, calcium oxalate crystals by eye piece micrometer |
| 5 | Determination of Fiber length and width |
| 6 | Determination of number of starch grains by Lycopodium spore method |
| 7 | Determination of Ash value |
| 8 | Determination of Extractive values of crude drugs |
| 9 | Determination of moisture content of crude drugs |
| 10 | Determination of swelling index and foaming |

Recommended Books:

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co.,London, 2009.
2. Tyler, V.E., Brady, L.R. and Robbers, J.E., Pharmacognosy, 9th Edn., Lea andFebiger, Philadelphia, 1988.
3. Text Book of Pharmacognosy by T.E. Wallis
4. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers &Distribution, New Delhi.
5. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition,Nirali Prakashan, New Delhi.
6. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, NewDelhi.
7. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, NewDelhi, 2007
8. Practical Pharmacognosy: C.K. Kokate, Purohit, Gokhlae
9. Anatomy of Crude Drugs byM.A. Iyengar.

Scheme of Study-Semester- V

| Sl. No. | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|---------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|------------|
| 1 | PHM25041 | Medicinal Chemistry II – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM25042 | Industrial PharmacyI– Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM25043 | Pharmacology II – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM25044 | Pharmacognosy II – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM25045 | Pharmaceutical Jurisprudence – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 6 | PHM25046 | Industrial PharmacyI– Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 7 | PHM25047 | Pharmacology II – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM25048 | Pharmacognosy II – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| Total | | | 26 | 27 | 5 | 650 | 480 | 105 | 39 | 26 |

SEMESTER-V
Subject: Medicinal Chemistry II – Theory
 Code: PHM25041
 4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Understand the chemistry of drugs with respect to their pharmacological activity

CO2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs

CO3. Know the Structural Activity Relationship of different class of drugs

CO4. Study the chemical synthesis of selected drugs

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*) | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| MODULE – I | Topics to be covered | 12 lectures |
| Antihistaminic agents | Histamine, receptors and their distribution in the human body | 1 |
| H1–antagonists: | Diphenhydramine hydrochloride*, Dimenhydrinate, Doxylamines succinate, Clemastine fumarate, Diphenylpyraline hydrochloride, | 1 |
| | Tripelenamine hydrochloride, Chlorcyclizine hydrochloride, Meclizine hydrochloride, Buclizine hydrochloride, Chlorpheniramine maleate, Triprolidine hydrochloride*, Phenidamine tartarate, | 2 |
| | Promethazine hydrochloride*, Trimeprazine tartrate, Cyproheptadine hydrochloride, Azatidine maleate, Astemizole, Loratadine, Cetirizine, Levocetrazine Cromolyn sodium | 1 |

| | | |
|----------------------------------------|--------------------------------------------------------------------------------------------------|---|
| H2-antagonists: | Cimetidine*, Famotidine, Ranitidin | 1 |
| Gastric Proton pump inhibitors: | Omeprazole, Lansoprazole, Rabeprazole, Pantoprazole | 1 |
| Anti-neoplastic agents: | Meclorethamine*, Cyclophosphamide, Melphalan, 107 Chlorambucil, Busulfan, Thiotepa | 1 |
| Antimetabolites: | Mercaptopurine*, Thioguanine, Fluorouracil, Floxuridine, Cytarabine, Methotrexate*, Azathioprine | 1 |
| Antibiotics: | Dactinomycin, Daunorubicin, Doxorubicin, Bleomycin | 1 |
| Plant products: | Etoposide, Vinblastin sulphate, Vincristin sulphate | 1 |
| Miscellaneous: | Cisplatin, Mitotane | 1 |

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

| MODULE – II | Topics to be covered | 11 lectures |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------|--------------------|
| Anti-anginal: | Amyl nitrite, Nitroglycerin*, Pentaerythritol tetranitrate, Isosorbide dinitrite*, Dipyridamole | 1 |
| Vasodilators: | | |
| Calcium channel blockers: | Verapamil, Bepridil hydrochloride, Diltiazem hydrochloride, Nifedipine, Amlodipine, Felodipine, Nicardipine, Nimodipine. | 2 |
| Diuretics: | Carbonic anhydrase inhibitors: Acetazolamide*, Methazolamide, Dichlorophenamide. | 1 |
| Thiazides: | Chlorthiazide*, Hydrochlorothiazide, Hydroflumethiazide, Cyclothiazide, | 1 |
| Loop diuretics: | Furosemide*, Bumetanide, Ethacrynic acid. | 1 |
| Potassium sparing Diuretics: | Spironolactone, Triamterene, Amiloride. | 1 |
| Osmotic Diuretics: | Mannitol | 1 |
| Anti-hypertensive Agents: | Timolol, Captopril, Lisinopril, | 2 |

| | | |
|--|--------------------------------------------------------------------------------------------------------------------------------|---|
| | Enalapril, Benazepril hydrochloride, Quinapril hydrochloride, Methyldopate hydrochloride,* Clonidine hydrochloride, | |
| | Guanethidine monosulphate, Guanabenz acetate, Sodium nitroprusside, Diazoxide, Minoxidil, Reserpine, Hydralazine hydrochloride | 1 |

Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted (*)

| MODULE – III | Topics to be covered | 05 lectures |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|
| Anti-arrhythmic Drugs: | Quinidine sulphate, Procainamide hydrochloride, Disopyramide phosphate*, Phenytoin sodium, Lidocaine hydrochloride, | 1 |
| | Tocainide hydrochloride, Mexiletine hydrochloride, Lorcinide hydrochloride, Amiodarone, Sotalol. | 1 |
| Anti-hyperlipidemic agents: | Clofibrate, Lovastatin, Cholesteramine and Cholestipol | 1 |
| Coagulant & Anticoagulants: | Menadione, Acetomenadione, Warfarin*, Anisindione, clopidogrel | 1 |
| Drugs used in Congestive Heart Failure: | Digoxin, Digitoxin, Nesiritide, Bosentan, Tezosentan. | 1 |

| MODULE – IV | Topics to be covered | 06 lectures |
|-----------------------------------------|----------------------------------------------------------------------------------------------|--------------------|
| Drugs acting on Endocrine system | Nomenclature, Stereochemistry and metabolism of steroids | 1 |
| Sex hormones: | Testosterone, Nandralone, Progestrones, Oestriol, Oestradiol, Oestrione, Diethyl stilbestrol | 1 |
| Drugs for erectile dysfunction: | Sildenafil, Tadalafil. | 1 |
| Oral contraceptives: | Mifepristone, Norgestril, Levonorgestrol | 1 |
| Corticosteroids: | Cortisone, Hydrocortisone, Prednisolone, Betamethasone, Dexamethasone | 1 |
| Thyroid and antithyroid | L-Thyroxine, L-Thyronine, | 1 |

| | | |
|---------------|--------------------------------|--|
| drugs: | Propylthiouracil, Methimazole. | |
|---------------|--------------------------------|--|

| MODULE V | Topics to be covered | 11 Lectures |
|----------------------------------------|-----------------------------------------------------------------------------------|--------------------|
| Antidiabetic agents | Insulin and its preparations | 1 |
| Sulfonyl ureas: | Tolbutamide*, Chlorpropamide, Glipizide, Glimepiride. | 1 |
| Biguanides: | Metformin. | 1 |
| Thiazolidinediones: | Pioglitazone, Rosiglitazone. | 1 |
| Meglitinides: | Repaglinide, Nateglinide. | 1 |
| Glucosidase inhibitors: | Acrabose, Voglibose. | 1 |
| Local Anesthetics | SAR of Local anesthetics | 1 |
| Benzoic Acid derivatives; | Cocaine, Hexylcaine, Meprylcaine, Cyclomethycaine, Piperocaine | 1 |
| Amino Benzoic acid derivatives: | Benzocaine*, Butamben, Procaine*, Butacaine, Propoxycaine, Tetracaine, Benoxinate | 1 |
| Lidocaine/Anilide derivatives: | Lignocaine, Mepivacaine, Prilocaine, Etidocaine | 1 |
| Miscellaneous: | Phenacaine, Dipherodon, Dibucaine* | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

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

SEMESTER-V
Subject: Industrial Pharmacy I - Theory
Code: PHM25042
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Know various pre-formulation considerations in development of pharmaceutical dosage forms

CO2. Formulate solid (tablet), liquid orals and evaluate them for their quality

CO3. Know the techniques of formulation of capsules/pellets and their quality evaluations

CO4. Understand the formulation aspects and quality control of sterile dosage forms

CO5. Know the preparation of various cosmetic products

CO6. Know the formulation and evaluation of aerosols and to understand materials used for packaging of pharmaceutical products.

| MODULE – I | Topics to be covered | 08 lectures |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Preformulation Studies: | Introduction to preformulation, goals and objectives, | 1 |
| | Study of physicochemical characteristics of drug substances. | 1 |
| Physical properties: | Physical form (crystal & amorphous), particle size, shape, flow properties, | 1 |
| | Solubility profile (pKa, pH, partition coefficient), polymorphism | 1 |
| Chemical Properties: | Hydrolysis, oxidation, reduction, racemisation, polymerization | 1 |
| | BCS classification of drugs & its significant | 1 |
| Application of preformulation | Application of preformulation considerations in the development of solid, liquid oral and parenteral dosage forms and its impact on | 2 |

| | | |
|--|---------------------------|--|
| | stability of dosage forms | |
|--|---------------------------|--|

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------|
| Tablets: | Introduction, ideal characteristics of tablets, classification of tablets. Excipients | 1 |
| | Formulation of tablets, granulation methods, compression and processing problems. | 2 |
| | Equipments and tablet tooling. | 1 |
| Tablet coating | Types of coating, coating materials, formulation of coating composition, | 1 |
| | Methods of coating equipment employed and defects in coating. | 1 |
| Quality control tests of tablets: | In process and finished product tests | 1 |
| Liquid orals: | Formulation and manufacturing consideration of syrups and elixirs suspensions and emulsions; Filling and packaging; | 2 |
| | Evaluation of liquid orals official in pharmacopoeia | 1 |

| MODULE – III | Topics to be covered | 10lectures |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------|-------------------|
| Capsules: | Introduction, ideal characteristics of capsules, classification of capsules. | 1 |
| Hard gelatin capsules: | Introduction, Production of hard gelatin capsule shells. size of capsules, Filling, finishing | 1 |
| | Special techniques of formulation of hard gelatin capsules, manufacturing defects. | 1 |
| | In process and final product quality control tests for capsules. | 1 |
| Soft gelatin capsules: | Nature of shell and capsule content, size of capsules, importance of base adsorption and minim/gram factors, production | 2 |
| | In process and final product quality control tests. | 1 |

| | | |
|-----------------|-----------------------------------------------------------------------------------------|---|
| | Packing, storage and stability testing of soft gelatin capsules and their applications. | 1 |
| Pellets: | Introduction, formulation requirements, pelletization process | 1 |
| | Equipments for manufacture of pellets | 1 |

| MODULE – IV | Topics to be covered | 10 lectures |
|---------------------------------|---------------------------------------------------------------------------------------------------|--------------------|
| Parenteral Products | Definition, types, advantages and limitations. Preformulation factors and essential requirements, | 1 |
| | Vehicles, additives, importance of isotonicity | 1 |
| | Production procedure, production facilities and controls, aseptic processing | 1 |
| | Formulation of injections, sterile powders, large volume parenterals and lyophilized products | 2 |
| | Containers and closures selection, filling and sealing of ampoules, vials and infusion fluids. | 1 |
| | Quality control tests of parenteral products. | 1 |
| Ophthalmic Preparations: | Introduction, formulation considerations; formulation of eye drops, eye ointments and eye lotions | 2 |
| | Methods of preparation; labeling, containers; evaluation of ophthalmic preparations: | 1 |

| MODULE V | Topics to be covered | 07 Lectures |
|-------------------|---------------------------------------------------------------------------------------------------------|--------------------|
| Cosmetics: | Formulation and preparation of the following cosmetic preparations: lipsticks, shampoos, cold cream | 2 |
| | Formulation and preparation of the following cosmetic preparations: vanishing cream, tooth pastes, hair | 2 |

| | | |
|-------------------------------------|-------------------------------------------------------------------------------------------|---|
| | dyes and sunscreens. | |
| Pharmaceutical Aerosols: | Definition, propellants, containers, valves, types of aerosol systems. | 1 |
| | Formulation and manufacture of aerosols; Evaluation of aerosols | 1 |
| | Quality control and stability studies.. | 1 |
| Packaging Materials Science: | Materials used for packaging of pharmaceutical products, | 1 |
| | Factors influencing choice of containers | 1 |
| | Legal and official requirements for containers, stability aspects of packaging materials, | 1 |
| | Quality control tests. | 1 |

| | | |
|-----------------|-----------------------------|--------------------|
| MODULE | Topics to be covered | 15 lectures |
| Tutorial | | |

SEMESTER-V
Subject: Industrial Pharmacy I - Practical
Code: PHM25046

2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment the student shall be able to

CO1. Know techniques for preparation of conventional parenteral dosage forms

CO2. Gain hands-on experience for the preparation and evaluation of uncoated tablets and to perform quality control test of marketed tablets

CO3. Know the instrumental techniques involved in coating of tablets

CO4. Know the formulation steps for development of conventional semisolids (cream/ointment/gel)

| Sl. No. | Category | Experiment |
|---------|----------------------------|-------------------------------------------|
| 1 | Preformulation studies | Paracetamol/asparin/or any other drug |
| 2 | Preparation and evaluation | Paracetamol tablets |
| | | Aspirin tablets |
| | | Tetracycline capsules |
| 3 | Coating of tablets | Film coating of tables/granules |
| 4 | Preparation of injection | Calcium Gluconate injection |
| | | Ascorbic Acid injection |
| 5 | Qulaity control test | Marketed tablets and capsules (as per IP) |
| 6 | Preparation | Eye drops/ and Eye ointments |
| | | Creams (cold / vanishing cream) |
| 7 | Evaluation | Glass containers (as per IP) |

Recommended Books:

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

SEMESTER-V
Subject: Pharmacology II – Theory
Code: PHM25043
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Understand the mechanism of drug action and its relevance in the treatment of different diseases

CO2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments

CO3. Demonstrate the various receptor actions using isolated tissue preparation

CO4. Appreciate correlation of pharmacology with related medical sciences

| MODULE – I | Topics to be covered | 06 lectures |
|-----------------------------------------------------------------|------------------------------------------------------------|-------------|
| Pharmacology of drugs acting on cardio vascular system : | Introduction to hemodynamic and electrophysiology of heart | 1 |
| | Drugs used in congestive heart failure . | 1 |
| | Anti-hypertensive drugs | 1 |
| | Anti-anginal drugs. | 1 |
| | Anti-arrhythmic drugs. | 1 |
| | Anti-hyperlipidemic drugs | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|---------------------------------------------------------------|--------------------------------------------|-------------|
| Pharmacology of drugs acting on cardio vascular system | Drug used in the therapy of shock. | 2 |
| | Hematinics, coagulants and anticoagulants. | 2 |
| | Fibrinolytics and anti-platelet drugs | 2 |
| | Plasma volume expanders | 2 |
| Pharmacology of drugs acting on urinary system : | Diuretics | 1 |
| | Anti-diuretics | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|------------------------------------|------------------------------------------------|--------------------|
| Autocoids and related drugs | Introduction to autacoids and classification | 1 |
| | Histamine, 5-HT and their antagonists. | 2 |
| | Prostaglandins, Thromboxanes and Leukotrienes. | 1 |
| | Angiotensin, Bradykinin and Substance P. | 2 |
| | Non-steroidal anti-inflammatory agents. | 2 |
| | Anti-gout drugs | 1 |
| | Antirheumatic drugs. | 1 |

| MODULE – IV | Topics to be covered | 10 lectures |
|---------------------------------------------------------|-----------------------------------------------------------------------------------|--------------------|
| Pharmacology of drugs acting on endocrine system | Basic concepts in endocrine pharmacology. | 1 |
| | Anterior Pituitary hormones- analogues and their inhibitors. | 1 |
| | Thyroid hormones- analogues and their inhibitors. | 2 |
| | Hormones regulating plasma calcium level- Parathormone, Calcitonin and Vitamin-D. | 2 |
| | Insulin, Oral Hypoglycemic agents and glucagon. | 2 |
| | ACTH and corticosteroids. | 2 |

| MODULE V | Topics to be covered | 09 Lectures |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------|
| Pharmacology of drugs acting on endocrine system | Androgens and Anabolic steroids. | 1 |
| | Estrogens, progesterone and oral contraceptives. | 2 |
| | Drugs acting on the uterus. | 2 |
| Bioassay | Principles and applications of bioassay.: | 1 |
| | Types of bioassay | 1 |
| | Bioassay of insulin, oxytocin, vasopressin, ACTH, d-tubocurarine, digitalis, histamine and 5-HT | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-V
Subject: Pharmacology II – Practical
Code: PHM25047

2 Credits

Total Practical Required – 4 Hours / week

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

CO01. Understand the mechanism of drug action and its relevance in the treatment of different diseases

CO02. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments

CO03. Demonstrate the various receptor actions using isolated tissue preparation

CO04. Appreciate correlation of pharmacology with related medical sciences

| Sl. No. | Category | Experiment |
|---------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| 1 | Salt solutions | In-vitro pharmacology and physiological |
| 2 | Effect of drugs | Isolated frog heart. |
| | | Blood pressure and heart rate of dog |
| 3 | Diuretic activity | Study of drugs using rats/mice |
| 4 | DRC | Acetylcholine using frog rectus abdominis muscle |
| | | Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum respectively. |
| 5 | Bioassay | Histamine using guinea pig ileum by matching method |
| | | Oxytocin using rat uterine horn by interpolation method |
| | | Serotonin using rat fundus strip by three point bioassay. |
| | | Acetylcholine using rat ileum/colon by four point bioassay. |
| 6 | | Determination of PA ₂ value of prazosin using rat anococcygeus muscle (by Schilds plot method) |
| 7 | | Determination of PD ₂ value using guinea pig ileum |
| 8 | | Effect of spasmogens and spasmolytics using rabbit jejunum |
| 9 | Anti-inflammatory activity | Drugs using carrageenan induced paw-edema model. |
| 10 | Analgesic activity | Drug using central and peripheral methods |

Recommended Books:

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill.
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs, The Point Lippincott Williams & Wilkins.
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews Pharmacology.
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher
8. Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata.
10. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan

SEMESTER-V
Subject: Pharmacognosy and Phytochemistry II - Theory

Code: PHM25044

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

Course Outcome: Upon completion of the course, the student shall be able

CO1. Know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

CO2. Understand the preparation and development of herbal formulation.

CO3. Understand the herbal drug interactions

CO4. Carry out isolation and identification of phytoconstituents

| MODULE – I | Topics to be covered | 07lectures |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------|
| Metabolic pathways in higher plants and their determination | Brief study of basic metabolic pathways | 2 |
| | Formation of different secondary metabolites through these pathways- Shikimic acid pathway, Acetate pathways and Amino acid pathway | 3 |
| | Study of utilization of radioactive isotopes in the investigation of Biogenetic studies.. | 2 |

| General introduction, composition, chemistry & chemical classes, biosources, therapeutic uses and commercial applications of following secondary metabolites | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|-------------------|
| MODULE – II | Topics to be covered | 16lectures |
| Alkaloids | Vinca, Rauwolfia, Belladonna, Opium. | 2 |
| Phenylpropanoids and Flavonoids | Lignans, Tea, Ruta | 2 |
| Steroids, Cardiac Glycosides & Triterpenoids | Liquorice, Dioscorea, Digitalis | 2 |
| Volatile oils | Mentha, Clove, Cinnamon, Fennel, Coriander | 2 |
| Tannins | Catechu, Pterocarpus | 2 |
| Resins | Benzoin, Guggul, Ginger, Asafoetida, Myrrh, Colophony | 2 |
| Glycosides | Senna, Aloes, Bitter Almond | 2 |
| Iridoids, Other terpenoids Naphthaquinones | Gentian, Artemisia, taxus, carotenoid | 2 |

| Isolation, Identification and Analysis of Phytoconstituents | | |
|--------------------------------------------------------------------|----------------------------------------|-------------------|
| MODULE – III | Topics to be covered | 08lectures |
| Terpenoids | Menthol, Citral, Artemisin | 2 |
| Glycosides | Glycyrrhetic acid & Rutin | 2 |
| Alkaloids | Atropine, Quinine, Reserpine, Caffeine | 2 |
| Resins | Podophyllotoxin, Curcumin | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|----------------------------------------------------------------------------------------------|-----------------------------------|--------------------|
| Industrial production, estimation and utilization of the following phytoconstituents: | Forskolin, Sennoside, Artemisinin | 2 |
| | Diosgenin, Digoxin, Atropine,... | 2 |
| | Podophyllotoxin, Caffeine, Taxol, | 2 |
| | Vincristine, Vinblastine. | 2 |

| MODULE V | Topics to be covered | 06 Lectures |
|---------------------------------|-------------------------------|--------------------|
| Basics of Phytochemistry | Modern methods of extraction, | 2 |

| | | |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | Application of latest techniques like Spectroscopy, chromatography and electrophoresis in the isolation, purification and identification of crude drugs. | 4 |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------|---|

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-V
Subject: Pharmacognosy and Phytochemistry II - Practical
 Code: PHM25048
 2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the course, the student shall be able

CO1. Know the modern extraction techniques, characterization and identification of the herbal drugs and phytoconstituents

CO2. Understand the preparation and development of herbal formulation.

CO3. Understand the herbal drug interactions

CO4. Carry out isolation and identification of phytoconstituents

| Sl. No. | Category | Experiment |
|---------|---------------------------------------------------------------------------|------------------------------------------------------------------|
| 1 | Morphology, histology and powder characteristics & extraction & detection | Cinchona |
| | | Cinnamon |
| | | Senna |
| | | Clove |
| | | Ephedra |
| | | Fennel |
| 2 | Exercise involving isolation & detection of active principles | Coriander |
| | | Caffeine - from tea dust. |
| | | Diosgenin from Dioscorea |
| | | Atropine from Belladonna |
| 3 | Paper chromatography | Sennosides from Senna |
| 4 | TLC | Separation of sugars by |
| | | Herbal extract |
| 5 | Analysis of crude drugs by chemical tests | Distillation of volatile oils and detection of phytoconstituents |
| | | Asafoetida |
| | | Benzoin |
| | | Colophony |
| | | Aloes. |
| | | Myrrh |

Recommended Books:

1. W.C.Evans, Trease and Evans Pharmacognosy, 16th edition, W.B. Saunders & Co., London, 2009.
2. Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
3. Text book of Pharmacognosy by C.K. Kokate, Purohit, Gokhlae (2007), 37th Edition, Nirali Prakashan, New Delhi.
4. Herbal drug industry by R.D. Choudhary (1996), Ist Edn, Eastern Publisher, New Delhi.
5. Essentials of Pharmacognosy, Dr.SH.Ansari, IInd edition, Birla publications, New Delhi, 2007
6. Herbal Cosmetics by H.Pande, Asia Pacific Business press, Inc, New Delhi. 7. A.N. Kalia, Textbook of Industrial Pharmacognosy, CBS Publishers, New Delhi, 2005.
8. R Endress, Plant cell Biotechnology, Springer-Verlag, Berlin, 1994.
9. Pharmacognosy & Pharmacobiotechnology. James Bobbers, Marilyn KS, VE Tylor.
10. The formulation and preparation of cosmetic, fragrances and flavours.
11. Remington's Pharmaceutical sciences.
12. Text Book of Biotechnology by Vyas and Dixit. 13. Text Book of Biotechnology by R.C. Dubey.

SEMESTER-V
Subject: Pharmaceutical Jurisprudence – Theory
Code: PHM25048
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO1. Understand about the Pharmaceutical legislations and their implications in the development and marketing of pharmaceuticals.

CO2. Understand various Indian pharmaceutical Acts and Laws

CO3. Understand regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO4. Understand the code of ethics during the pharmaceutical practice

| MODULE – I | Topics to be covered | 08lectures |
|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|
| Drugs and Cosmetics Act, 1940 and its rules 1945 | Objectives, Definitions, Legal definitions of schedules to the Act and Rules | 2 |
| | Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. | 2 |
| | Manufacture of drugs – Prohibition of manufacture and sale of certain drugs | 2 |
| | Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license | 2 |

| MODULE – II | Topics to be covered | 10lectures |
|---------------------------------------------------------|---------------------------------------------------------------------------------------|------------|
| Drugs and Cosmetics Act, 1940 and its rules 1945 | Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) . | 2 |

| | | |
|--|-------------------------------------------------------------------------------------------------------------------------------|---|
| | Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties | 1 |
| | Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, | 2 |
| | List of permitted colors. Offences and penalties | 1 |
| | Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, | 2 |
| | Government drug analysts, Licensing authorities controlling authorities, Drugs Inspectors | 2 |

| MODULE – III | Topics to be covered | 12lectures |
|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Pharmacy Act –1948 | Objectives, Definitions, Pharmacy Council of India; its constitution and functions | 1 |
| | Education Regulations, State and Joint state pharmacy councils constitution and functions, Registration of Pharmacists, Offences and Penalties | 2 |
| Medicinal and Toilet Preparation Act –1955 | Objectives, Definitions, Licensing, Manufacture In bond and Outside bond. | 1 |
| | Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties. | 2 |
| Narcotic Drugs and Psychotropic substances Act-1985 and Rules | Objectives, Definitions, Authorities and Officers | 1 |
| | Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, | 2 |
| | Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, | 2 |
| | manufacture, sale and export of opium, Offences and Penalties | 1 |

| MODULE – IV | Topics to be covered | 10 lectures |
|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Study of Salient Features of Drugs and Magic Remedies Act and its rules : | Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties | 2 |
| Prevention of Cruelty to animals Act-1960 | Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, | 2 |
| | Performance of Experiments, Transfer and acquisition of animals for experiment, | 2 |
| | Records, Power to suspend or revoke registration, Offences and Penalties | 2 |
| National Pharmaceutical Pricing Authority | Drugs Price Control Order (DPCO)2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM) | 2 |

| MODULE V | Topics to be covered | 05 Lectures |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pharmaceutical Legislations | A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee | 1 |
| Code of Pharmaceutical ethics | Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath | 1 |
| Medical Termination of Pregnancy Act | | 1 |
| Right to Information Act | | 1 |
| Introduction to Intellectual Property Rights (IPR) | | 1 |

Recommended books:

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

Scheme of Study-Semester- VI

| Sl. No | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|------------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|------------|
| 1 | PHM26049 | Medicinal Chemistry III – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM26050 | Pharmacology III – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM26051 | Herbal Drug Technology – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM26052 | Biopharmaceutics and Pharmacokinetics – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM26053 | Pharmaceutical Biotechnology– Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 6 | PHM26054 | Quality Assurance– Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 7 | PHM26055 | Medicinal chemistry III – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 8 | PHM26056 | Pharmacology III – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 9 | PHM26057 | Herbal Drug Technology – Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| Total | | | 30 | 30 | 6 | 750 | 555 | 120 | 45 | 30 |

SEMESTER-VI
Subject: Medicinal Chemistry III - Theory

Code: PHM26049

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is designed to impart fundamental knowledge on the structure, chemistry and therapeutic value of drugs. The subject emphasis on modern techniques of rational drug design like quantitative structure activity relationship (QSAR), Prodrug concept, combinatorial chemistry and Computer aided drug design (CADD). The subject also emphasizes on the chemistry, mechanism of action, metabolism, adverse effects, Structure Activity Relationships (SAR), therapeutic uses and synthesis of important drugs.

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

CO1 Understand about the importance of drug design and different techniques of drug design.

CO2. Understand about the chemistry of drugs with respect to their biological activity.

CO3. Know the metabolism, adverse effects and therapeutic value of drugs.

CO4. Know the importance of SAR of drugs

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*) | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| MODULE – I | Topics to be covered | 6lectures |
| Antibiotics | Historical background, Nomenclature, Stereochemistry, Structure activity relationship | 1 |
| β-Lactam antibiotics | Chemical degradation classification and important products of Penicillin, Cephalosporins, β- Lactamase inhibitors, Monobactams | 2 |
| Aminoglycosides | Chemical degradation classification and important products of Streptomycin, Neomycin, Kanamycin | 1 |
| Tetracyclines: | Chemical degradation classification and important products of Tetracycline, Oxytetracycline, Chlortetracycline, Minocycline, Doxycycline | 2 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*) | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|------------|
| MODULE – II | Topics to be covered | 11lectures |
| Antibiotics | Historical background, Nomenclature, Stereochemistry, Structure activity relationship | 1 |
| Macrolide: | Chemical degradation classification and important products of Erythromycin Clarithromycin, Azithromycin. | 2 |
| Miscellaneous | Chemical degradation classification and important products of Chloramphenicol*, Clindamycin. | 1 |
| Prodrugs | Basic concepts and application of prodrugs design | 1 |
| Antimalarials | Etiology of malaria. | 1 |
| Quinolines: | SAR, Quinine sulphate, Chloroquine*, Amodiaquine, Primaquine phosphate, Pamaquine*, Quinacrine hydrochloride, Mefloquine | 2 |
| Biguanides and dihydro triazines: | Cycloguanil pamoate, Proguanil | 1 |
| Miscellaneous | Pyrimethamine, Artesunate, Artemether, Atovaquone | 2 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*) | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| MODULE – III | Topics to be covered | 9lectures |
| Anti-tubercular Agents | Isoniazid*, Ethionamide, Ethambutol, Pyrazinamide, Para amino salicylic acid.* | 1 |
| Synthetic anti tubercular agents | | |
| Anti tubercular antibiotics | Rifampicin, Rifabutin, Cycloserine Streptomycin, Capreomycin sulphate. | 2 |
| Urinary tract anti-infective agents | SAR of quinolones, Nalidixic Acid, Norfloxacin, Enoxacin, Ciprofloxacin*, Ofloxacin, Lomefloxacin, Sparfloxacin, Gatifloxacin, Moxifloxacin. | 2 |
| Quinolones | | |
| Miscellaneous | Furazolidine, Nitrofurantoin*, Methanamine . | 2 |

| | | |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| Antiviral agents | Amantadine hydrochloride, Rimantadine hydrochloride, Idoxuridine trifluoride, Acyclovir*, Gancyclovir, Zidovudine, Didanosine, Zalcitabine, Lamivudine, Loviride, Delavirding, Ribavirin, Saquinavir, Indinavir, Ritonavir | 2 |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*) | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| MODULE – IV | Topics to be covered | 14 lectures |
| Antifungal agents: | Amphotericin-B, Nystatin, Natamycin, Griseofulvin | 2 |
| Antifungal antibiotics | | |
| Synthetic Antifungal agents | Clotrimazole, Econazole, Butoconazole, Oxiconazole Tioconazole, Miconazole*, Ketoconazole, Terconazole, Itraconazole, Fluconazole, Naftifine hydrochloride, Tolnaftate | 2 |
| Anti-protozoal Agents | Metronidazole*, Tinidazole, Ornidazole, Diloxanide, Iodoquinol, Pentamidine Isethionate, Atovaquone, Eflornithine | 2 |
| Anthelmintics | Diethylcarbamazine citrate*, Thiabendazole, Mebendazole*, Albendazole, Niclosamide, Oxamniquine, Praziquantal, Ivermectin | 2 |
| Sulphonamides and Sulfones | Historical development, chemistry, classification | 2 |
| | SAR of Sulfonamides: Sulphamethizole, Sulfisoxazole, Sulphamethizine, Sulfacetamide*, Sulphapyridine, Sulfamethoxazole*, Sulphadiazine, Mefenide acetate, Sulfasalazine | 2 |
| Folate reductase inhibitors | Trimethoprim*, Cotrimoxazole | 1 |
| Sulfones | Dapsone* | 1 |

| Study of the development of the following classes of drugs, Classification, mechanism of action, uses of drugs mentioned in the course, Structure activity relationship of selective class of drugs as specified in the course and synthesis of drugs superscripted by (*) | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| MODULE V | Topics to be covered | 05 Lectures |
| Introduction to Drug Design | Various approaches used in drug design | 1 |
| | Physicochemical parameters used in quantitative structure activity relationship (QSAR) such as partition coefficient, Hammett's electronic parameter, Taft's steric parameter and Hansch analysis | 2 |
| | Pharmacophore modeling and docking techniques | 1 |
| Combinatorial Chemistry | Concept and applications chemistry: solid phase and solution phase synthesis | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Subject: Medicinal Chemistry III - Practical

Code: PHM26055

2 Credits | Semester VI

Total Practical Required – 4 Hours / week**Course Outcome:** Upon completion of the experiment student shall be able to

CO1. Understand about the importance of drug design and different techniques of drug design.

CO2. Understand about the chemistry of drugs with respect to their biological activity.

CO3. Know the metabolism, adverse effects and therapeutic value of drugs.

CO4. Know the importance of SAR of drugs

| Sl. No. | Category | Experiment |
|---------|---------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Preparation of drugs and intermediates | Sulphanilamide |
| | | 7-Hydroxy, 4-methyl coumarin |
| | | Chlorobutanol |
| | | Triphenyl imidazole |
| | | Tolbutamide |
| | | Hexamine |
| 2 | Assay of drugs | Isonicotinic acid hydrazide. |
| | | Chloroquine |
| | | Metronidazole |
| | | Dapsone |
| | | Chlorpheniramine maleate |
| | | Benzyl penicillin |
| 3 | | Preparation of medicinally important compounds or intermediates by Microwave irradiation technique |
| 4 | | Drawing structures and reactions using chem draw |
| 5 | Determination of physicochemical properties | logP, clogP, MR, Molecular weight, Hydrogen bond donors and acceptors for class of drugs course content using drug design software Drug likeliness screening (Lipinskies RO5) |

Recommended Books:

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

SEMESTER-VI
Subject: Pharmacology III – Theory
Code: PHM26050
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is intended to impart the fundamental knowledge on various aspects (classification, mechanism of action, therapeutic effects, clinical uses, side effects and contraindications) of drugs acting on respiratory and gastrointestinal system, infectious diseases, immuno-pharmacology and in addition, emphasis on the principles of toxicology and chronopharmacology.

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

CO1. Understand the mechanism of drug action and its relevance in the treatment of different diseases

CO2. Understand the mechanism of drug action and its relevance in the treatment of different infectious diseases

CO3. Understand the mechanism of drug action and its relevance in the immunotherapy

CO4. Appreciate correlation of pharmacology with related medical sciences.

CO5. Understand about symptoms of several poisonings

CO6. Understand the principles of toxicology and treatment of various poisonings

| MODULE – I | Topics to be covered | 10lectures |
|-------------------------------------------------------------------|---------------------------------------|------------|
| Pharmacology of drugs acting on Respiratory system | Anti -asthmatic drugs | 5 |
| | Drugs used in the management of COPD | |
| | Expectorants and antitussives | |
| | Nasal decongestants | |
| | Respiratory stimulants | |
| Pharmacology of drugs acting on the Gastrointestinal Tract | Antiulcer agents | 5 |
| | Drugs for constipation and diarrhoea | |
| | Appetite stimulants and suppressants. | |
| | Digestants and carminatives. | |
| | Emetics and anti-emetics | |

| MODULE – II | Topics to be covered | 5lectures |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Chemotherapy | General principles of chemotherapy | 1 |
| | Sulfonamides and cotrimoxazole. | 1 |
| | Antibiotics- Penicillins, cephalosporins, chloramphenicol, macrolides, quinolones and fluoroquinolins, tetracycline and aminoglycosides | 4 |

| MODULE – III | Topics to be covered | 8 lectures |
|---------------------|-----------------------------|-------------------|
| Chemotherapy | Antitubercular agents | 8 |
| | Antileprotic agents | |
| | Antifungal agents | |
| | Antiviral drugs | |
| | Anthelmintics | |
| | Antimalarial drugs | |
| | Antiamoebic agents | |

| MODULE IV | Topics to be covered | 8 Lectures |
|-------------------------------------------------|---------------------------------------------------------------------------|-------------------|
| Chemotherapy Combinatorial Chemistry | Urinary tract infections and sexuallytransmitted diseases | 2 |
| | Chemotherapy of malignancy | 1 |
| Immunopharmacology | Immunostimulants | 1 |
| | Immunosuppressant | 1 |
| | Protein drugs, monoclonal antibodies target drugs to antigen, biosimilars | 3 |

| MODULE V | Topics to be covered | 14 lectures |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Principles of toxicology | Definition and basic knowledge of acute, subacute and chronic toxicity | 2 |
| | Definition and basic knowledge of genotoxicity, carcinogenicity, teratogenicity and mutagenicity | 3 |
| | General principles of treatment of poisoning | 2 |
| | Clinical symptoms and management of barbiturates, morphine, organophosphorus compound and lead, mercury and arsenic poisoning | 3 |
| Chronopharmacology | Definition of rhythm and cycles | 2 |
| | Biological clock and their significance leading to chronotherapy. | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-VI
Subject: Pharmacology III – Practical
Code: PHM26056
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of this experiment the student should be able to:

CO1. Know the dose calculation in pharmacological experiments.

CO2. Determination of hypoglycemic effects of Insulin in rabbits

CO3. Demonstration of animal experiments using simulated methods.

CO4. Understand the acute skin/acute eye irritation of a test substance.

| Sl. No. | Experiment |
|---------|-------------------------------------------------------------------------------------------------------------|
| 1 | Dose calculation in pharmacological experiments |
| 2 | Antiallergic activity by mast cell stabilization assay |
| 3 | Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model |
| 4 | Study of effect of drugs on gastrointestinal motility |
| 5 | Effect of agonist and antagonists on guinea pig ileum |
| 6 | Estimation of serum biochemical parameters by using semi- autoanalyser |
| 7 | Effect of saline purgative on frog intestine. |
| 8 | Insulin hypoglycemic effect in rabbit |
| 9 | Test for pyrogens (rabbit method) |
| 10 | Determination of acute oral toxicity (LD50) of a drug from a given data |
| 11 | Determination of acute skin irritation / corrosion of a test substance |
| 12 | Determination of acute eye irritation / corrosion of a test substance |
| 13 | Calculation of pharmacokinetic parameters from a given data |
| 14 | Biostatistics methods in experimental pharmacology(student's t test, ANOVA) |
| 15 | Biostatistics methods in experimental pharmacology (Chi square test, Wilcoxon Signed Rank test) |

Recommended Books:

1. Rang H. P., Dale M. M., Ritter J. M., Flower R. J., Rang and Dale's Pharmacology, Churchill Livingstone Elsevier
2. Katzung B. G., Masters S. B., Trevor A. J., Basic and clinical pharmacology, Tata Mc Graw-Hill
3. Goodman and Gilman's, The Pharmacological Basis of Therapeutics
4. Marry Anne K. K., Lloyd Yee Y., Brian K. A., Robbin L.C., Joseph G. B., Wayne A. K., Bradley R.W., Applied Therapeutics, The Clinical use of Drugs. The Point Lippincott Williams & Wilkins
5. Mycek M.J, Gelnet S.B and Perper M.M. Lippincott's Illustrated Reviews Pharmacology
6. K.D.Tripathi. Essentials of Medical Pharmacology, , JAYPEE Brothers Medical Publishers (P) Ltd, New Delhi.
7. Sharma H. L., Sharma K. K., Principles of Pharmacology, Paras medical publisher Modern Pharmacology with clinical Applications, by Charles R.Craig & Robert,
8. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata,
9. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,
10. N.Udupa and P.D. Gupta, Concepts in Chronopharmacology

SEMESTER-VI
Subject: Herbal Drug Technology – Theory

Code: PHM26051

4 Credits

Total Lectures Required –45

Total Tutorials Required – 10

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

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

CO1. Understand raw material as source of herbal drugs from cultivation to herbal drug product

CO2. Know about the WHO and ICH guidelines for evaluation of herbal drugs

CO3. Know about the herbal cosmetics, natural sweeteners, nutraceuticals

CO4. Appreciate patenting of herbal drugs, GMP.

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Herbs as raw materials | Definition of herb, herbal medicine, herbal medicinal product, herbal drug preparation Source of Herbs | 5 |
| | Selection, identification and authentication of herbal materials | |
| | Processing of herbal raw material | |
| Biodynamic Agriculture | Good agricultural practices in cultivation of medicinal plants including Organic farming. Pest and Pest management in medicinal plants: Biopesticides/Bioinsecticides | |
| Indian Systems of Medicine | Basic principles involved in Ayurveda, Siddha, Unani and Homeopathy | 5 |
| | Preparation and standardization of Ayurvedic formulations viz Aristas and Asawas, Ghutika, Churna, Lehya and Bhasma | |

| MODULE – II | Topics to be covered | 6lectures |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| Nutraceuticals | General aspects, Market, growth, scope and types of products available in the market. Health benefits and role of Nutraceuticals in ailments like Diabetes, CVS diseases, Cancer, Irritable bowel syndrome and various Gastro intestinal diseases. | 1 |
| | Study of following herbs as health food: Alfaalfa, Chicory, Ginger, Fenugreek, Garlic, Honey, Amla, Ginseng, Ashwagandha, Spirulina. | 1 |
| Herbal-Drug and Herb-Food Interactions | General introduction to interaction and classification. Study of following drugs and their possible side effects and interactions: Hypercium, kava-kava, Ginkobiloba, Ginseng, Garlic, Pepper & Ephedra | 4 |

| MODULE – III | Topics to be covered | 10lectures |
|----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Herbal Cosmetics | Sources and description of raw materials of herbal origin used via, fixed oils, waxes, gums colours, perfumes, protective agents, bleaching agents, antioxidants in products such as skin care, hair care and oral hygiene products | 4 |
| Herbal excipients | Herbal Excipients – Significance of substances of natural origin as excipients – colorants, sweeteners, binders, diluents, viscosity builders, disintegrants, flavors & perfumes. | 4 |
| Herbal formulations | Conventional herbal formulations like syrups, mixtures and tablets and Novel dosage forms like phytosomes | 2 |

| MODULE IV | Topics to be covered | 9Lectures |
|------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|------------------|
| Evaluation of Drugs | WHO & ICH guidelines for the assessment of herbal drugs Stability testing of herbal drugs | 2 |
| Patenting and Regulatory requirements of natural products | Definition of the terms: Patent, IPR, Farmers right, Breeder's right, Bioprospecting and Biopiracy | 2 |

| | | |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------|---|
| | Patenting aspects of Traditional Knowledge and Natural Products. Case study of Curcuma & Neem | 2 |
| Regulatory Issues | Regulations in India (ASU DTAB, ASU DCC), Regulation of manufacture of ASU drugs - Schedule Z of Drugs & Cosmetics Act for ASU drugs | 3 |

| MODULE V | Topics to be covered | 10 lectures |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| General Introduction to Herbal Industry | Herbal drugs industry: Present scope and future prospects. A brief account of plant based industries and institutions involved in work on medicinal and aromatic plants in India | 5 |
| Schedule T – Good Manufacturing Practice of Indian systems of medicine | Components of GMP (Schedule – T) and its objectives Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records. | 5 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-VI
Subject: Herbal Drug Technology – Practical
Code: PHM26057
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of this experiment the student should be able to:

CO01. Understand raw material as source of herbal drugs from cultivation to herbal drug product

CO02. Know about the WHO and ICH guidelines for evaluation of herbal drugs

CO03. Know about the herbal cosmetics, natural sweeteners, nutraceuticals

CO04. Appreciate patenting of herbal drugs, GMP

| Sl. No. | Experiment |
|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | To perform preliminary phytochemical screening of crude drugs. |
| 2 | Determination of the alcohol content of Asava and Arista |
| 3 | Evaluation of excipients of natural origin |
| 4 | Incorporation of prepared and standardized extract in cosmetic formulations like creams, lotions and shampoos and their evaluation. |
| 5 | Incorporation of prepared and standardized extract in formulations like syrups, mixtures and tablets and their evaluation as per Pharmacopoeial requirements |
| 6 | Monograph analysis of herbal drugs from recent Pharmacopoeias |
| 7 | Determination of Aldehyde content. |
| 8 | Determination of Phenol content |
| 9 | Determination of total alkaloids Asava and Arista |

SEMESTER-VI
Subject: Biopharmaceutics and Pharmacokinetics – Theory
Code: PHM26052
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is designed to impart knowledge and skills of Biopharmaceutics and pharmacokinetics and their applications in pharmaceutical development, design of dose and dosage regimen and in solving the problems arising therein.

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

CO01. Understand the basic concepts in biopharmaceutics and pharmacokinetics and their significance.

CO02. Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

CO03. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.

CO04. Understand various pharmacokinetic parameters, their significance & applications.

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Introduction to Biopharmaceutics | Absorption; Mechanisms of drug absorption through GIT, factors influencing drug absorption through GIT, absorption of drug from Non per oral extra-vascular routes | 5 |
| | Distribution Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs | 5 |

| MODULE – II | Topics to be covered | 12 lectures |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Elimination: | Drug metabolism and basic understanding metabolic pathways renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, Non renal routes of drug excretion of drugs . | 6 |
| Bioavailability and Bioequivalence: | Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies, methods to enhance the dissolution rates and bioavailability of poorly soluble drugs. | 6 |

| MODULE – III | Topics to be covered | 8 lectures |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Pharmacokinetics | Definition and introduction to Pharmacokinetics, Compartment models, Non compartment models, physiological models, One compartment open model. (a). Intravenous Injection (Bolus) (b). Intravenous infusion and (c) Extra vascular administrations. Pharmacokinetics parameters - KE ,t _{1/2} ,V _d ,AUC,K _a , Cl _t and CLR- definitions methods of eliminations, understanding of their significance and application | 8 |

| MODULE IV | Topics to be covered | 9 Lectures |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Multicompartment models | Two compartment open model. IV bolus Kinetics of multiple dosing, steady state drug levels, calculation of loading and maintenance doses and their significance in clinical settings | 8 |

| MODULE V | Topics to be covered | 7 lectures |
|-----------------------------------|-----------------------------------------------------------------------------------------|-------------------|
| Nonlinear Pharmacokinetics | Introduction, | 7 |
| | Factors causing Non-linearity. | |
| | Michaelis-menton method of estimating parameters, Explanation with example of drugs. | |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition, Prentice-Hall International edition, USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Gibaldi and Donald R. Mercey Dekker Inc.
6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
7. Biopharmaceutics; By Swarbrick
8. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozer, Lea and Febiger, Philadelphia, 1995.
9. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
10. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
11. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania
- 12.

SEMESTER-VI
Subject: Pharmaceutical Biotechnology - Theory
Code: PHM26053
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: Biotechnology has a long promise to revolutionize the biological sciences and technology. Scientific application of biotechnology in the field of genetic engineering, medicine and fermentation technology makes the subject interesting. Biotechnology is leading to new biological revolutions in diagnosis, prevention and cure of diseases, new and cheaper pharmaceutical drugs. Biotechnology has already produced transgenic crops and animals and the future promises lot more. It is basically a research-based subject.

Course Outcome: Upon completion of the subject student shall be able to;

CO1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries

CO2. Genetic engineering applications in relation to production of pharmaceuticals

CO3. Importance of Monoclonal antibodies in Industries

CO4. Appreciate the use of microorganisms in fermentation technology

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Brief introduction | Biotechnology with reference to Pharmaceutical Sciences | 1 |
| Enzyme Biotechnology | Methods of enzyme immobilization and applications. | 2 |
| Biosensors | Working and applications of biosensors in Pharmaceutical Industries | 2 |
| | Brief introduction to Protein Engineering Use of microbes in industry. Production of Enzymes- General consideration Amylase, Catalase, Peroxidase, Lipase, Protease, Penicillinase | 3 |
| Basic principles | Genetic engineering | 2 |

| MODULE – II | Topics to be covered | 10lectures |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| | Study of cloning vectors, restriction endonucleases and DNA ligase. | 2 |
| | Recombinant DNA technology. Application of genetic engineering in medicine | 2 |
| | Application of r DNA technology and genetic engineering in the production of: i) Interferon ii) Vaccines- hepatitis- B iii) Hormones- Insulin. | 4 |
| | Brief introduction to PCR | 2 |

| MODULE – III | Topics to be covered | 10lectures |
|---------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Types of immunity | Humoral immunity, cellular immunity | 1 |
| Structure | Immunoglobulins | 1 |
| Structure and Function | MHC | 2 |
| | Hypersensitivity reactions, Immune stimulation and Immune suppressions. | |
| General method of the preparation of | Bacterial vaccines, toxoids, viral vaccine, antitoxins, serum-immune blood derivatives and other products relative to immunity | 2 |
| Storage conditions and stability | Official vaccines | 1 |
| Hybridoma technology | Production, Purification and Applications | 2 |
| | Blood products and Plasma Substitutes | 1 |

| MODULE – IV | Topics to be covered | 8 lectures |
|------------------------------------|--------------------------------------------------------------------------------------------------|-------------------|
| Immuno blotting techniques- | ELISA, Western blotting, Southern blotting | 2 |
| Genetic organization of | Eukaryotes and Prokaryotes | 1 |
| | Microbial genetics including transformation, transduction, conjugation, plasmids and transposons | 2 |
| Introduction | Microbial biotransformation and applications | 2 |
| Mutation | Types of mutation/mutants | 1 |

| MODULE V | Topics to be covered | 7 Lectures |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------|-------------------|
| Fermentation | Methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring | 3 |
| | Large scale production fermenter design and its various controls | |
| Study of the production of | Penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, | 2 |
| Blood Products | Collection, Processing and Storage of whole human blood, dried human plasma, plasma Substitutes | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books

1. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
2. RA Goldshy et. al., : Kuby Immunology.
3. J.W. Goding: Monoclonal Antibodies.
4. J.M. Walker and E.B. Gingold: Molecular Biology and Biotechnology by Royal Society of Chemistry.
5. Zaborsky: Immobilized Enzymes, CRC Press, Degraland, Ohio.
6. S.B. Primrose: Molecular Biotechnology (Second Edition) Blackwell Scientific Publication.
7. Stanbury F., P., Whitakar A., and Hall J., S., Principles of fermentation technology, 2nd edition, Aditya books Ltd., New Delhi

SEMESTER-VI
Subject: Quality Assurance - Theory
Code: PHM26054
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

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

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

CO01. Understand the importance of quality in pharmaceutical products.

CO02 Know the importance of Good manufacturing practices and the factors affecting the quality of pharmaceuticals

CO03. Know the importance of Good laboratory practices and its documentation

CO04. Understand the various documentation processes

CO05. Understand calibration and validation and predict the errors and analyse the root cause.

CO06. Know the process involved in manufacturing of pharmaceuticals in different departments

| MODULE – I | Topics to be covered | 10 lectures |
|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Quality Assurance and Quality Management concepts | Definition and concept of Quality control, Quality assurance and GMP | 2 |
| Total Quality Management (TQM) | Definition, elements, philosophies | 1 |
| ICH Guidelines | Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines | 3 |
| Quality by design (QbD) | Definition, overview, elements of QbD program, tools | 2 |
| ISO 9000 & ISO14000 | Overview, Benefits, Elements, steps for registration | 1 |
| NABL accreditation | Principles and procedures | 1 |

| MODULE – II | Topics to be covered | 6 lectures |
|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Organization and personnel | Personnel responsibilities, training, hygiene and personal records | 2 |
| Premises | Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination | 2 |
| Equipments and raw materials | Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials | 2 |

| MODULE – III | Topics to be covered | 10lectures |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Quality Control | Quality control test for containers, rubber closures and secondary packing, materials | 5 |
| Good Laboratory Practices | General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation, Test and Control Articles, Protocol for Conduct of a Nonclinical Laboratory Study, Records and Reports, Disqualification of Testing Facilities | 5 |

| MODULE – IV | Topics to be covered | 10 lectures |
|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Complaints | Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal. | 5 |
| Document maintenance in pharmaceutical industry | Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records. | 5 |

| MODULE V | Topics to be covered | 9Lectures |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------|------------------|
| Calibration and Validation | Methods and general requirements, study of media, equipments, sterilization methods, aeration process, stirring | 5 |
| | Large scale production fermenter design and its various controls | |
| Warehousing | Penicillins, citric acid, Vitamin B12, Glutamic acid, Griseofulvin, | 4 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Quality Assurance Guide by organization of Pharmaceutical Products of India.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69.
3. Quality Assurance of Pharmaceuticals- A compendium of Guide lines and Related materials Vol I WHO Publications.
4. A guide to Total Quality Management- Kushik Maitra and Sedhan K Ghosh
5. How to Practice GMP's– P P Sharma.
6. ISO 9000 and Total Quality Management – Sadhank G Ghosh
7. The International Pharmacopoeia – Vol I, II, III, IV- General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excipients and Dosage forms
8. Good laboratory Practices – Marcel Dekker Series
9. ICH guidelines, ISO 9000 and 14000 guidelines

Scheme of Study-Semester- VII

| Sl. No | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|--------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|----|------------|
| 1 | PHM27058 | Instrumental Methods of Analysis – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM27059 | Industrial Pharmacy – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM27060 | Pharmacy Practice – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 4 | PHM27061 | Novel Drug Delivery System – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 5 | PHM27062 | Instrumental Methods of Analysis Practical | 2 | 4 | - | 50 | 35 | 10 | 3 | 2 |
| 6 | PHM27063 | Practice School* | 6 | 12 | - | 150 | 125 | - | 21 | 4 |
| Total | | | 24 | 28 | 4 | 600 | 460 | 70 | 48 | 22 |

SEMESTER-VII
Subject: Instrumental Methods of Analysis - Theory
Code: PHM27058
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart a fundamental knowledge on the principles and instrumentation of spectroscopic and chromatographic technique. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

CO01. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis

CO02. Understand the functional group determination by IR spectroscopy

CO03. Gain knowledge on adsorption and partition chromatography

CO04. Understand various instrumentation of GC and HPLC

CO05. Understand various types of chromatographic techniques.

CO06. Understand electrophoretic methods

| MODULE – I | Topics to be covered | 10 lectures |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| UV Visible spectroscopy | Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations. | 1 |
| | Instrumentation - Sources of radiation, wavelength selectors, sample cells, | 1 |
| | Detectors- Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode. | 1 |
| | Applications- Spectrophotometric titrations | 1 |
| | Single component and multi component analysis | 1 |
| Fluorimetry | Theory, Concepts of singlet, doublet and triplet electronic | 1 |

| | | |
|--|-------------------------------------------|---|
| | states | |
| | Internal and external conversions | 1 |
| | Factors affecting fluorescence, quenching | 1 |
| | Instrumentation | 1 |
| | Applications | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------|
| IR spectroscopy | Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations | 1 |
| | Instrumentation - Sources of radiation, wavelength selectors | 1 |
| | Detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector | 1 |
| | Applications | 1 |
| Flame Photometry- | Principle, interferences, instrumentation | 1 |
| | Applications | 1 |
| Atomic absorption spectroscopy- | Principle, interferences, instrumentation and applications | 1 |
| | Applications | 1 |
| Nepheloturbidometry | Principle, instrumentation | 1 |
| | Applications | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|--------------------------------------------------------|----------------------------------------------------------|--------------------|
| Introduction to chromatography | Introduction to chromatography | 1 |
| Adsorption and partition column chromatography- | Methodology | 2 |
| | Advantages,disadvantages and applications | 1 |
| Thin layer chromatography- | Introduction, Principle, Methodology | 1 |
| | Rf values,advantages, disadvantages and applications | 1 |
| Paper chromatography- | Introduction, methodology, development techniques, | 1 |
| | Advantages, disadvantages and applications | 1 |
| Electrophoresis | Introduction, factors affecting electrophoretic mobility | 1 |

| | | |
|--|-------------------------------------------------------------------|---|
| | Techniques of paper, gel, capillary electrophoresis, applications | 1 |
|--|-------------------------------------------------------------------|---|

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------------------------------------|--------------------------------------------|--------------------|
| Gas chromatography | Introduction, theory | 1 |
| | Instrumentation | 1 |
| | Derivatization, temperature programming, | 1 |
| | Advantages, disadvantages and applications | 1 |
| High performance liquid chromatography (HPLC) | Introduction | 1 |
| | Theory | 1 |
| | Instrumentation, | 1 |
| | Advantages and applications. | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|------------------------------------|--------------------------------------------------------|--------------------|
| Ion exchange chromatography | Introduction, classification | 1 |
| | Ion exchange resins, properties | 1 |
| | Mechanism of ion exchange process | |
| | Factors affecting ion exchange | |
| | Methodology and applications | 1 |
| Gel chromatography | Introduction, theory, instrumentation and applications | 1 |
| Affinity chromatography | Introduction, theory, instrumentation and applications | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

SEMESTER-VII
Subject: Instrumental Methods of Analysis - Practical
Code: PHM27062
2 Credits

Total Practical Required – 4 Hours / week

Course Outcome: Upon completion of the experiment the student shall be able to

CO1. Understand the samples analysis by spectroscopy

CO2. Construction of calibration curve with spectrophotometer

CO3. Interpret the various functional group by spectroscopy

CO4. Know analysis of drugs using various analytical instruments

| Sl.No | Experiment |
|-------|-----------------------------------------------------------------------------------------------------|
| 1 | Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds |
| 2 | Estimation of dextrose by colorimetry |
| 3 | Estimation of sulfanilamide by colorimetry |
| 4 | Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy |
| 5 | Assay of paracetamol by UV- Spectrophotometry |
| 6 | Estimation of quinine sulfate by fluorimetry |
| 7 | Study of quenching of fluorescence |
| 8 | Determination of sodium by flame photometry |
| 9 | Determination of potassium by flame photometry |
| 10 | Determination of chlorides and sulphates by nephelo turbidometry |
| 11 | Separation of amino acids by paper chromatography |
| 12 | Separation of sugars by thin layer chromatography |
| 13 | Separation of plant pigments by column chromatography |
| 14 | Demonstration experiment on HPLC |
| 15 | Demonstration experiment on Gas Chromatography |

Recommended Books

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

SEMESTER-VII
Subject: Industrial Pharmacy II – Theory

Code: PHM27059

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

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

CO1. Know the process of pilot plant and scale up of pharmaceutical dosage forms

CO2. Understand the process of technology transfer from lab scale to commercial batch.

CO3. Know different laws and acts that regulate pharmaceutical industry

CO4. Understand the approval process and regulatory requirements for drug products

CO5. Understand the quality management systems and its certifications

CO6. Understand the Indian Regulatory requirements and approval procedures for New Drugs

| MODULE – I | Topics to be covered | 10 lectures |
|----------------------------------------|---------------------------------------------------------------------------------|-------------|
| Pilot plant scale up techniques | General considerations - including significance of personnel requirements | 2 |
| | Space requirements | 1 |
| | Raw materials | 1 |
| | Pilot plant scale up | 1 |
| | Considerations for solids, liquid orals, semi solids and relevant documentation | 2 |
| | SUPAC guidelines | 2 |
| | Introduction to platform technology | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|--------------------------------------------|---------------------------------------------------------------------------------------------|-------------|
| Technology development and transfer | WHO guidelines for Technology Transfer (TT): Terminology, Technology transfer protocol | 1 |
| | Quality risk management, Transfer from R& D to production (Process, packaging and cleaning) | 1 |
| | Granularity of TT Process (API, | 1 |

| | | |
|--|--------------------------------------------------------------------------------------|---|
| | excipients, finished products, packaging materials) Documentation | |
| | Premises and equipments, qualification and validation | 1 |
| | Quality control, analytical method transfer, Approved regulatory bodies and agencies | 1 |
| | Commercialization - practical aspects and problems (case studies) | 1 |
| | TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI | 1 |
| | TT related documentation - confidentiality agreement | 1 |
| | Licensing, MoUs, | 1 |
| | Legal issues | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Regulatory affairs | Introduction, Historical overview of Regulatory Affairs | 1 |
| | Regulatory authorities, Role of Regulatory affairs department | 1 |
| | Responsibility of Regulatory Affairs Professionals | 1 |
| Regulatory requirements for drug approval | Drug Development Teams, Non-Clinical Drug Development, Pharmacology | 1 |
| | Drug Metabolism and Toxicology | 1 |
| | General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA) | 1 |
| | Clinical research / BE studies, Clinical Research Protocols | 1 |
| | Biostatistics in Pharmaceutical Product Development | 1 |
| | Data Presentation for FDA Submissions | 1 |

| | | |
|--|--------------------------------|---|
| | Management of Clinical Studies | 1 |
|--|--------------------------------|---|

| MODULE – IV | Topics to be covered | 08 lectures |
|-----------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|
| Quality management systems | Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD) | 1 |
| | Six Sigma concept, Out of Specifications (OOS), Change control | 1 |
| | Introduction to ISO 9000 series of quality systems standards, | 1 |
| | ISO 14000, NABL, GLP | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|---------------------------------------|-----------------------------------------------------------------------------------|--------------------|
| Indian Regulatory Requirements | Central Drug Standard Control Organization(CDSCO): Organization, Responsibilities | 3 |
| | State Licensing Authority: Organization, Responsibilities, | 2 |
| | Certificate ofPharmaceutical Product (COPP) | 1 |
| | Regulatory requirements and approval procedures forNew Drugs. | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

SEMESTER-VII
Subject: Pharmacy Practice – Theory
Code: PHM27060
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug information, and therapeutic drug monitoring for improved patient care. In community pharmacy, students will be learning various skills such as dispensing of drugs, responding to minor ailments by providing suitable safe medication, patient counselling for improved patient care in the community set up.

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

CO1. Acquire knowledge of the organization and functions of hospital, hospital pharmacy and community pharmacy

CO2. Acquire knowledge of drug distribution system, different committee and program in hospital.

CO3. Understand the drug and therapy related problems with the concept of Rational drug therapy to provide patient-centred care to diverse patients using the best available evidence and monitor drug therapy.

CO4. Understand the preparation and implementation of budget and concepts of clinical pharmacy

CO5. Acquire knowledge of drug store management and inventory control

CO6. Understand the interpretation of clinical laboratory data and utilisation of information services.

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------|-------------|
| Hospital and it's organization | Definition, Classification of hospital-Primary, Secondary and Tertiary hospitals | 1 |
| | Classification based on clinical and non- clinical basis | 1 |
| | Organization Structure of aHospital, and Medical staffs involved in the hospital and their functions. | 1 |
| Hospital pharmacy and its organization | Definition, functions of hospital pharmacy, Organization structure | 1 |
| | Location, Layoutand staff requirements, and Responsibilities and functions of hospital pharmacists. | 1 |
| Adverse drug reaction | Classifications - Excessive pharmacological effects, secondary | 2 |

| | | |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs | |
| | Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management. | 1 |
| Community Pharmacy | Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store | 1 |
| | Dispensing of proprietary products, maintenance of records of retail and wholesale drug store. | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|-----------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Drug distribution system in a hospital | Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labelling, | 1 |
| | Dispensing of drugs to ambulatory patients, and Dispensing of controlled drugs. | 1 |
| Hospital formulary | Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list | 1 |
| | Preparation and revision, and addition and deletion of drug from hospital formulary. | 1 |
| Therapeutic drug monitoring | Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring. | 2 |
| Medication adherence | Causes of medication non-adherence, pharmacist role in the medication adherence, and monitoring of patient medication adherence. | 2 |
| Patient medication history interview | Need for the patient medication history interview, medication interview forms. | 1 |
| Community pharmacy management | Financial, materials, staff, and infrastructure requirements. | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pharmacy and therapeutic committee | Introduction, Historical overview of Regulatory Affairs | 1 |
| | Regulatory authorities, Role of Regulatory affairs department | 1 |
| | Responsibility of Regulatory Affairs Professionals | 1 |
| Regulatory requirements for drug approval | Drug Development Teams, Non-Clinical Drug Development, Pharmacology | 1 |
| | Drug Metabolism and Toxicology | 1 |
| | General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA) | 1 |
| | Clinical research / BE studies, Clinical Research Protocols | 1 |
| | Biostatistics in Pharmaceutical Product Development | 1 |
| | Data Presentation for FDA Submissions | 1 |
| | Management of Clinical Studies | 1 |

| MODULE – IV | Topics to be covered | 08 lectures |
|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------|--------------------|
| Budget preparation and implementation | Budget preparation and implementation | 1 |
| Clinical Pharmacy | Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist | 2 |
| | Drug therapy monitoring - medication chart review | 1 |
| | Clinical review, pharmacist intervention | 1 |
| | Ward round participation, Medication history and Pharmaceutical care | 1 |
| | Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern. | 1 |
| Over the counter (OTC) sales | Introduction and sale of over the counter, and Rational use of common over the counter medications | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------|
| Drug store management and inventory control | Organisation of drug store | 1 |
| | types of materials stocked and storage conditions | 1 |
| | Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking | 1 |
| | Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure | 1 |
| Investigational use of drugs | Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee. | 2 |
| Interpretation of Clinical Laboratory Tests | Blood chemistry, hematology, and urinalysis | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Merchant S.H. and Dr. J.S.Quadry. *A textbook of hospital pharmacy*, 4th ed.Ahmadabad: B.S. Shah Prakakshan; 2001.
2. Parthasarathi G, Karin Nyfort-Hansen, Milap C Nahata. *A textbook of Clinical Pharmacy Practice- essential concepts and skills*, 1st ed. Chennai: Orient Longman Private Limited; 2004.
3. William E. Hassan. *Hospital pharmacy*, 5th ed. Philadelphia: Lea & Febiger;1986.
4. Tipnis Bajaj. *Hospital Pharmacy*, 1st ed. Maharashtra: Career Publications; 2008.
5. Scott LT. *Basic skills in interpreting laboratory data*, 4th ed. American Society of Health System Pharmacists Inc; 2009.
6. Parmar N.S. *Health Education and Community Pharmacy*, 18th ed. India: CBS Publishers & Distributers; 2008.

Journals:

1. Therapeutic drug monitoring. ISSN: 0163-4356
2. Journal of pharmacy practice. ISSN : 0974-8326
3. American journal of health system pharmacy. ISSN: 1535-2900 (online)
4. Pharmacy times (Monthly magazine)

SEMESTER-VII
Subject: Novel Drug Delivery System – Theory
Code: PHM27061
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is designed to impart basic knowledge on the area of novel drug delivery systems.

Course Outcome: Upon completion of the course student shall be able

CO1. Understand controlled drug delivery system and its design.

CO2. Understand various approaches for development of microencapsulation, mucosal, implantable drug delivery systems

CO3 Understand formulation approaches of transdermal, gastroretentive, nasopulmonary drug delivery system and its applications

CO4. Understand various targeted drug delivery systems and their applications

CO5. Understand and apply the knowledge of ocular and intrauterine drug delivery systems

CO6. Applications of polymers in formulation of novel drug delivery systems

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-------------|
| Controlled drug delivery systems | Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. | 2 |
| | Approaches to design controlled release formulations based on diffusion, dissolution and ion exchange principles. | 2 |
| | Physicochemical and biological properties of drugs relevant to controlled release formulations | 2 |
| Polymers | Introduction, classification, properties, advantages polymers in formulation of controlled release drug delivery systems. | 2 |
| | Application of polymers in formulation of controlled release drug delivery systems. | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Microencapsulation | Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, | 3 |
| | Methods of microencapsulation, applications | 3 |
| Mucosal Drug Delivery system | Introduction, Principles of bioadhesion / mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems | 2 |
| Implantable Drug Delivery Systems | Introduction, advantages and disadvantages, concept of implants and osmotic pump | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Transdermal Drug Delivery Systems | Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, | 2 |
| | Basic components of TDDS, formulation approaches | 1 |
| Gastroretentive drug delivery systems | Introduction, advantages, disadvantages, approaches for GRDDS | 2 |
| | Floating, high density systems, inflatable and gastroadhesive systems and their applications | 1 |
| Nasopulmonary drug delivery system | Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers | 4 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-------------------------------|---------------------------------------------------------------------------------------------------------|--------------------|
| Targeted drug Delivery | Concepts and approaches advantages and disadvantages, introduction to liposomes, and their applications | 2 |
| | Concepts and approaches | 2 |

| | | |
|--|--------------------------------------------------------------------------------------------------------------------------------|---|
| | advantages and disadvantages, introduction to niosomes, their applications | |
| | Concepts and approaches advantages and disadvantages, introduction to nanoparticles, and their applications | 2 |
| | Concepts and approaches advantages and disadvantages, introduction to monoclonal antibodies and their applications | 2 |

| MODULE-V | Topics to be covered | 07 Lectures |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------|--------------------|
| Ocular Drug Delivery Systems | Introduction, intra ocular barriers and | 1 |
| | Methods to overcome –Preliminary study | 2 |
| | Ocular formulations and ocuserts | 1 |
| Intrauterine Drug Delivery Systems | Introduction, advantages and disadvantages, development of intra uterine devices (IUDs) and applications | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books: (Latest Editions)

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. Edith Mathiowitz, Published by Wiley Interscience 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, Vallabh Prakashan, New Delhi, First edition 2002.

Journals

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian Drugs (IDMA)
3. Journal of Controlled Release (Elsevier Sciences)
4. Drug Development and Industrial Pharmacy (Marcel & Decker)
5. International Journal of Pharmaceutics (Elsevier Sciences)

SEMESTER-VII
Subject: Practice School
Code: PHM27063
6 Credits

Total Contact Hours Required – 12 hrs/week

Course Outcomes: At the end of the course, students will be able to

- CO.1. Understand concepts and techniques of pharmacy practice/ Clinical Pharmacy
- CO.2. Understand the concepts and techniques of dispensing and patient counseling of drugs
- CO.3. Know about drug formulary and PTC (Pharmacy and Therapeutics Committee)
- CO.4. Understand the techniques used in procurement and storage of drugs
- CO.5. Understand the techniques used in inventory management of drugs and expiry settlement
- CO.6. Know about prescription reading, handling and auditing

In the VII semester, every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains for practice school declared by the program committee from time to time.

At the end of the practice school, every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages). Along with the exams of semester VII, the report submitted by the student, knowledge and skills acquired by the student through practice school shall be evaluated by the subject experts at college level and grade point shall be awarded.

Scheme of Study-Semester- VIII

| Sl. No. | Course Code | Name of the Subject | Credits | Contact Hours Per Week | Tutorial | Total Marks | End Term Theory/Practical Exam | Mid Term Theory/Practical Exam | CM | Attendance |
|--------------|-------------|---------------------------------------------------------|---------|------------------------|----------|-------------|--------------------------------|--------------------------------|-----|------------|
| 1 | PHM28064 | Biostatistics and Research Methodology – Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 2 | PHM28065 | Social and Preventive Pharmacy– Theory | 4 | 3 | 1 | 100 | 75 | 15 | 6 | 4 |
| 3 | PHM28066 | Pharmaceutical Marketing– Theory | 4+4=8 | 3+3+ | 2 | 100+100=200 | 75+75 | 15+15 | 6+6 | 4+4 |
| 4 | PHM28067 | Pharmaceutical Regulatory Science – Theory | | | | | | | | |
| 5 | PHM28068 | Pharmacovigilance – Theory | | | | | | | | |
| 6 | PHM28069 | Quality Control and Standardization of Herbals – Theory | | | | | | | | |
| 7 | PHM28070 | Computer Aided Drug Design –Theory | | | | | | | | |
| 8 | PHM28071 | Cell and Molecular Biology – Theory | | | | | | | | |
| 9 | PHM28072 | Cosmetic Science – Theory | | | | | | | | |
| 10 | PHM28073 | Experimental Pharmacology – Theory | | | | | | | | |
| 11 | PHM28074 | Advanced Instrumentation Techniques – Theory | | | | | | | | |
| 12 | PHM28075 | Dietary Supplements and Nutraceuticals | | | | | | | | |
| 13 | PHM28076 | Project Work | 6 | 12 | - | 150 | 150 | - | - | - |
| Total | | | 22 | 24 | 4 | 550 | 450 | 60 | 24 | 16 |

SEMESTER-VIII
Subject: Biostatistics and Research Methodology – Theory
Code: PHM28064
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: To understand the applications of Biostatistics in Pharmacy. This subject deals with descriptive statistics, Graphics, Correlation, Regression, logistic regression Probability theory, Sampling technique, Parametric tests, Non Parametric tests, ANOVA, Introduction to Design of Experiments, Phases of Clinical trials and Observational and Experimental studies, SPSS, R and MINITAB statistical software's, analyzing the statistical data using Excel.

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

CO1. Understand basic needs of Statistics and Biostatistics. Learn concept of Frequency distribution Measures of central tendency, Measures of dispersion and Correlation

CO2. Learn basics of Regression, Parametric test and probability distribution with examples

CO3. Learn the basics of Non-Parametric tests with examples. Learn the application of biostatistics for assessing the pharmaceutical experimental data by Curve fitting. Understand the basic need for research; protocol preparation, Experimental Design Technique, plagiarism and representation of data

CO4. Learn basics of Blocking design and Hypothesis testing in Simple and Multiple regression models. Understand basic needs of Industrial and Clinical Trials Problems using Statistical Analysis tools; Excel, SPSS, MINITAB®, DOE

CO5. Learn the confounding system for Two-level factorial design and Advantage of factorial design. Learn the basics of Response Surface methodology

CO6. Understand the applications of Biostatistics in Pharmacy. Appreciate statistical techniques in solving the problems

| MODULE – I | Topics to be covered | 10 lectures |
|--------------|---------------------------------------------------|-------------|
| Introduction | Statistics, Biostatistics, Frequency distribution | 2 |

| | | |
|-------------------------------------|--------------------------------------------------------------------------------------------------------|---|
| Measures of central tendency | Mean, Median, Mode- Pharmaceutical examples | 2 |
| Measures of dispersion | Dispersion, Range, standard deviation, Pharmaceutical problems | 3 |
| Correlation | Definition, Karl Pearson's coefficient of correlation, Multiple correlation - Pharmaceuticals examples | 3 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Regression | Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$ | 2 |
| | Multiple regression, standard error of regression– Pharmaceutical Examples | 2 |
| Probability | Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties - problems Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis | 2 |
| | Sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples | 2 |
| Parametric test | t-test(Sample, Pooled or Unpaired and Paired) , | 1 |
| | ANOVA, (One way and Two way), Least Significance difference | 1 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------------|---------------------------------------------------------------------------------|--------------------|
| Non Parametric tests | Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test | 2 |
| Introduction to Research | Need for research, Need for design of Experiments, | 1 |
| | Experiential Design Technique, plagiarism | 1 |
| Graphs | Histogram, Pie Chart, Cubic | 2 |

| | | |
|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---|
| | Graph, response surface plot, Counter Plot graph | |
| Designing the methodology | Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies | 2 |
| | Experimental studies, Designing clinical trial, various phases. | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| | Blocking and confounding system for Two-level factorials | 3 |
| Regression modeling | Hypothesis testing in Simple and Multiple regression models | 3 |
| Introduction to Practical components of Industrial and Clinical Trials Problems: | Statistical Analysis Using Excel, SPSS, MINITAB®, DESIGN OF EXPERIMENTS, R -Online Statistical Software's to Industrial and Clinical trial approach | 2 |

| MODULE-V | Topics to be covered | 07 Lectures |
|-------------------------------------------------------------|----------------------------------------------------------------------|--------------------|
| Design and Analysis of experiments: Factorial Design | Definition, 2^2 , 2^3 design. Advantage of factorial design | 4 |
| Response Surface methodology | Central composite design, Historical design, Optimization Techniques | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Pharmaceutical statistics- Practical and clinical applications, Sanford Bolton, publisher Marcel Dekker Inc. NewYork.
2. Fundamental of Statistics – Himalaya Publishing House- S.C.Guptha
3. Design and Analysis of Experiments –PHI Learning Private Limited, R. Pannerselvam,
4. Design and Analysis of Experiments – Wiley Students Edition, Douglas and C. Montgomery

SEMESTER-VIII
Subject: Social and Preventive Pharmacy- Theory
Code: PHM28065
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: The purpose of this course is to introduce to students a number of health issues and their challenges. This course also introduced a number of national health programmes. The roles of the pharmacist in these contexts are also discussed.

Course Outcome: After the successful completion of this course, the student shall be able to:

CO1. Acquire high consciousness/realization of current issues related to health

CO2. Get knowledge about pharmaceutical problems within the country and worldwide

CO3. Understand about various preventive medicines

CO4. Have a critical way of thinking based on current healthcare development

CO5. Evaluate alternative ways of solving problems related to health and pharmaceutical issues

CO6. Design a better health care service system

| MODULE – I | Topics to be covered | 10 lectures |
|--------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Concept of health and disease | Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick. | 3 |
| Social and health education | Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention. | 3 |
| Sociology and health | Socio cultural factors related to health and disease, Impact of urbanization on health and | 2 |

| | | |
|---------------------------|----------------------------------------------------|---|
| | disease, Poverty and health | |
| Hygiene and health | Personal hygiene and health care; avoidable habits | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|----------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Preventive medicine | General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections | 2 |
| | General principles of prevention and control of diseases such as malaria, chicken guinea, dengue | 2 |
| | General principles of prevention and control of diseases such as lymphatic filariasis, pneumonia, hypertension | 2 |
| | General principles of prevention and control of diseases such as diabetes mellitus, cancer | 2 |
| | Drug addiction-drug substance abuse | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|-------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|--------------------|
| National health programs, its objectives, functioning and outcome of the following | HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP) | 2 |
| | National leprosy control programme | 2 |
| | National mental health program | 2 |
| | National programme for prevention and control of deafness | 2 |
| | Universal immunization programme, National programme for control of blindness, Pulse polio programme | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-----------------------------------|------------------------------------------------------------------------------------------------------------|--------------------|
| Quality management systems | Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD) | 1 |
| | Six Sigma concept, Out of Specifications (OOS), Change control | 1 |
| | Introduction to ISO 9000 series of quality systems standards, | 1 |
| | ISO 14000, NABL, GLP | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|---------------------------------------|------------------------------------------------------------------------------------|--------------------|
| Indian Regulatory Requirements | Central Drug Standard Control Organization (CDSCO): Organization, Responsibilities | 3 |
| | State Licensing Authority: Organization, Responsibilities, | 2 |
| | Certificate of Pharmaceutical Product (COPP) | 1 |
| | Regulatory requirements and approval procedures for New Drugs. | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books: (Latest Editions)

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. available at <http://www.iraup.com/about.php>
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
4. Regulatory Affairs brought by learning plus, inc. available at <http://www.cgmp.com/ra.htm>.

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Pharmaceutical Marketing- Theory

Code: PHM28066

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: The pharmaceutical industry not only needs highly qualified researchers, chemists and, technical people, but also requires skilled managers who can take the industry forward by managing and taking the complex decisions which are imperative for the growth of the industry. The Knowledge and Know-how of marketing management groom the people for taking a challenging role in Sales and Product management.

Course Outcome: After the successful completion of this course, the student shall be able to:

CO1. Understand of marketing concepts and techniques of pharmaceutical products

CO2. Understand the Pharma market

CO3. Know about pharmaceutical product management

CO4. Understand the promotion techniques and understand the job of professional sales representative

CO5. Know about pharmaceutical marketing channels

CO6. Know the pricing of pharmaceuticals

| MODULE – I | Topics to be covered | 10 lectures |
|------------------------------|--------------------------------------------------------------------------|--------------------|
| Marketing | Definition, general concepts and scope of marketing | 1 |
| | Distinction between marketing & selling | 1 |
| | Marketing environment; Industry and competitive analysis | 1 |
| | Analyzing consumer buying behavior; industrial buying behavior | 1 |
| Pharmaceutical market | Quantitative and qualitative aspects; size and composition of the market | 1 |
| | Demographic descriptions and socio-psychological characteristics of the | 1 |

| | | |
|--|---------------------------------------------------------------------------------------------------------|---|
| | consumer | |
| | Market segmentation & targeting. Consumer profile | 1 |
| | Motivation and prescribing habits of the physician; patients' choice of physician and retail pharmacist | 2 |
| | Analyzing the Market; Role of market research | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|-------------------------|---------------------------------------------------------------------------|--------------------|
| Product decision | Classification, product line and product mix decisions | 3 |
| | product life cycle, product portfolio analysis; product positioning | 2 |
| | New product decisions; Product branding, packaging and labeling decisions | 3 |
| | Product management in pharmaceutical industry | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Promotion | Methods, determinants of promotional mix, promotional budget | 4 |
| | An overview of personal selling, advertising, direct mail, journals, sampling, retailing, medical exhibition, public relations, online promotional techniques for OTC Products. | 6 |

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Pharmaceutical marketing channels | Designing channel, channel members, selecting the appropriate channel, conflict in channels, physical distribution management: | 2 |
| | Strategic importance, tasks in physical distribution management. | 2 |
| Professional sales | Duties of PSR, purpose of | 2 |

| | | |
|-----------------------------|--------------------------------------------------------------------------|---|
| representative (PSR) | detailing, selection and training, supervising, norms for customer calls | |
| | Motivating, evaluating, compensation and future prospects of the PSR. | 2 |

| MODULE-V | Topics to be covered | 07 Lectures |
|---------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------|
| Pricing | Meaning, importance, objectives, determinants of price; pricing methods and strategies | 1 |
| | issues in price management in pharmaceutical industry | 1 |
| | An overview of DPCO (Drug Price Control Order) and NPPA (National Pharmaceutical Pricing Authority) | 1 |
| Emerging concepts in marketing | Vertical & Horizontal Marketing | 1 |
| | Rural Marketing | 1 |
| | Consumerism | 1 |
| | Industrial Marketing Global Marketing | 1 |

Recommended Books: (Latest Editions)

1. Philip Kotler and Kevin Lane Keller: Marketing Management, Prentice Hall of India, New Delhi
2. Walker, Boyd and Larreche : Marketing Strategy- Planning and Implementation, Tata MC Graw Hill, New Delhi.
3. Dhruv Grewal and Michael Levy: Marketing, Tata MC Graw Hill
4. Arun Kumar and N Menakshi: Marketing Management, Vikas Publishing, India
5. Rajan Saxena: Marketing Management; Tata MC Graw-Hill (India Edition)
6. Ramaswamy, U.S & Nanakamari, S: Marketing Managemnt: Global Perspective, Indian Context, Macmillan India, New Delhi.
7. Shanker, Ravi: Service Marketing, Excell Books, New Delhi
8. Subba Rao Changanti, Pharmaceutical Marketing in India (GIFT – Excel series) Excel Publications

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

Subject: Pharmaceutical Regulatory Science – Theory

Code: PHM28067

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia, UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.

Course Outcome: Upon completion of the subject student shall be able to;

CO1. Know about the process of drug discovery and development

CO2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals

CO3. Know the regulatory approval process and their registration in Indian and international markets

CO4. Know about legal aspects and quality policies for drug manufacturing

CO5. Develop knowledge on the procedure of conducting and safely monitoring the clinical trials

CO6. Produce responsible Regulatory affairs professional and technically expertise in Regulatory Aspects

| MODULE – I | Topics to be covered | 10 lectures |
|-------------------------------------------|-------------------------------------------|-------------|
| New Drug Discovery and development | Stages of drug discovery, | 2 |
| | Drug development process | 2 |
| | Pre-clinical studies, | 1 |
| | Non-clinical activities, clinical studies | 1 |
| | Innovator and generics | 2 |
| | Concept of generics | 1 |
| | Generic drug product development. | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------|-----------------------------------------------------------------------------|-------------|
| Regulatory Approval Process | Approval processes and timelines involved in Investigational New Drug (IND) | 3 |

| | | |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | New Drug Application (NDA), Abbreviated New Drug Application (ANDA) | 2 |
| | Changes to an approved NDA / ANDA. | 2 |
| Regulatory authorities and agencies | Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications) | 3 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------------|
| Registration of Indian drug product in overseas market | Procedure for export of pharmaceutical products, Technical documentation | 3 |
| | Drug Master Files (DMF), Common Technical Document (CTD) | 2 |
| | Electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research | 3 |

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------|----------------------------------------------------------------------------------------------|--------------------|
| Clinical trials | Developing clinical trial protocols | 2 |
| | Institutional Review Board / Independent Ethics committee - formation and working procedures | 2 |
| | Informed consent process and procedures | 1 |
| | GCP obligations of Investigators, sponsors & Monitors | 1 |
| | Managing and Monitoring clinical trials | 1 |
| | Pharmacovigilance - safety monitoring in clinical trials | 1 |
| | | |

| MODULE-V | Topics to be covered | 07 Lectures |
|----------------------------|------------------------------------------------------|--------------------|
| Regulatory Concepts | Basic terminology, guidance, guidelines, regulations | 3 |
| | Laws and Acts, Orange book, Federal Register | 2 |
| | Code of Federal Regulatory, Purple book | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended books:

1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and
3. Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185. Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations By Richard A
5. Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
6. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc.
7. FDA Regulatory Affairs: a guide for prescription drugs, medical devices, and biologics /edited by Douglas J. Pisano, David Mantus.
8. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143
9. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams
10. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
11. Drugs: From Discovery to Approval, Second Edition By Rick Ng

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

**SEMESTER-VIII
Subject: Pharmacovigilance – Theory**

Code: PHM28068
4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This paper will provide an opportunity for the student to learn about development of pharmacovigilance as a science, basic terminologies used in pharmacovigilance, global scenario of Pharmacovigilance, train students on establishing pharmacovigilance programme in an organization, various methods that can be used to generate safety data and signal detection. This paper also develops the skills of classifying drugs, diseases and adverse drug reactions.

Course Outcome: At completion of this paper it is expected that students will be able to

CO1. Know the importance and attributes of drug safety monitoring

CO2. Know the history, development and procedures of pharmacovigilance

CO3. Aware about the national and international scenario of pharmacovigilance

CO4. Develop the skills of classifying drugs, diseases and adverse drug reactions in students

CO5. Know the stock holders and guidelines of pharmacovigilance programmes

CO6. Know the dictionaries, coding and terminologies used in pharmacovigilance

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------------------|----------------------------------------------------------|-------------|
| Introduction to Pharmacovigilance | History and development of Pharmacovigilance | 1 |
| | Importance of safety monitoring of Medicine | 1 |
| | WHO international drug monitoring programme | 1 |
| | Pharmacovigilance Program of India (PvPI) | 1 |
| Introduction to adverse drug reactions | Definitions and classification of ADRs | 1 |
| | Detection and reporting, Methods in Causality assessment | 1 |
| | Severity and seriousness | 1 |

| | | |
|------------------------------------------------------|----------------------------------------------------------|---|
| | assessment, Predictability and preventability assessment | |
| | Management of adverse drug reactions | 1 |
| Basic terminologies used in pharmacovigilance | Terminologies of adverse medication related events | 1 |
| | Regulatory terminologies | 1 |

| MODULE – II | Topics to be covered | 10 lectures |
|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------|
| Drug and disease classification | Anatomical, therapeutic and chemical classification of drugs, International classification of diseases | 1 |
| | Daily defined doses, International Non proprietary Names for drugs | 1 |
| Drug dictionaries and coding in pharmacovigilance | WHO adverse reaction terminologies, MedDRA and Standardised MedDRA queries | 1 |
| | WHO drug dictionary, Eudravigilance medicinal product dictionary | 1 |
| Information resources in pharmacovigilance | Basic drug information resources | 1 |
| | Specialised resources for ADRs | 1 |
| Establishing pharmacovigilance programme | Establishing in a hospital, Establishment & operation of drug safety department in industry | 2 |
| | Contract Research Organisations (CROs), Establishing a national programme | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|------------------------------------|---------------------------------------------------------------------------------------|--------------------|
| Vaccine safety surveillance | Vaccine Pharmacovigilance, Vaccination failure, Adverse events following immunization | 2 |
| Pharmacovigilance methods | Passive surveillance – Spontaneous reports and case series, Stimulated reporting | 1 |
| | Active surveillance – Sentinel sites, drug event monitoring and registries, | 2 |

| | | |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|---|
| | Comparative observational studies – Cross sectional study, case control study and cohort study, Targeted clinical investigations | |
| Communication in pharmacovigilance | Effective communication in Pharmacovigilance, Communication in Drug Safety Crisis management | 3 |
| | Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media | 2 |

| MODULE – IV | Topics to be covered | 08 lectures |
|---------------------------------------------|----------------------------------------------------------------|--------------------|
| Safety data generation | Pre clinical phase, Clinical phase, Post approval phase (PMS) | 2 |
| ICH Guidelines for Pharmacovigilance | Organization and objectives of ICH, Expedited reporting | 2 |
| | Individual case safety reports, Periodic safety update reports | 2 |
| | Post approval expedited reporting, Pharmacovigilance planning | 1 |
| | Good clinical practice in pharmacovigilance studies | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|-----------------------------------------------------|-----------------------------------------------------------------------------------------|--------------------|
| Pharmacogenomics of adverse drug reactions | Genetics related ADR with example focusing PK parameters. | 2 |
| Drug safety evaluation in special population | Paediatrics, Pregnancy and lactation, Geriatrics | 2 |
| CIOMS | CIOMS Working Groups, CIOMS Form | 1 |
| CDSCO (India) and Pharmacovigilance | D&C Act and Schedule Y, Differences in Indian and global pharmacovigilance requirements | 2 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z By Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal
11. Text book of Pharmacovigilance: concept and practice by GP Mohanta and PK Manna
12. <http://www.who.int/monitorsys/dynPage.aspx?id=105825&mn1=7347&mn2=7259&mn3=7297>
13. <http://www.ich.org/>
14. <http://www.cioms.ch/>
15. <http://cdsco.nic.in/>
16. http://www.who.int/vaccine_safety/en/
17. http://www.ipc.gov.in/PvPI/pv_home.html

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Quality Control and Standardization of Herbals – Theory

Code: PHM28069

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: In this subject the student learns about the various methods and guidelines for evaluation and standardization of herbs and herbal drugs. The subject also provides an opportunity for the student to learn cGMP, GAP and GLP in traditional system of medicines.

Course Outcome: Upon completion of the subject student shall be able to;

CO1.Know WHO guidelines for quality control of herbal drugs

CO2.Know Quality assurance in herbal drug industry

CO3.Know the regulatory approval process and their registration in Indian and international markets

CO4.Appreciate EU and ICH guidelines for quality control of herbal drugs

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------|-----------------------------------------------------------------------------------------------------------|-------------|
| Basic tests for drugs | Pharmaceutical substances, Medicinal plants materials and dosage forms | 5 |
| | WHO guidelines for quality control of herbal drugs. Evaluation of commercial crude drugs intended for use | 5 |

| MODULE – II | Topics to be covered | 10 lectures |
|-------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Quality assurance | Quality assurance in herbal drug industry of cGMP, GAP, GMP and GLP in traditional system of medicine. | 5 |
| | WHO Guidelines on current good manufacturing Practices (cGMP) for Herbal Medicines WHO Guidelines on GACP for Medicinal Plants. | 5 |

| MODULE – III | Topics to be covered | 10 lectures |
|------------------------------|--------------------------------------------------------------------------------|--------------------|
| EU and ICH guidelines | EU and ICH guidelines for quality control of herbal drugs. | 5 |
| Research Guidelines | Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines | 5 |

| MODULE – IV | Topics to be covered | 08 lectures |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Stability testing | Stability testing of herbal medicines. Application of various chromatographic techniques in standardization of herbal products. | 4 |
| Preparation of documents | Preparation of documents for new drug application and export registration | 2 |
| GMP | GMP requirements and Drugs & Cosmetics Act provisions. | 2 |

| MODULE-V | Topics to be covered | 07 Lectures |
|--------------------------------|--------------------------------------------------------------------------------------|--------------------|
| Regulatory Requirements | Regulatory requirements for herbal medicines. | 3 |
| | WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems | 2 |
| | Comparison of various Herbal Pharmacopoeias. | 1 |
| | Role of chemical and biological markers in standardization of herbal products | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Pharmacognosy by Trease and Evans
2. Pharmacognosy by Kokate, Purohit and Gokhale
3. Rangari, V.D., Text book of Pharmacognosy and Phytochemistry Vol. I , Carrier Pub., 2006.
4. Aggrawal, S.S., Herbal Drug Technology. Universities Press, 2002.
5. EMEA. Guidelines on Quality of Herbal Medicinal Products/Traditional Medicinal
1. Products,
6. Mukherjee, P.W. Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals. Business Horizons Publishers, New Delhi, India, 2002.
7. Shinde M.V., Dhalwal K., Potdar K., Mahadik K. Application of quality control principles to herbal drugs. International Journal of Phytomedicine 1(2009); p. 4-8.
8. WHO. Quality Control Methods for Medicinal Plant Materials, World Health Organization, Geneva, 1998. WHO. Guidelines for the Appropriate Use of Herbal Medicines. WHO Regional Publications, Western Pacific Series No 3, WHO Regional office for the Western Pacific, Manila, 1998.
9. WHO. The International Pharmacopeia, Vol. 2: Quality Specifications, 3rd edn. World Health Organization, Geneva, 1981.
10. WHO. Quality Control Methods for Medicinal Plant Materials. World Health Organization, Geneva, 1999.
11. WHO. WHO Global Atlas of Traditional, Complementary and Alternative Medicine. 2 vol. set. Vol. 1 contains text and Vol. 2, maps. World Health Organization, Geneva, 2005.
12. WHO. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. World Health Organization, Geneva, 2004.

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Computer Aided Drug Design –Theory

Code: PHM28070

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is designed to provide detailed knowledge of rational drug design process and various techniques used in rational drug design process.

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

CO1. Understand Design and discovery of lead molecules

CO2. Understand The role of drug design in drug discovery process

CO3. Understand The concept of QSAR and docking

CO4. Understand Various strategies to develop new drug like molecules.

CO5. Understand The design of new drug molecules using molecular modeling software

| MODULE – I | Topics to be covered | 10 lectures |
|-------------------------------------------------------|----------------------------------------------------------------------------------------|-------------|
| Introduction to Drug Discovery and Development | Stages of drug discovery and development | 1 |
| Lead discovery and Analog Based Drug Design | Rational approaches to lead discovery based on traditional medicine, | 2 |
| | Random screening, Non-random screening, serendipitous drug discovery | 2 |
| | lead discovery based on drug metabolism, lead discovery based on clinical observation. | 2 |
| Analog Based Drug Design | Bioisosterism, Classification, Bioisosteric replacement. Any three case studies | 3 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------------------------------|----------------------------------------------------------------------------------|-------------|
| Quantitative Structure Activity Relationship (QSAR) | SAR versus QSAR, History and development of QSAR | 3 |
| | Types of physicochemical parameters, experimental and theoretical approaches for | 5 |

| | | |
|--|-------------------------------------------------------------------------------------------------------------------------------------------|---|
| | the determination of physicochemical parameters such as Partition coefficient, Hammett's substituent constant and Taft's steric constant. | |
| | Hansch analysis, Free Wilson analysis, 3D-QSAR approaches like COMFA and COMSIA. | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|-------------|
| Molecular Modeling and virtual screening techniques | Drug likeness screening, Concept of pharmacophore mapping and pharmacophore based Screening, | 5 |
| Molecular docking | Rigid docking, flexible docking, manual docking, Docking based screening. <i>De novo</i> drug design. | 5 |

| MODULE – IV | Topics to be covered | 08lectures |
|-------------------------------------------------|----------------------------------------------------|------------|
| Informatics & Methods in drug design | Introduction to Bioinformatics | 3 |
| | Chemoinformatics | 2 |
| | ADME databases | 2 |
| | Chemical, biochemical and pharmaceutical databases | 3 |

| MODULE-V | Topics to be covered | 07 Lectures |
|---------------------------|----------------------------------------------------------------------|-------------|
| Molecular Modeling | Introduction to molecular mechanics and quantummechanics. | 2 |
| | Energy Minimization methods | 2 |
| | Conformational Analysis, global conformational minima determination. | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|----------------------|-------------|
| Tutorial | | |

Recommended Books (Latest Editions)

1. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press Baltimore.
2. Martin YC. "Quantitative Drug Design" Dekker, New York.
3. Delgado JN, Remers WA eds "Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
4. Foye WO "Principles of Medicinal chemistry 'Lea & Febiger.
5. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley
1. Interscience.
6. Wolf ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry"
JohnWiley& Sons, New York.
7. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
8. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
9. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press
New York.

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Cell and Molecular Biology – Theory

Code: PHM28071

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: Cell biology is a branch of biology that studies cells – their physiological properties, their structure, the organelles they contain, interactions with their environment, their life cycle, division, death and cell function. This is done both on a microscopic and molecular level. Cell biology research encompasses both the great diversity of single-celled organisms like bacteria and protozoa, as well as the many specialized cells in multi-cellular organisms such as humans, plants, and sponges.

Course Outcome: Upon completion of the subject student shall be able to;

CO1. Learn about cell and molecular biology history.

CO2. Describe the chemical foundations of cell biology.

CO3. Understand protein structure and function.

CO4. Understand cellular membrane structure and function.

| MODULE – I | Topics to be covered | 10 lectures |
|-----------------------------------|------------------------------------------------------------------------|-------------|
| Cell and Molecular Biology | Definitions theory and basics and Applications. History and Summation. | 2 |
| | Properties of cells and cell membrane. | 2 |
| | Prokaryotic versus Eukaryotic | 2 |
| | Cellular Reproduction | 2 |
| | Chemical Foundations – an Introduction and Reactions (Types) | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|--------------------------------------|-------------------------------|-------------|
| Flow of Molecular Information | DNA and DNA Functioning | 4 |
| | RNA and Types of RNA | 3 |
| | Transcription and Translation | 3 |

| MODULE – III | Topics to be covered | 10 lectures |
|-----------------|--------------------------------------------|-------------|
| Proteins | Defined and Amino Acids, Protein Structure | 4 |

| | | |
|--|--------------------------------------------------------|---|
| | Regularities in Protein Pathways Cellular Processes | 3 |
| | Positive Control and significance of Protein Synthesis | 3 |

| MODULE – IV | Topics to be covered | 08 lectures |
|----------------------------|-------------------------------------|--------------------|
| Science of Genetics | Transgenics and Genomic Analysis | 2 |
| | Cell Cycle analysis | 2 |
| | Mitosis and Meiosis | 1 |
| | Cellular Activities and Checkpoints | 1 |

| MODULE-V | Topics to be covered | 07 Lectures |
|---------------------|------------------------------------------|--------------------|
| Cell Signals | Introduction, Receptors for Cell Signals | 3 |
| | Signaling Pathways: Overview | 1 |
| | Misregulation of Signaling Pathways | 2 |
| | Protein-Kinases: Functioning | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. Edward: Fundamentals of Microbiology.
10. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
11. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company
12. B.R. Glick and J.J. Pasternak: Molecular Biotechnology: Principles and Applications of RecombinantDNA: ASM Press Washington D.C.
13. RA Goldshy et. al., : Kuby Immunology.

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

**SEMESTER-VIII
Subject: Cosmetic Science – Theory**

Code: PHM28072

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Course Outcome: Upon completion of the subject student shall be able to

CO1. Explain Knowledge of regulations and guidelines of cosmetics. To have a thorough understanding about the ingredients of cosmetics. To understand the anatomy and physiology of skin, hair and oral cavity.

CO2. Understand the principles of formulation and building blocks of skin care products

CO3. Understand the principles of formulation and building blocks of hair and dental care products

CO4. Understand the role of herbs in cosmetics

CO5. Understand the principles of Cosmetic evaluation

CO6. Understand the Cosmetic problems associated with Hair and skin.

| MODULE – I | Topics to be covered | 10 lectures |
|----------------------------|----------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Classification | Classification of cosmetic and cosmeceutical products | 2 |
| Definition | Definition of cosmetics as per Indian and EU regulations, Evolution of cosmeceuticals from cosmetics, cosmetics as quasi and OTC drugs | 2 |
| Cosmetic excipients | Surfactants, rheology modifiers, humectants, emollients, preservatives. Classification and application | 2 |
| Skin | Basic structure and function of skin. | 1 |
| Hair | Basic structure of hair. Hair growth cycle. | 1 |
| Oral Cavity | Common problem associated with teeth and gums | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Principles of formulation and building blocks of skin care products | Face wash, Moisturizing cream, Cold Cream, Vanishing cream and their advantages and disadvantages. | 2 |
| | Application of these products in formulation of cosmeceuticals. | 2 |
| Antiperspirants & deodorants | Actives & mechanism of action | 2 |
| Principles of formulation and building blocks of Hair care products | Conditioning shampoo, Hair conditioner, anti-dandruff shampoo. Hair oils. Chemistry and formulation of Para-phenylene diamine based hair dye. | 2 |
| Principles of formulation and building blocks of oral care products | Toothpaste for bleeding gums, sensitive teeth. Teeth whitening, Mouthwash | 2 |

| MODULE – III | Topics to be covered | 10 lectures |
|-----------------------------------|-----------------------------------------------------------------------------------------|--------------------|
| Sun protection | Classification of Sunscreens and SPF. | 3 |
| Role of herbs in cosmetics | Skin Care: Aloe and turmeric Hair care: Henna and amla. Oral care: Neem and clove | 3 |
| Analytical cosmetics | BIS specification and analytical methods for shampoo, skincream and toothpaste. | 4 |

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------------------------|--------------------------------------------------------------------------------------------------------|--------------------|
| Principles of Cosmetic Evaluation | Principles of sebumeter, corneometer. | 4 |
| | Measurement of TEWL, Skin Color | 2 |
| | Hair tensile strength, Hair combing properties Soaps, and syndet bars. Evolution and skin benefits. | 2 |

| MODULE-V | Topics to be covered | 07 Lectures |
|--------------------------------|-----------------------------------|--------------------|
| Regulatory Requirements | Oily and dry skin, causes leading | 2 |

| | | |
|--|-------------------------------------------------------------------------------------------------------------------------------------------|---|
| | to dry skin, skin moisturisation. | |
| | Basic understanding of the terms Comedogenic, dermatitis. Cosmetic problems associated with Hair and scalp: Dandruff, Hair fall causes | 2 |
| | Cosmetic problems associated with skin: blemishes, wrinkles, acne, prickly heat and body odor. | 2 |
| | Antiperspirants and Deodorants- Actives and mechanism of action | 1 |

| | | |
|-----------------|-----------------------------|--------------------|
| MODULE | Topics to be covered | 15 lectures |
| Tutorial | | |

Recommended Books:

1. Harry's Cosmeticology, Wilkinson, Moore, Seventh Edition, George Godwin.
2. Cosmetics – Formulations, Manufacturing and Quality Control, P.P. Sharma, 4th Edition, Vandana Publications Pvt. Ltd., Delhi.
3. Text book of cosmeticology by Sanju Nanda & Roop K. Khar, Tata Publishers.

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

**SEMESTER-VIII
Subject: Experimental Pharmacology – Theory**

Code: PHM28073

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

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

CO1. Appreciate the applications of various commonly used laboratory animals.

CO2. Appreciate and demonstrate the various screening methods used in preclinical research

CO3. Appreciate and demonstrate the importance of biostatistics and research methodology

CO4. Design and execute a research hypothesis independently

| MODULE – I | Topics to be covered | 08 lectures |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Laboratory Animals | Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals | 1 |
| | Common lab animals: Description and applications of different species and strains of animals. Popular transgenic and mutant animals. | 2 |
| | Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection and euthanasia. | 2 |

| MODULE – II | Topics to be covered | 10 lectures |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Preclinical screening models | Introduction: Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. | 3 |

| | | |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| | Rationale for selection of animal species and sex for the study. | |
| Study of screening animal models for | Diuretics, nootropics, anti-Parkinson's, antiasthmatics, | 3 |
| Preclinical screening models | for CNS activity- analgesic, antipyretic, anti-inflammatory, general anaesthetics, sedative and hypnotics, antipsychotic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease | 4 |

| MODULE – III | Topics to be covered | 10 lectures |
|-------------------------------------|-----------------------------------------------------------------------------------------------|--------------------|
| Preclinical screening models | for ANS activity, sympathomimetics, sympatholytics, parasympathomimetics, parasympatholytics, | 5 |
| | Skeletal muscle relaxants, drugs acting on eye, local anaesthetics | 5 |

| MODULE – IV | Topics to be covered | 08 lectures |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Preclinical screening models | For CVS activity- antihypertensives, diuretics, antiarrhythmic, antidyslipidemic, anti aggregatory, coagulants, and anticoagulants | 4 |
| | Preclinical screening models for other important drugs like antiulcer, antidiabetic, anticancer and antiasthmatics. | 4 |

| MODULE-V | Topics to be covered | 07 Lectures |
|------------------------------------------------|-----------------------------------------------------------------------------------------|--------------------|
| Research methodology and Bio-statistics | Selection of research topic, review of literature, research hypothesis and study design | 2 |
| | Pre-clinical data analysis and interpretation using Students 't' test and One-way ANOVA | 2 |
| | Conformational Analysis, global conformational minima determination. | 3 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books (latest edition):

1. Fundamentals of experimental Pharmacology-by M.N. Ghosh
2. Hand book of Experimental Pharmacology-S.K. Kulakarni
3. CPCSEA guidelines for laboratory animal facility.
4. Drug discovery and Evaluation by Vogel H.G.
5. Drug Screening Methods by Suresh Kumar Gupta and S. K. Gupta
6. Introduction to biostatistics and research methods by PSS Sundar Rao and J Richard

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Advanced Instrumentation Techniques – Theory

Code: PHM28074

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject deals with the application of instrumental methods in qualitative and quantitative analysis of drugs. This subject is designed to impart advanced knowledge on the principles and instrumentation of spectroscopic and chromatographic hyphenated techniques. This also emphasizes on theoretical and practical knowledge on modern analytical instruments that are used for drug testing.

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

CO1. Understand the advanced instruments used and its applications in drug analysis

CO2. Understand the chromatographic separation and analysis of drugs.

CO3. Understand the calibration of various analytical instruments

CO4. Know analysis of drugs using various analytical instruments.

| MODULE – I | Topics to be covered | 10 lectures |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Nuclear Magnetic Resonance spectroscopy | Principles of H-NMR and C-NMR, chemical shift | 2 |
| | Factors affecting chemical shift, coupling constant, Spin - spin coupling, relaxation, instrumentation and applications | 3 |
| Mass Spectrometry | Principles, Fragmentation | 2 |
| | Ionization techniques – Electron impact, chemical ionization, MALDI, FAB, Analyzers-Time of flight and Quadrupole, instrumentation, applications | 3 |

| MODULE – II | Topics to be covered | 10 lectures |
|------------------------------------|-------------------------------------------------|-------------|
| Thermal Methods of Analysis | Principles, instrumentation and applications of | 2 |

| | | |
|----------------------------------|------------------------------------------------------------------------------------------------|---|
| | Thermogravimetric Analysis (TGA) | |
| | Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) | 2 |
| X-Ray Diffraction Methods | Origin of X-rays, basic aspects of crystals, X-ray Crystallography, rotating crystal technique | 3 |
| | Single crystal diffraction, powder diffraction, structural elucidation and applications. | 3 |

| MODULE – III | Topics to be covered | 10 lectures |
|---------------------------------------------|-------------------------------------------------------------------------|--------------------|
| Calibration and validation | As per ICH and USFDA guidelines | 2 |
| Calibration of following Instruments | Electronic balance, UV-Visible spectrophotometer, IR spectrophotometer, | 4 |
| | Fluorimeter, Flame Photometer, HPLC and GC | 4 |

| MODULE – IV | Topics to be covered | 08 lectures |
|------------------------------|-----------------------------------------------------------------------------------------------------|--------------------|
| Radio immune assay | Importance, various components, Principle, different methods, Limitation and | 2 |
| | Applications of Radio immuno assay | 2 |
| Extraction techniques | General principle and procedure involved in the solid phase extraction and liquid-liquid extraction | 4 |

| MODULE-V | Topics to be covered | 07 Lectures |
|------------------------------|-------------------------------|--------------------|
| Hyphenated techniques | LC-MS/MS, GC-MS/MS, HPTLC-MS. | 7 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. Organic spectroscopy by Y.R Sharma
3. Text book of Pharmaceutical Analysis by Kenneth A. Connors
4. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
5. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
6. Organic Chemistry by I. L. Finar
7. Organic spectroscopy by William Kemp
8. Quantitative Analysis of Drugs by D. C. Garrett
9. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi
10. Spectrophotometric identification of Organic Compounds by Silverstein

**Discipline Specific Elective (DSE) Course
(Select any TWO)**

SEMESTER-VIII

Subject: Dietary Supplements and Nutraceuticals- Theory

Code: PHM28075

4 Credits

Total Lectures Required – 45 hrs

Total Tutorials Required – 15 hrs

Title: This subject covers foundational topic that are important for understanding the need and requirements of dietary supplements among different groups in the population. This module aims to provide an understanding of the concepts behind the theoretical applications of dietary supplements.

Course Outcome: By the end of the course, students should be able to :

CO1. Understand the need of supplements by the different group of people to maintain healthy life.

CO2. Understand the outcome of deficiencies in dietary supplements.

CO3. Appreciate the components in dietary supplements and the application.

CO4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

| MODULE – I | Topics to be covered | 07 lectures |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| Definitions of Functional foods | Definitions of Functional foods, Nutraceuticals and Dietary supplements. | 1 |
| | Classification of Nutraceuticals, hypertension etc. | 1 |
| | Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer, heart disease, stress, osteoarthritis, | 1 |
| Public health nutrition | Public health nutrition, maternal and child nutrition, nutrition and ageing, nutrition education in community | 2 |
| Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional | Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds | 2 |

| | | |
|-------|--|--|
| foods | | |
|-------|--|--|

| MODULE – II | Topics to be covered | 15 lectures |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Phytochemicals nutraceuticals | Occurrence and characteristic features(chemical nature medicinal benefits) of following Carotenoids- α and β -Carotene, Lycopene, Xanthophylls, leutin, Sulfides: Diallyl sulfides, Allyl trisulfide, Polyphenolics: Resveratrol | 1 |
| | Occurrence and characteristic features(chemical nature medicinal benefits) of following Flavonoids- Rutin , Naringin, Quercetin, Anthocyanidins, catechins, Flavones, Prebiotics / Probiotics.: Fructo oligosaccharides, Lacto bacillum, Phyto estrogens : Isoflavones, daidzein, Geobactin, lignans | 1 |
| | Occurrence and characteristic features(chemical nature medicinal benefits) of following Tocopherols, Proteins, vitamins, minerals, cereal, vegetables and beverages as functional foods: oats, wheat bran, rice bran, sea foods, coffee, tea and the like. | 1 |

| MODULE – III | Topics to be covered | 07 lectures |
|------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| Introduction to free radicals | Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids. | 4 |
| Dietary fibres and complex carbohydrates | As functional food ingredients | 3 |

| MODULE – IV | Topics to be covered | 10 lectures |
|---------------|-----------------------|-------------|
| Free radicals | In Diabetes mellitus, | 4 |

| | | |
|--|---------------------------------------------------------------------|---|
| | Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, | |
| | In brain metabolism and pathology, kidney damage, muscle damage. | 3 |
| | In other disorders. Free radicals theory of ageing. | 3 |

| MODULE-V | Topics to be covered | 06 Lectures |
|-----------------|---------------------------------------------------------------------------------------------------------------------|--------------------|
| | Effect of processing, storage and interactions of various environmental factors on the potential of nutraceuticals. | 3 |
| | Regulatory Aspects; FSSAI, FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods. | 2 |
| | Pharmacopoeial Specifications for dietary supplements and nutraceuticals. | 1 |

| MODULE | Topics to be covered | 15 lectures |
|-----------------|-----------------------------|--------------------|
| Tutorial | | |

Recommended Books:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K.T Agusti and P.Faizal: BSPunblication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A.Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C.williams Editors 2000 *Functional foods* Woodhead Publ.Co.London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of FunctionalFoods* M.K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

SEMESTER-VIII
Subject: Project Work

Code: PHM28076
6 Credits

Total Contact Hours Required – 12 hrs/week

Course Outcomes: At the end of the course, students will be able to:

- [CO.1]. Understand some basic concepts of research and its methodologies
- [CO.2]. Understand some basic concepts of review.
- [CO.3]. Identify correct research and review topics
- [CO.4]. Select and define appropriate research problems and parameters.
- [CO.5]. Carry out research work and interpret the results
- [CO.6]. Write a research report and thesis

All the students shall undertake a project under the supervision of a teacher and submit a report. The area of the project shall directly relate any one of the elective subject opted by the student in semester VIII. The project shall be carried out in group not exceeding 5 in number. The project report shall be submitted in triplicate (typed & bound copy not less than 25 pages). The internal and external examiner appointed by the University shall evaluate the project at the time of the Practical examinations of other semester(s). Students shall be evaluated in groups for four hours (i.e., about half an hour for a group of five students).