JIWAJI UNIVERSITY, GWALIOR School of Studies in Pharmaceutical Sciences

The pharmaceutical industry has made a spectacular progress in the last few decades in India; it is the third largest producer by volume in the world. In this scenario the actual role of the pharmacist is changing to become an active member of the health system. The pharmacist therefore is required to undergo a rigorous upgrading of his knowledge particularly in the field of pharmaceutical research. Keeping in view all these objectives, the School of Studies in Pharmaceutical Sciences, Jiwaji University, Gwalior came into existence in 1997. Over a period of time, it has acquired prestigious status at National level. To prepare academicians and trained Pharmacy professionals, scientists for top position in R & D and Teaching including Industrial sector, the school is running B.Pharm. Course since 1997.

PROGRAM OUTCOMES (POS)

B. PHARMACY

The designing of the Pharmacy program at the Jiwaji University is to provide the key knowledge base and laboratory resources to prepare students for careers as professionals in the field of Pharmacy, for further studies, and related fields. The faculty is committed to provide an environment that addresses the individual needs of each student and encourages them to develop their potential.

Our distinguishing features include up-to-date knowledge of broad range of disciplines of Pharmaceutical Sciences and to provide theoretical and practical knowledge of Analytical and Instrumental Techniques.

- PO 1: The Pharmacy graduates are required to learn and acquire adequate knowledge, necessary skills to practice the profession of pharmacy. Adequate knowledge and scientific information regarding basic principles of Pharmaceutical & Medicinal Chemistry, Pharmaceutics, including Cosmetology, Pharmacology, Pharmacognosy including herbal medicines.
- PO 2: The graduate should have adequate knowledge of synthesis & analysis of medicinal agents, their mode and mechanism of action, drug interactions, patient counseling and adequate technical information to be exchanged with the physician and other health professionals.
- PO 3: Adequate knowledge of practical aspects of Synthesis of APIs & its intermediates and analysis of various pharmaceutical dosage forms Formulation developments & quality assurance of various pharmaceutical dosage forms including those of herbal origin as per

standards of official books, WHO and other regulatory agencies like USFDA, MHRA etc., pharmacological screening and biological standardization and in-vivo drug interactions, preparation & analysis of suitable plants material/extracts of medicinal importance for various herbal formulations, Clinical studies, patient counseling leading to physical and social well-being of the patients, Product detailing, marketing, distribution and selling of pharmaceutical products.

- PO 4: A graduate should be able to demonstrate skills necessary for practice of a Pharmacy viz. able to synthesize, purify, identify and analyze medicinal agents, able to formulate, store, dispense, manufacture the pharmaceutical products and analyze the prescriptions, able to learn and apply the quality assurance principles in regulatory and ethical aspects, able to extract, purify, identify and understand the therapeutic value of herbal/crude/natural products, able to screen various medicinal agents using animal models for pharmacological activity.
- PO 5: A graduate should develop the attitudes during the course which includes willing to apply the current knowledge of Pharmacy in the best interest of the patients and the community, maintain high standards of professional ethics in discharging professional obligations, continuously upgrade professional information and be conversant with latest advances in the field of pharmacy to serve community better, willing to participate in continuing education programs of PCI / AICTE / JIWAJI UNIVERSITY to upgrade the knowledge and professional skills, to help and participate in the implementation of National Health Programs.
- PO 6: The graduates are required to acquire in depth knowledge of formulation, quality assurance and storage of various pharmaceutical dosage forms including herbal medicines.
- **PO 7:** The graduates should also understand the concept of community pharmacy and be able to participate in health care programs.
- PO 8: They are also required to detail the physicians and market the medicinal agents for diagnosis, prevention and therapeutic purposes.

PROGRAM SPECIFIC OUTCOMES (PSO'S)

- PSO 1: To prepare graduates to succeed in technical or professional careers in various pharmaceutical industry and / or institute and /or Health care system through excellent real time exposure to rigorous education.
- **PSO 2:** To prepare graduate of the program to learn and adapt in a globe of constantly developing trends.
- **PSO 3:** To prepare the graduate to have foundation in science, formulation technology, synthetic knowledge, Discovery tools as per the requirement of Pharmaceutical sectors.
- PSO 4: To strengthen the professional and ethical attitude, effective communication skills, teamwork skills, multidisciplinary approach, and an ability to relate pharmaceutical sciences issues to broader social context.
- **PSO 5**: To streams a lifelong career of personal and practicing professional growth with ethical codes and self esteem

COURSE OUTCOMES (COs)

SEMESTER I

BP101T. HUMAN ANATOMY AND PHYSIOLOGY-I (Theory)

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.

Upon completion of this course the student should be able to

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

BP102T. PHARMACEUTICAL ANALYSIS (Theory)

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

Upon completion of the course student shall be able to

- 1. understand the principles of volumetric and electro chemical analysis
- 2. carry out various volumetric and electrochemical titrations
- 3. develop analytical skills

BP103T. PHARMACEUTICS- I (Theory)

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

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

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

BP104T. PHARMACEUTICAL INORGANIC CHEMISTRY (Theory)

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

Upon completion of course student shall be able to

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

BP105T.COMMUNICATION SKILLS (Theory)

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.

Upon completion of the course the student shall be able to

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

BP 106 RBT. REMEDIAL BIOLOGY (Theory)

The subject is designed to learn and understand the components of living world, structure and functional system of plant and animal kingdom.

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

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

BP 106RMT.REMEDIAL MATHEMATICS (Theory)

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.

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

- **1.** Know the theory and their application in Pharmacy
- 2. Solve the different types of problems by applying theory
- **3.** Appreciate the important application of mathematics in Pharmacy

SEMESTER II

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

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.

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

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

BP202T. PHARMACEUTICAL ORGANIC CHEMISTRY - I (Theory)

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.

Upon completion of the course the student shall be able to

- 1. write the structure, name and the type of isomerism of the organic compound
- 2. write the reaction, name the reaction and orientation of reactions
- 3. account for reactivity/stability of compounds,
- 4. identify/confirm the identification of organic compound

BP203 T. BIOCHEMISTRY (Theory)

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.

Upon completion of course student shell able to

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

BP 204T.PATHOPHYSIOLOGY (THEORY)

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.

Upon completion of the subject student shall be able to -

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

BP205 T. COMPUTER APPLICATIONS IN PHARMACY (Theory)

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

Upon completion of the course the student shall be able to

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

BP 206 T. ENVIRONMENTAL SCIENCES (Theory)

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.

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

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

SEMESTER III

BP301T. PHARMACEUTICAL ORGANIC CHEMISTRY -II (Theory)

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.

Upon completion of the course the student shall be able to

- 1. write the structure, name and the type of isomerism of the organic compound
- 2. write the reaction, name the reaction and orientation of reactions
- 3. account for reactivity/stability of compounds,
- 4. prepare organic compounds

BP302T. PHYSICAL PHARMACEUTICS-I (Theory)

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.

Upon the completion of the course student shall be able to

- 1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
- 2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- 3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

BP 303 T. PHARMACEUTICAL MICROBIOLOGY (Theory)

It's the study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes etc.

Upon completion of the subject student shall be able to:

- 1. Understand methods of identification, cultivation and preservation of various microorganisms
- 2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry
- 3. Learn sterility testing of pharmaceutical products.

- 4. Carried out microbiological standardization of Pharmaceuticals.
- 5. Understand the cell culture technology and its applications in pharmaceutical industries.

BP 304 T. PHARMACEUTICAL ENGINEERING (Theory)

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

Upon completion of the course student shall be able:

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

SEMESTER IV

BP401T. PHARMACEUTICAL ORGANIC CHEMISTRY –III (Theory)

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.

At the end of the course, the student shall be able to

- 1. understand the methods of preparation and properties of organic compounds
- 2. explain the stereo chemical aspects of organic compounds and stereo chemical reactions
- 3. know the medicinal uses and other applications of organic compounds

BP402T. MEDICINAL CHEMISTRY – I (Theory)

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.

Upon completion of the course the student shall be able to

- 1. understand the chemistry of drugs with respect to their pharmacological activity
- understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
- 3. know the Structural Activity Relationship (SAR) of different class of drugs
- 4. write the chemical synthesis of some drugs

BP 403 T. PHYSICAL PHARMACEUTICS-II (Theory)

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.

Upon the completion of the course student shall be able to

- 1. Understand various physicochemical properties of drug molecules in the designing the dosage forms
- 2. Know the principles of chemical kinetics & to use them for stability testing and determination of expiry date of formulations
- 3. Demonstrate use of physicochemical properties in the formulation development and evaluation of dosage forms.

BP 404 T. PHARMACOLOGY-I (Theory)

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.

Upon completion of this course the student should be able to

- 1. Understand the pharmacological actions of different categories of drugs
- 2. Explain the mechanism of drug action at organ system/sub cellular/macromolecular levels.
- 3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.
- 4. Observe the effect of drugs on animals by simulated experiments
- 5. Appreciate correlation of pharmacology with other bio medical sciences

BP 405 T.PHARMACOGNOSY AND PHYTOCHEMISTRY I (Theory)

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.

Upon completion of the course, the student shall be able

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

SEMESTER - V

BP501T. MEDICINAL CHEMISTRY – II (Theory)

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.

Upon completion of the course the student shall be able to

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

BP 502 T. INDUSTRIAL PHARMACY (Theory)

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.

Upon completion of the course the student shall be able to

- 1. Know the various pharmaceutical dosage forms and their manufacturing techniques.
- 2. Know various considerations in development of pharmaceutical dosage forms
- 3. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality

BP503.T. PHARMACOLOGY-II (Theory)

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.

Upon completion of this course the student should be able to

- 1. Understand the mechanism of drug action and its relevance in the treatment of different diseases
- 2. Demonstrate isolation of different organs/tissues from the laboratory animals by simulated experiments
- 3. Demonstrate the various receptor actions using isolated tissue preparation
- 4. Appreciate correlation of pharmacology with related medical sciences

BP504 T. PHARMACOGNOSY AND PHYTOCHEMISTRY II (Theory)

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

Upon completion of the course, the student shall be able

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

- 2. to understand the preparation and development of herbal formulation.
- 3. to understand the herbal drug interactions
- 4. to carryout isolation and identification of phytoconstituents

BP 505 T. PHARMACEUTICAL JURISPRUDENCE (Theory)

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

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

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

SEMESTER - VI

BP601T. MEDICINAL CHEMISTRY – III (Theory)

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.

Upon completion of the course student shall be able to

- 1. Understand the importance of drug design and different techniques of drug design.
- 2. Understand the chemistry of drugs with respect to their biological activity.
- 3. Know the metabolism, adverse effects and therapeutic value of drugs.
- 4. Know the importance of SAR of drugs.

BP602 T. PHARMACOLOGY-III (Theory)

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.

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

- 1. understand the mechanism of drug action and its relevance in the treatment of different infectious diseases
- 2. comprehend the principles of toxicology and treatment of various poisonings and
- 3. appreciate correlation of pharmacology with related medical sciences.

BP 603 T. HERBAL DRUG TECHNOLOGY (Theory)

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, nutraceuticals etc. The subject also emphasizes on Good Manufacturing

Practices (GMP), patenting and regulatory issues of herbal drugs

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

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

BP 604 T. BIOPHARMACEUTICS AND PHARMACOKINETICS

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 arise therein.

Upon completion of the course student shall be able to:

- 1. Understand the basic concepts in Biopharmaceutics and pharmacokinetics and their significance.
- Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.
- 3. To understand the concepts of bioavailability and bioequivalence of drug products and their significance.
- 4. Understand various pharmacokinetic parameters, their significance & applications.

BP 605 T. PHARMACEUTICAL BIOTECHNOLOGY (Theory)

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.

Upon completion of the subject student shall be able to;

- 1. Understanding the importance of Immobilized enzymes in Pharmaceutical Industries
- 2. Genetic engineering applications in relation to production of pharmaceuticals
- 3. Importance of Monoclonal antibodies in Industries
- 4. Appreciate the use of microorganisms in fermentation technology

BP606TPHARMACEUTICAL QUALITY ASSURANCE (Theory)

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

Upon completion of the course student shall be able to:

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

SEMESTER - VII

BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

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.

Upon completion of the course the student shall be able to

- 1. Understand the interaction of matter with electromagnetic radiations and its applications in drug analysis
- 2. Understand the chromatographic separation and analysis of drugs.
- 3. Perform quantitative & qualitative analysis of drugs using various analytical instruments.

BP 702 T. INDUSTRIAL PHARMACY-II (Theory)

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

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

- 1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
- 2. Understand the process of technology transfer from lab scale to commercial batch
- 3. Know different Laws and Acts that regulate pharmaceutical industry
- 4. Understand the approval process and regulatory requirements for drug products

BP 703T. PHARMACY PRACTICE (Theory)

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

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

- 1. know various drug distribution methods in a hospital
- 2. appreciate the pharmacy stores management and inventory control
- monitor drug therapy of patient through medication chart review and clinical review
- 4. obtain medication history interview and counsel the patients
- 5. identify drug related problems
- 6. detect and assess adverse drug reactions
- 7. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states
- 8. know pharmaceutical care services
- 9. do patient counseling in community pharmacy;
- 10. appreciate the concept of Rational drug therapy.

BP 704T: NOVEL DRUG DELIVERY SYSTEMS (Theory)

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

Upon completion of the course student shall be able

- 1. To understand various approaches for development of novel drug delivery systems.
- 2. To understand the criteria for selection of drugs and polymers for the development of Novel drug delivery systems, their formulation and evaluation

SEMESTER - VIII

BP801T. BIOSTATISITCS AND RESEARCH METHODOLOGY (Theory)

This subject is designed to understand the applications of Biostatics 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.

Upon completion of the course the student shall be able to

- 1. Know the operation of M.S. Excel, SPSS, R and MINITAB, DoE (Design of Experiment)
- 2. Know the various statistical techniques to solve statistical problems
- 3. Appreciate statistical techniques in solving the problems.

BP 802T SOCIAL AND PREVENTIVE PHARMACY

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.

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

- 1. Acquire high consciousness/realization of current issues related to health and pharmaceutical problems within the country and worldwide.
- 2. Have a critical way of thinking based on current healthcare development.
- 3. Evaluate alternative ways of solving problems related to health and pharmaceutical issues

BP803ET. PHARMA MARKETING MANAGEMENT (Theory)

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.

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

- 1. To understand the marketing concepts and techniques and
- 2. Their applications in the pharmaceutical industry.

BP804 ET: PHARMACEUTICAL REGULATORY SCIENCE (Theory)

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.

Upon completion of the subject student shall be able to:

- 1. Know about the process of drug discovery and development
- 2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals
- 3. Know the regulatory approval process and their registration in Indian and international markets

BP 805T: PHARMACOVIGILANCE (Theory)

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.

At completion of this paper it is expected that students will be able to know, do, and appreciate:

- 1. Why drug safety monitoring is important?
- 2. History and development of pharmacovigilance
- 3. National and international scenario of pharmacovigilance
- 4. Dictionaries, coding and terminologies used in pharmacovigilance
- 5. Detection of new adverse drug reactions and their assessment
- 6. International standards for classification of diseases and drugs

- 7. Adverse drug reaction reporting systems and communication in pharmacovigilance
- 8. Methods to generate safety data during pre-clinical, clinical and post approval phases of drugs' life cycle
- 9. Drug safety evaluation in paediatrics, geriatrics, pregnancy and lactation
- 10. Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India
- 11.ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning
- 12. CIOMS requirements for ADR reporting
- 13. Writing case narratives of adverse events and their quality.

BP 806 ET. QUALITY CONTROL AND STANDARDIZATION OF HERBALS

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.

Upon completion of the subject student shall be able to;

- 1. know WHO guidelines for quality control of herbal drugs
- 2. know Quality assurance in herbal drug industry
- 3. know the regulatory approval process and their registration in Indian and international markets
- 4. appreciate EU and ICH guidelines for quality control of herbal drugs

BP 807 ET. COMPUTER AIDED DRUG DESIGN (Theory)

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

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

- 1. Design and discovery of lead molecules
- 2. The role of drug design in drug discovery process
- 3. The concept of QSAR and docking
- 4. Various strategies to develop new drug like molecules.
- 5. The design of new drug molecules using molecular modeling software

BP808ET: CELL AND MOLECULAR BIOLOGY (Elective subject)

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.

Upon completion of the subject student shall be able to;

1. Summarize cell and molecular biology history.

- 2. Summarize cellular functioning and composition.
- 3. Describe the chemical foundations of cell biology.
- 4. Summarize the DNA properties of cell biology.
- 5. Describe protein structure and function.
- 6. Describe cellular membrane structure and function.
- 7. Describe basic molecular genetic mechanisms.
- 8. Summarize the Cell Cycle

BP809ET. COSMETIC SCIENCE (Theory)

Understand the concepts of cosmetics, anatomy of skin v/s hair, general excipients used in cosmetics.

- 1. Explain formulation of cosmetics for skin, manufacturing, equipments & evaluation of creams like cold cream, vanishing cream etc. & powder cosmetics.
- 2. Explain formulation of cosmetics for hair, manufacturing & evaluation of hair shampoos, tonics etc.
- 3. Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadow etc.
- 4. Understand formulation of manicure products like nail lacquer, remover etc.
- 5. Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.
- 6. Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceutical agents.

BP810 ET. PHARMACOLOGICAL SCREENINGMETHODS

This subject is designed to impart the basic knowledge of preclinical studies in experimental animals including design, conduct and interpretations of results.

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

- 1. Appreciate the applications of various commonly used laboratory animals.
- 2. Appreciate and demonstrate the various screening methods used in preclinical research
- 3. Appreciate and demonstrate the importance of biostatistics and research methodology
- 4. Design and execute a research hypothesis independently

BP 811 ET. ADVANCED INSTRUMENTATION TECHNIQUES

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.

Upon completion of the course the student shall be able to

- 1. understand the advanced instruments used and its applications in drug analysis
- 2. understand the chromatographic separation and analysis of drugs.
- 3. understand the calibration of various analytical instruments
- 4. know analysis of drugs using various analytical instruments.

BP 812 ET. DIETARY SUPPLEMENTS AND NUTRACEUTICALS

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. By the end of the course, students shall be able to:

- 1. Understand the need of supplements by the different group of people to maintain healthy life.
- 2. Understand the outcome of deficiencies in dietary supplements.
- 3. Appreciate the components in dietary supplements and the application.
- 4. Appreciate the regulatory and commercial aspects of dietary supplements including health claims.

JIWAJI UNIVERSITY, GWALIOR School of Studies in Pharmaceutical Sciences

The pharmaceutical industry has made a spectacular progress in the last few decades in India; it is the third largest producer by volume in the world. In this scenario the actual role of the pharmacist is changing to become an active member of the health system. The pharmacist therefore is required to undergo a rigorous upgrading of his knowledge particularly in the field of pharmaceutical research. Keeping in view all these objectives, the School of Studies in Pharmaceutical Sciences, Jiwaji University, Gwalior came into existence in 1997. Over a period of time, it has acquired prestigious status at National level. To prepare academicians and trained Pharmacy professionals, scientists for top position in R & D and Teaching including Industrial sector, the school is running M.Pharm. courses in Pharmaceutics and industrial pharmacy.

PROGRAM OUTCOMES (POs)

M. PHARMACY

After completion of M. Pharm. in various subjects,

- Academics: As professors in B. Pharm. Institutes, to build up skills in new comers in Pharmacy. They have to give complete Information of practical and theory to students related to the subjects.
- 2. Research: As Scientists in various state and central laboratories, in industries (in F & D and R & D sessions). Many scholarships are open in various state and central funding agencies to promote research in fields of pharmaceutical sciences in India and abroad. Candidates are hired to work as project assistants at research institute or as research fellows. Here they are required to assist and work on a particular project this makes them gain experience and move ahead in research field.
- 3. Clinical Research as clinical programmer
- 4. Production managers in Pharmaceutical Industries: In corporate sector students with higher capabilities are selected for deserving positions e.g. Cadila, Glenmark, Dr. Reddy's Lab, Cipla and more. These companies also organize campus recruitment where students get a better chance to demonstrate their skills.
- 5. Quality control and Quality assurance sectors in various pharmaceutical companies.
- Overseas career: Some of the M. Pharm students are choosing to fly overseas and make their career bright by scoring well in GRE, TOEFL. IELTS entrances. They can pursue MBA and other pharmacy related courses in US, UK, Australia etc.
- 7. For Higher studies: After completing M. Pharm, there are various opportunities for the individual, they can either go for higher studies like Ph. D for improving their skills and up gradation of their degree or they can go for jobs in the chemical companies, research institutes, Pharmaceutical companies, even universities and colleges.

PROGRAM SPECIFIC OUTCOMES (PSOs)

After successful completion of the program the graduate will be able to:

- **PSO1:** Apply the principles of drug delivery system in the development of ecofriendly, efficacious dosage forms.
- **PSO2**: Develop an ability to undertake multidisciplinary tasks in the pharmaceutical quality system.
- **PSO3**: Analyze, criticize, organize, improvise and manage documents, data and information related to pharmaceutical production process.
- **PSO4:** Imbibe ethical practices and moral values in personal and professional endeavors.
- **PSO5**: Execute team based research to implement innovative solutions in the area of formulation, quality assurance and technology transfer.
- **PSO6:** Apply problem-based learning approach and analytical thinking in academic and professional life.
- **PSO7**: Validate the knowledge and skills gained through education to gain recognition in Pharmaceutical society and related field.
- **PSO8:** Set-up pharmaceutical production unit to design and formulate pharmaceutical dosage forms.

COURSE OUTCOMES (COs)

M.PHARMACY (PHARMACEUTICS)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MPH 101T)

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

After completion of course student is able to know,

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

DRUG DELIVERY SYSTEMS (MPH 102T)

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

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

1. The various approaches for development of novel drug delivery systems.

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

MODERN PHARMACEUTICS (MPH 103T)

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

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

- 1. The elements of preformulation studies.
- 2. The Active Pharmaceutical Ingredients and Generic drug Product development
- 3. Industrial Management and GMP Considerations.
- 4. Optimization Techniques & Pilot Plant Scale Up Techniques
- 5. Stability Testing, sterilization process & packaging of dosage forms.

REGULATORY AFFAIRS (MPH 104T)

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents: filing process of IND, NDA and ANDA to know the approval process, to know the chemistry, manufacturing controls and their regulatory importance and to learn the documentation requirements.

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

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

MOLECULAR PHARMACEUTICS (NANO TECHNOLOGY & TARGETED DDS) (NTDS) (MPH 201T)

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

Upon completion of the course student shall be able to understand

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

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MPH 202T)

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

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

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

COMPUTER AIDED DRUG DEVELOPMENT (MPH 203T)

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

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

- 1. History of Computers in Pharmaceutical Research and Development
- 2. Computational Modeling of Drug Disposition
- 3. Computers in Preclinical Development
- 4. Optimization Techniques in Pharmaceutical Formulation
- 5. Computers in Market Analysis
- 6. Computers in Clinical Development
- 7. Artificial Intelligence (AI) and Robotics
- 8. Computational fluid dynamics(CFD)

COSMETICS AND COSMECEUTICALS (MPH 204T)

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

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

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

M. PHARM. (INDUSTRIALPHARMACY)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MIP 101T)

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

After completion of course student is able to know,

- 1. The analysis of various drugs in single and combination dosage forms
- 2. Theoretical and practical skills of the instruments

PHARMACEUTICAL FORMULATION DEVELOPMENT (MIP 102T)

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

On completion of this course it is expected that students will be able to understand-

- 1. The scheduled activities in a Pharmaceutical firm.
- 2. The pre formulation studies of pilot batches of pharmaceutical industry.
- 3. The significance of dissolution and product stability

NOVEL DRUG DELIVERY SYSTEMS (MIP 103T)

This course is designed to impart knowledge and skills necessary to train the students in the area of novel drug delivery systems.

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

- 1. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms.
- 2. To formulate and evaluate various novel drug delivery systems

INTELLECTUAL PROPERTY RIGHTS (MIP 104T)

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

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

- 1. Assistance in Regulatory Audit process.
- 2. Establishment of regulatory guidelines for drug and drug products
- 3. The Regulatory requirements for contract research organization

ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS (MIP 201T)

This course is designed to impart knowledge and skills necessary for dose calculations, dose adjustments and to apply Biopharmaceutics theories in practical problem solving.

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

- 1. The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- 3. To critically evaluate Biopharmaceutics studies involving drug product equivalency.
- 4. To design and evaluate dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.

SCALE UP AND TECHNOLOGY TRANSFER (MIP 202T)

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safety issues.

On completion of this course it is expected that students will be able to understand.

- 1. Manage the scale up process in pharmaceutical industry.
- 2. Assist in technology transfer.
- 3. To establish safety guidelines, which prevent industrial hazards.

PHARMACEUTICAL PRODUCTION TECHNOLOGY (MIP 203T)

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in Production

On completion of this course it is expected that students will be able to understand.

- 1. Handle the scheduled activities in a Pharmaceutical firm.
- 2. Manage the production of large batches of pharmaceutical formulations.

ENTREPRENEURSHIP MANAGEMENT (MIP 204T)

This course is designed to impart knowledge and skills necessary to train the students on entrepreneurship management.

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

- 1. Demands and challenges of Growth Strategies And Networking
- 2. The Role of enterprise in national and global economy
- 3. Dynamics of motivation and concepts of entrepreneurship