SVU COLLEGE OF PHARMACEUTICAL SCIENCES
SRI VENKATESWARA UNIVERSITY,
Tirupati - 517502

RESTRUCTURED CURRICULUM FOR M. PHARMACY PROGRAMME (Self Supporting Course) TO BE IMPLEMENTED WITH EFFECT FROM THE ACADEMIC YEAR 2017-2018

SYLLABUS
Choice based credit system (CBCS) Pattern

M. PHARMACY PROGRAMME
Choice based credit system (CBCS) Pattern

(Pharmaceutics)

Vision

1. To impart quality and value embedded education and research in Pharmaceutical Sciences.
2. To create technologically superior and ethically strong global manpower, in the arena of Pharmacy Profession.
3. Carving the youth as dynamic, competent, valued and knowledgeable Professionals of Pharmacy field.

Mission

1. Transforming Students into Full-fledged Pharmacists and participate actively in the field of Pharmacy.
2. Promoting Quality Research in Emerging Areas of Pharmaceutical Sciences.
3. To instill scientific zeal and develop skilled human resource to meet contemporary challenges in Pharmacy Profession.
4. To facilitate young adult learners with opportunities to hone their ethics and leadership potential.
5. Imparting technical education that encourages Independent thinking, develops strong domain of knowledge, hones contemporary skills and Positive attitudes towards holistic growth of young minds.
6. Evolving the Institution into a Center of Academic and Research Excellence in Pharmaceutical Education and lead the field of pharmaceutical sciences and pharmacy practice with the mission of strengthening the healthcare of the country.

Programme Objectives

1. To uphold all laws, regulations, safety and ethical standards that apply to the experimental procedures of the pharmaceutical formulations
2. To Provide a practical knowledge of the basic pharmaceutical sciences and the skill, acquire to deal with problems in pharmaceutical field
3. To To update the knowledge through continuous learning to face the challenges for better services to the community.
4. Acquire practical knowledge in various analytical techniques
5. To prepare the students in teamwork, lifelong learning and continuous improvement

Programme Outcomes

After the completion of the M.Pharm Pharmaceutics programme the students will be able to,

1. Produce Pharmacy graduates with strong basics and high technical knowledge to cater the various areas of Pharmaceutical industry.
2. Develop an understanding for the need of pharmaceutical sciences and technology towards giving quality life to people in society through the quality of medicines.
3. Apply the knowledge and skills gained through education to gain recognition in professional course and society.
4. Impart knowledge and skills on criteria for selection of drugs, dose calculations, dose adjustments by applying biopharmaceutical theories, pharmacokinetic and bioequivalence models which gives technical skill knowledge in In-vitro and In-vivo studies using computer simulations.
5. Act efficiently as a leader in the diverse areas of the profession to demonstrate the ability to plan and implement professional activities.
6. Provide a practical knowledge of the basic pharmaceutical sciences and the skill, acquire to deal with problems in pharmaceutical field

7. Develop ability for in-depth information and critical thinking in order to identify, formulate and solve the issues related to Pharmaceutical Industry, Regulatory Agencies, Hospital Pharmacy & clinical Pharmacy for better services to the community.
8. Identify the goals and regulations involved in the drug discovery and development, manufacture, distribution and sale of medicines and develop problem-based learning approach and analytical thinking in his/her academic and professional life.
9. To update the knowledge through continuous learning to face the challenges for better services to the community.
10. Design and develop process to perform experiments in various pharmaceutical areas like Pharmacognosy, Pharmaceutical Chemistry including Analytical Chemistry, Pharmaceutical Biotechnology, Pharmacology, Formulation and Development.
11. Fill the gap with other health care communities to provide innovative solutions for the purpose of maintain public health.
12. Understand, analyze and communicate the value of their professional roles in society (e.g. health care professionals, promoters of health, educators, managers, employers, employees).

Programme Specific Outcomes

At the end of successful completion of programme, a Post graduate will

1. Have adequate knowledge and scientific information regarding basic principles of Pharmaceutical & Medicinal Chemistry, Pharmaceutics including Cosmeticology.
2. Be able to develop and assure the quality 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.
3. Be able to apply the knowledge and skill gained from various subjects and the aptitude developed throughout the course of the program in performing a job either independently or as a member of a team in various fields of pharmacy profession.

4. Be able to perform research on various medical aspects and implement the Pharmaceutical knowledge in formulating the best suitable dosage form to provide high quality medicines to the society.
5. Render the services to the public by providing patient centric effective treatments to curb the therapeutic issues with the required medicines and explain the effects of the drugs by analyzing the scientific literature for improving their health and well-being.

SRI VENKATESWARA UNIVERSITY
M.Pharmacy (Pharmaceutics/Pharmacology)
Choice Based Credit System (CBCS)-Syllabus: w.e.f. 2016-17.

Semester	Course code	Title of the course	Instruction hours / per week	No.of credits	Internal marks	Semester end marks	Total marks
FIRST SEMESTER							
Core Paper-1	MPH 101A (Pharmacology)	General & Systemic Pharmacology	6	4	20	80	100
	MPH 101B (Pharmaceutics)	Advnced Pharmaceutical Technology					
Core Paper -2	MPH 102 A (Pharmacology)	Clinical Pharmacology & Toxicology	6	4	20	80	100
	MPH 102 B (Pharmaceutics)	Advanced Pharmaceutics					
Core Paper-3	MPH 103	Practical 1	6	4	-	100	100
Core Paper-4	MPH 104	Practical 2	6	4	-	100	100
Compulsory Foundation Paper-5	MPH 105	Modern Analytical Techniques and biostatistics	6	4	20	80	100
Elective Foundation Paper-6	MPH 106	Human values and Professional ethics-I	6	4	20	80	100
	MPH 107	Comprehensive Viva	-	2	-	50	50
SECOND SEMESTER							
Core Paper-1	MPH 201A (Pharmacology)	Molecular Pharmacology	6	4	20	80	100
	MPH 201B (Pharmaceutics)	Industrial Pharmacy					
Core Paper -2	MPH 202 A (Pharmacology)	Methods in Drug Evaluation	6	4	20	80	100
	MPH 202 B (Pharmaceutics)	Process Validation & CGMP.					
Core Paper-3	MPH 203	Practical 1	6	4	-	100	100
Core Paper-4	MPH 204	Practical 2	6	4	-	100	100
Compulsory Foundation Paper-5	MPH 205	Bio-Pharmaceutics& Pharmacokinetics	6	4	20	80	100
Elective Foundation Paper-6	MPH 206	Human values and Professional ethics-I I	6	4	20	80	100
	MPH 207	Comprehensive Viva	-	2	-	50	50

THIRD SEMESTER							
Core Paper-1	**MPH 301**	**Mid-Term Evaluation of Research project.**	**-**	**8**	**-**	**200**	**200**
Open Elective to others **(For other department students)**	**A** **General Pharmacology**		**6**	**4**	**20**	**80**	**100**
	B **Industrial Pharmacy**						
FOURTH SEMESTER							
Core Paper-1	**MPH 401**	**Project thesis submission & presentation**	**-**	**10**	**-**	**250**	**250**
		Project Viva voce	**-**	**2**	**-**	**50**	**50**
Open Elective to others **(For other department students)**	**A** **Molecular Pharmacology**		**6**	**4**	**20**	**80**	**100**
	B **Drug Regulatory Affairs**						

FIRST SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 101B	**ADVANCED PHARMACEUTICAL TECHNOLOGY**	06	04
Sessional Marks: 20		**End Semester Examination Marks : 80**	

OBJECTIVES:

1. Handle the scheduled activities in a pharmaceutical firm.
2. Manage the production of large batches of pharmaceutical formulations
3. To apply the knowledge to develop new procedures of their own design of Pilot layouts
4. Student shall be able to understand the Quality by design practices of sterile and non-sterile dosage forms.
5. Student shall be able to understand the practices of packaging technology

COURSE CONTENT:

Unit I

Drug Targeting Principles: Targeting, Principles and its importance in therapeutics. Methods in drugtargeting. Advantages and disadvantages of targeting. Protein and peptide-based drug delivery systems.

Carrier based drug delivery: Principles, formulation and evaluation of microparticulate drug carrierssuch as Niosomes, resealed erythrocytes, monoclonal antibodies, Cell ghost and cell ghosts.

Genetic vaccines: A role of liposomes. Preparation and evaluation of liposomes.

Unit II

Transdermal drug delivery: Theory, formulation and product evaluation.

Implants: Types of implants, Osmotic pumps, design and evaluation methods.

Inserts: Types of inserts, Design and evaluation methods.

Nano particles: Nano capsules preparation, characterisation and therapeutic applications. Polymeric nanoparticles as drug carriers. Dendrimers as nanoparticulate carriers. Magnetic nanoparticles and its applications. Solid Lipid nanoparticles.

Unit III

Theory of Controlled release: Fundamental Concepts in controlled release. Factors influencing the kinetics of solute release. Zero Order Kinetics. Theory of diffusion, release and diffusion of drugs from polymers, Mechanism and Kinetics. Evaluation of controlled drug delivery systems.

Unit IV

Microencapsulation. Biodegradable polymers, non-degradable polymers, natural polymers and hydrogels.Bio-adhesive drug delivery systems, Mucosal drug delivery systems like Nasal, ocular etc.,Diffusion controlled Matrix systems, Erodible systems, Osmotic drug delivery, Oral controlledrelease drug delivery.

REFERENCES:

1. The theory and practice of Industrial Pharmacy by L Lachman
2. Modern pharmaceutics by Banker
3. Dispersed system vol 1,2,3 by Lachman
4. Mathowiz,Encyclopedia of Controlled Drug delivery.
5. Agis Kydonieus, Treatise on controlled drug delivery.
6. Alfred Martin, Essential of Physical Pharmacy.

COURSE OUTCOMES:

1. Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceutical industries.
2. The Active Pharmaceutical Ingredients and Generic drug Product
3. The elements of Preformulation studies, Objectives Upon completion of the course, student shall be able to understand Optimization Techniques.
4. Industrial Management and GMP Considerations, development & Stability Testing, sterilization process, Pilot Plant Scale Up Techniques & packaging of dosage forms.

5. Demonstrate the behavior and mechanism of drugs and excipients in the formulation development and evaluation of dosage forms.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	2	3	2	1	3	2	2	1	3	2
CO2	2	3	1	3	2	3	1	3	2	2	3	1
CO3	3	2	3	2	2	3	1	3	2	3	1	3
CO4	2	3	2	2	3	3	2	3	3	1	2	3
CO5	3	3	2	3	2	3	3	2	2	3	2	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 102B(Pharmaceutics)	**Advanced Pharmaceutics**	06	04
Sessional Marks: 20		**End Semester Examination Marks : 80**	

Objectives:

1. To impart knowledge on basic theories of dissolution, invitro dissolution models based on GIT Physiology and Invitro-invivo correlation.
2. Solubilisation technologies and its applications in developing the conventional dosage forms, solutions of electrolytes and its equilibrium.
3. Polymer science to dertermine its molecular weight, to prepare the formulations according to its viscosity and also to determine the drug –polymer compatability studies.
4. Stability studies to determine the shelf life, expiry date and stability of the dosage form

Course Content:

Unit I

Diffusion and dissolution.

a) Diffusion: Measurement of diffusion coefficients.Ficks Laws of Diffusion. Hixon-Crowells Cube root Law. Higuchi Model of Drug Release.

b) Dissolution: Basic theories of dissolution. Physiological parameters relevant to dissolution testing. Development of dissolution tests based on GIT physiology. Dissolution method development. Invitro dissolution testing models and compendial dissolution testing requirements. Fitment of dissolution data into various mathematical equations,f1 and f2 test's.
Sink conditions and its importance.Invitro-invivocorelation and its interpretation.

Unit II

Equilibrium Phenomenon.

a)Solutions of electrolytes and Ionic equilibrium: Strong acids and bases,Monoprotic weak acids and bases,Polyprotic weak acids and bases,Sparingly soluble salts.
b)Solubility and solubilization technology: Importance of solubility,Phasesolubilityanalysis..Factors affecting solubility. Applications of solubilization.
c) Solutions and distribution: Solutions of solids and non-volatile liquids in liquids.
Solutions of volatile liquids in liquids.Solutions of gases in liquids(Henry's law).
Colligative properties.Distribution law(partition coefficient).

Unit III

Polymer Science.

Classification of polymers. Molecular weight determination and molecular weight distribution of polymers. Characterization of polymers by viscosity method, Osmometry,lightscattering,Size exclusion chromatography etc,. Drug-polymer compatibility studies by DSC, IR, XRD and Biological evaluation.

Unit IV

Stability studies.

Principles and methods,ICHguidelines,Protocols and testing programs for solid, liquid and semisolid dosage forms. Methods of stabilization.Methods of accelerated stability testing in dosage forms.Stability testing of light sensitive and water sensitive drugs. working principle of drug stability chambers.

Books recommended:

1) Cherng-Ju Kim , Advanced Pharmaceutics,Physicochemical principles. CRC press.
2) Alfred Martin, Essentials Of Physical Pharmacy,Walter and Kluwers.
3) ICH guidelines.
4) J.T.Cartensen, Drug Stability:Principles and practices.

Course Outcomes:

1. Upon completion of this program the student will have fundamental knowledge in preparing conventional dosage forms, pharmaceutical calculation involved in formulation and appreciate the importance of good formulation for effectiveness.
2. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms using solubility studies and basic theories of dissolution.
3. To formulate and evaluate various novel drug delivery systems based on the molecular weight determination of polymers and its stability studies.
4. Preparation of various conventional dosage forms.
5. Study the preformulation of tablets, Compressibility index, Heckle treatment and Kawakita plots.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	3	1	2	2	1	3	2	2	1	3	2
CO2	3	2	1	3	2	1	2	2	3	1	3	1
CO3	2	3	2	2	3	2	3	1	2	3	2	2

CO4	1	2	2	1	1	2	1	3	2	1	2	1
CO5	1	2	1	2	1	1	1	2	1	1	2	1

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 103	Practical-I(PHARMACEUTICS)	6	04
Sessional Marks: 00		**End Semester Examination Marks : 100**	

Objectives:

1. This course is designed to impart a fundamental and skills necessary for dose calculations, dose adjustments.
2. Basic theoretical discussions of the principles of biopharmaceutics and pharmacokinetics are provided to help the students' to clarify the concepts.
3. Determination of polymers based on its molecular weight and its uses in developing the dosage forms according to its viscosity.
4. To conduct stability studies based on ICH Guidelines.

Course Content:

1. Estimation of calibration curve of Paracetamol
2. Estimation of calibration curve of Aspirin
3. Estimation of calibration curve of Amoxicillin
4. Determination of in-vitro dissolution test for paracetamol
5. Determination of in-vitro dissolution test for Aspirin
6. Determination of in-vitro dissolution test for Amoxicillin
7. Comparison of dissolution data for different marketed products

Course Outcomes:

Gives knowledge to understand

1. The passage of drugs, biopharmaceutical parameters.
2. How to do dissolution studies for the dosage forms to know the bioavailability of the drugs.
3. Solubility studies for the drugs based on its pH and its applications in the formulations of drug delivery systems.

4. To determine the molecular weight of the polymers.
5. Gives an fundamental knowledge on the stability studies
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	1	3	2	2	1	2	2	1	2	1	2	2
CO2	1	2	2	2	3	3	3	2	2	1	1	2
CO3	2	2	1	1	2	1	2	1	2	1	2	3
CO4	1	3	2	2	3	3	1	2	1	2	3	1
CO5	2	2	1	1	2	2	2	3	2	1	2	1

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 104	Practical-II(MAT)	6	04
Sessional Marks: 00		**End Semester Examination Marks : 100**	

Objectives:

1. Discusses the effect of impurities on the quality of drugs and behavioural pattern of drugs
2. Aids in understanding the SOP and usage of software associated with various analytical instruments
3. Helps in gaining knowledge of interpretation of spectra and of chromatograms.

Course Content:

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

Course outcomes

1. Explains the importance of modern instrumentation in pharmaceutical analysis
2. Describes the fundamental principles and applications of spectroscopic techniques Viz., UV- Visible, IR, FTIR.
3. Discusses the principle and applications of chromatographic techniques
4. Identify appropriate instrumental techniques for the analysis of drugs in bulk or in various dosage form.
5. Understand the theoretical principles of assay of drugs covering titrimetric, spectrophotometric, HPLC, argentometric, conductometric, and potentiometric end-point determination.
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	1	2	3	2	1	2	1	2	1	1
CO2	2	2	3	1	3	2	1	2	2	1	2	1
CO3	3	2	3	2	1	2	1	2	1	2	1	2
CO4	2	3	2	1	2	3	1	3	1	3	2	1
CO5	1	2	1	2	1	2	1	2	1	2	1	1

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 105	**Modern Analytical Techniques and biostatics Theory**	06	04
Sessional Marks : 20		**End Semester Examination Marks : 80**	

Objectives:

4. Explains the importance of modern instrumentation in pharmaceutical analysis
5. Describes the fundamental principles and applications of spectroscopic techniques Viz., UV- Visible, IR, FTIR.
6. Discusses the principle and applications of chromatographic techniques
7. Identify appropriate instrumental techniques for the analysis of drugs in bulk or in various dosage forms.

8. Explains the concepts of Statistics and their applications in pharmacy.

Course Content:

Unit I

Thermal methods: Principle,Instrumentation involved in DSC. Glass transition temperature. Sample preparation. Gases used in this method. Plotting graphs of DSC.Interpretation of Graphs of DSC. Applications of DSC.

X-ray crystallography: Generation of X-rays. Introduction.Elementary crystallography, miller indices,X-ray diffraction,Bragg'slaw,X-ray powder diffractometer, sample preparation.

UV-Visible spectroscopy: Electromagnetic spectrum. Chromophores and their interaction with electromagnetic radiation.Absorption spectra of organic compounds and its utilization in quantitaive and qualitative analysis of drugs. Instrumentation and working of various types of UV-Vis spectroscopes. Derivatisation spectrophotometry. Shifts and their effects. Solvent effects.

Unit II

Chromatographic techniques: Liquid Chromatography: Principle involved in HPLC.Instrumentation in HPLC, analytical, preparative and micropore columns,normal and reverse phase packing materials,reverse phase HPLC. Gas chromatography: Principle involved in GC. Instrumentation GC.

Unit III

Nuclear Magnetic resonance spectroscopy: Fundamental principles of NMR(magnetic properties of nuclei, applied field, precissional frequency, absorption and transition frequency). Chemical shift,isotopicnuclei,reference standards.

Infra red spectroscopy, Mass spectrometry: Basic principle and brief outline of instrumentation and working.

Unit IV

Definition of Statistics: Concepts, relevance and general applications of statistics in pharmaceutical sciences.

Collection, Classification, presentation, analysis and interpretation of data.

Definition and concept of Degrees of freedom, precision, accuracy, mean error, relative error, significant numbers

Normal distribution: Concept and properties, Sampling distribution, Standard error

Parametric tests: Z-test, students T test: paired and unpaired. F-Test,ANOVA,Multiple ANOVA

Course Outcomes:

1. Explains the importance of modern instrumentation in pharmaceutical analysis
2. Describes the fundamental principles and applications of spectroscopic techniques Viz., UV- Visible, IR, FTIR.
3. Discusses the principle and applications of chromatographic techniques
4. Identify appropriate instrumental techniques for the analysis of drugs in bulk or in various dosage forms.
5. Explains the concepts of Statistics and their applications in pharmacy
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	3	1	2	3	1	2	3	1	2	3
CO2	2	2	1	2	1	1	2	3	1	2	3	1
CO3	3	2	1	3	2	2	3	2	2	3	2	1
CO4	3	2	3	2	2	2	1	2	1	2	1	2
CO5	2	2	1	2	3	2	1	2	3	1	1	2

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 106	**Human Values and Professional Ethics-I**	06	04
Sessional Marks : 20		**End Semester Examination Marks : 80**	

Objectives:

1. To familiarize students with basic ethical theories.
2. To create ethical awareness to help them in dealing with issues around them.
3. To grasp the traditional ethical theories as well as to help students apply it on the practical front.
4. It is a curriculum which enables students to develop ability for moral reasoning and act with ethical deliberations.

Course Content:

Unit I

Definition and Nature of Ethics- Its relation to Religion, Politics, Business, Law, Medicine and Environment. Need and Importance of Professional Ethics- Goals- Ethical Values in various Professions.

Unit II

Nature of Values – Good and Bad, Ends and Means , Actual and potential Values, Objective and Subjective Values, Analysis of basic moral concepts- right , ought, duty, obligation, justice, responsibity and freedom , Good behavior and respect for elders, Character and Conduct.

Unit III

Individual and Society:
Ahimsa (Non- Violence), Satya (Truth), Brahmacharya (Celibacy), Asteya (Non possession) and Aparigraha (Non- stealing). Purusharthas (Cardinal virtues) – Dharma (Righteousness), Artha (Wealth), Kama (Fulfillment Bodily Desires), Moksha (Liberation).

Unit IV

Bhagavad Gita- (a) Niskama Karma (b) Buddhism- The Four Noble Truths- Arya astanga marga, (c) Jainism- mahavratas and anuvratas. Values Embeded in various Religions, Religious Tolerance, Gandhian Ethics.

Unit V

Crime and Theories of punishment (a) Reformative , Retributive and Deterrent. (b) Views on manu and Yajnavalkya.

Text Books:

1. John S Mackenjie: A manual of ethics.
2. The Ethics of Management" by Larue Tone Hosmer, Richard .D. Irwin Inc.
3. Management Ethics-integrity at work" by Joseph A. Petrick and John F. Quinn, Response Books: New Delhi.
4. Ethics in management" by S.A.Sherlekar, Himalaya Publishing House.
   Harold H. Titus:Ethics for Today.Maitra,S.K: Hindu Ethics.
5. William Lilly : Introduction to Ethics

Course Outcomes:

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

1. Awareness of ethical issues and basic ethical approaches.
2. Improved writing skills and understanding of ethical conflict.
3. Enables students to develop ability for moral reasoning and act with ethical deliberations.
4. After studying ethics one is equipped with the ethical sensitivity and moral understanding required to solve complex ethical dilemmas.
5. Learn how to live peacefully

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	1	2	1	2	3	1	1	1	3	2
CO2	2	2	1	2	1	2	1	2	1	2	2	1
CO3	1	2	1	2	1	3	1	2	2	1	2	3
CO4	1	1	2	1	2	1	2	2	1	2	2	1

CO5	2	2	1	3	2	1	3	2	2	1	2	2

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 107	**Comprehensive Viva**	00	02
Sessional Marks : 00		**End Semester Examination Marks : 50**	

Course Outcomes:

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

1. Industrial Management and GMP Considerations, development & Stability Testing, sterilization process, Pilot Plant Scale Up Techniques & packaging of dosage forms.
2. The need, concept, design and evaluation of various customized, sustained and controlled release dosage forms using solubility studies and basic theories of dissolution.
3. Identify appropriate instrumental techniques for the analysis of drugs in bulk or in various dosage forms.
4. After studying ethics one is equipped with the ethical sensitivity and moral understanding required to solve complex ethical dilemmas.
5. Enables students to develop ability for moral reasoning and act with ethical deliberations.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	3	2	1	2	1	3	2	1	3	2
CO2	3	2	1	2	2	1	3	3	1	2	1	2
CO3	1	1	2	2	1	2	3	1	2	3	1	2
CO4	3	2	2	3	3	1	1	2	3	1	2	3
CO5	2	2	1	3	3	2	1	2	3	1	2	2

SECOND SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 201B (Pharmaceutics)	**INDUSTRIAL PHARMACY**	06	04
Sessional Marks:20		**End Semester Examination Marks :80**	

Objectives:

1. Course designed to impart advanced knowledge and skills required to learn various aspects and concepts at pharmaceuticalindustries
2. Understand various formulation aspects of tablets and capsulesand also provide knowledge about selection of excipients in the preparation of same.
3. To understand insight area of aseptic area conditions andparenteral.
4. Provide knowledge on packaging materials used in pharmaceuticalproducts.

Course Content:

UNIT I

Preformulation studies in Pharmaceutical product development-Factors involved in Formulation. Physical characteristics- Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, pKa and solubility partition coefficient, crystal morphology, polymorphism, wetting of solids, flow characteristics, compressibility and Partition coefficient. Chemical Characteristics- Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies. Biopharmaceutical Characteristics- Lipid solubility, dissociation constant, dissolution rate, drug stability in G.I.tract, complexation.

UNIT – II

Compaction and compaction: Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression. Effect of particle size,moisturecontent,lubrication etc., on the strength of thetablets.

UNIT – III

Improved tablet production: Tablet production process, unit operation improvements, granulation and pelletizationequipments, granulators, spheronizers and drying equipments, Coating technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Capsule production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered

UNIT IV

Parenteral production: Area planning and environmental control, wall and floor treatment, and machineries, change rooms, personnel flow, utilities and equipment location, engineering and maintenance. Lyophillization technology: Principles, process and freeze drying equipments.

REFERENCES:

1. Pharmaceutical production facilities byCole
2. Pharmaceutical dosage forms (tablets) vol-1, 2,and by Haliberman
3. Encyclopaedia of pharmaceutical technology set 2nd end 2002 by Swarbrick
4. Pharmaceutical Engineering by KSambamurthy.
5. The theory and Practices of Industrial Pharmacy by Lachman and Lieberman. Pharmaceutical Product development by NKJain.
6. Remington's Pharmaceutical Sciences, L.Wiliams& Wilkins, 21st Ed. (Vol. I &II)
7. Theory & Practice of Industrial Pharmacy byLachman.
8. Pharmaceutics of Solids and Solid dosage forms by J.Cartensen.
9. Advances in Pharm. Sciences by Beckett.
10. Pharmaceutical Technology byParrot.

Course Outcomes:

At completion of this subject it is expected that students will be able to understand –

1. The elements of preformulationstudies.
2. Acquire skill in preparation of different types oftablets.
3. Acquire knowledge for evaluation of various dosageforms.
4. Acquire the knowledge of processing of dosage form on large scale that suit pharma industry.
5. Formulate solid, liquid and semisolid dosage forms and evaluate them for their quality.
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	2	3	2	1	3	2	1	3	2	2	1
CO2	2	2	3	2	1	2	3	1	2	3	2	2
CO3	3	3	2	3	2	3	2	1	2	3	2	1
CO4	1	2	1	2	2	2	1	2	1	2	1	2
CO5	3	3	2	1	3	2	3	2	3	2	1	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH202B(Pharmaceutics)	**PROCESS VALIDATION & CGMP**	06	04
Sessional Marks : 20		**End Semester Examination Marks : 80**	

Objectives:

1. Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
2. Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
3. Understand the importance of effective documentation.
4. To prepare professionally competent individuals with Quality concept being engrained to achieve global quality standards in pharmaceutical industries.

Course Content

Unit I

Basic concepts of quality assurance: Requirements of cGMP/GLP. ISO 9000 series. Quality audits. Concept of Validation: Validation of manufacturing equipment and analytical equipments. Process validation in production of pharmaceuticals. Preparation of documents for NDA and export registration.

Unit II

Statistical concepts in process validation and cGMP: Precision, Accuracy and Biases. Sampling operation.Sampling plans. Operating characteristic curves. Statistical inference in estimation of hypothesis testing. Statistical procedures in assay development.

Unit III

Development of new analytical methods like, dissolution tests,assays using HPLC,GC and other chromatographic techniques and other similar tests.

Unit IV

In-Process Quality control tests for various dosage forms.
In-Process Quality control tests for packaging and labelling operations.

Books :

1) S.H.Willig, GMP for phamaceuticals.
2) B.T.Loftus, Pharmaceutical process validation.
3) S.Bolton, Pharmaceutical statistics: Practical and statistical applications.
4) G.S.Banker, Modern Pharmaceutics.

Course outcomes

1. Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.

2. Address quality issues and provide solutions needed to attain Quality leadership in an environment of continual improvement.
3. Understand the importance of effective documentation.
4. To prepare professionally competent individuals with Quality concept being engrained to achieve global quality standards in pharmaceutical industries.
5. To create, select appropriate techniques.
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	2	1	2	3	2	1	3	2	3	2	3
CO2	2	2	2	3	2	1	2	3	2	2	3	1
CO3	3	2	3	2	3	2	1	2	3	2	3	2
CO4	3	3	2	2	3	2	3	2	1	2	3	2
CO5	2	2	1	2	2	2	1	1	2	1	2	3

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 203	Practical-I	6	04
Sessional Marks: 00		**End Semester Examination Marks : 100**	

Objectives:

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

LIST OF EXPERIMENTS;

1. Formulation and evaluation of paracetamol Tablets.
2. Formulation and evaluation of nateglinide mucoadhesive tablets
3. Formulation and evaluation of sodium alginate beads.
4. Preparation and evaluation of microspheres.
5. Preparation of solid dispersion method.
6. Comparision of two marketed tablets.
7. Formulation and evaluation of diclofenac tablets.

8. Formulation and evaluations of paracetamol transdermal patches.

Course Outcomes:

At completion of this subject it is expected that students will be able to understand –

1.Gain knowledge and acquire skills to prepare different types of tablets.

2. Highlights the handling of different equipment's for the preparation and evaluation of various dosage forms.

3. Maintaining quality of information and its significance and evolving definition of process validation.

4. The new validation parameters and quality by design concepts and their application.

5. Making Pharmaceutical development and good manufacturing practices.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	3	2	3	2	3	2	1	2	3	2	3
CO2	1	2	1	1	2	2	2	3	1	3	2	3
CO3	2	3	1	2	3	3	2	1	2	2	3	3
CO4	1	2	2	3	2	2	1	2	1	2	1	1
CO5	2	3	2	1	2	3	2	1	3	1	2	3

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 204	Practical-II(BPT)	6	04
Sessional Marks: 00		**End Semester Examination Marks : 100**	

Objectives:

1. Understanding mechanism of drug absorption and various affecting drug absorption.
2. Understanding various biopharmaceutic factors affecting drug bioavailability.
3. Understanding the various method of dissolution testing in vitro in vivo correlation dissolution data

4. Understand basic considerations of Pharmacokinetic models. Understand different compartment model and non-compartment model.

Course Content:

1. In vitro dissolution study of compressed tablet
2. In Vitro dissolution study of marketed sustained release tablet
3. Determination of Partition coefficient and dissociation constant
4. Determination of Partition coefficient and dissociation constant of ibuprofen
5. Protein binding study using dynamic dialysis method
6. Determination of protein binding using equilibrium dialysis method.
7. Design and evaluation of transdermal patches containing diclofenac sodium
8. Formulation and evaluation of transdermal patches of ibuprofen
9. Modelling of drug release form delivery system using kinetic software
10. Determination of release for kinetics for the dissolution data.
11. Absorption study for diclofenac sodium.

Text Books:

1. Practical book by Hedaya in Bio Pharmacokinetics
2. JC Wagner, fundamentals of clinical Pharmacokinetics
3. Bert N Ladu, Fundamental practical book for drug metabolism and disposition

Course Outcomes:

After Completion of the course the student able toperform experiments like

1. Compare and differentiate between compartmental and non compartmental analysis
2. Identify the physiological, Physicochemical and dosage form related factors that affects drug absorption from different dosage forms
3. Examine the absolute and relative bioavailability of drugs form different dosage forms using either plasma or urine data.
4. Compare the bioequivalence of two drug products.
5. Use plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.

6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	1	2	2	3	3	1	1	1	3	3	2	2
CO2	2	3	2	1	2	3	2	2	3	1	2	1
CO3	3	3	2	2	3	1	3	1	3	1	3	2
CO4	2	2	1	2	3	3	2	1	2	3	1	1
CO5	1	2	1	2	1	3	2	1	1	2	1	2

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 205	**BIO-PHARMACEUTICS& PHARMACOKINETICS**	06	04
Sessional Marks: 20		**End Semester Examination Marks: 80**	

OBJECTIVES:

1. Define and differentiate between basic concepts of pharmacokinetics and pharmaco-dynamics, identify the physiological, physicochemical and dosage form-related factors that affect drug absorption.
2. Analyze different compartmental and non-compartmental models of pharmacokinetics and determine the basic linear and non-linear pharmacokinetic parameters that describe drug absorption and disposition.
3. Describe concept and principles of dissolution studies and in vitro-in vivo correlation for different drug products and pharmacokinetic basis of modified release dosage forms of medications.

COURSE CONTENT:

Unit I

Foundations of pharmacokinetics: The Birth of compartments: The Rutherford equations, The Benke Equations, The Toerell Equations and Tracer kinetics. Compartmental modelling. Basics of Model building. One Compartmental Model. Two Compartmental Model. Multi Compartmental Model.

Unit II

Physiological Pharmacokinetic modelling: Blood flow rate limited models, blood clearance, lung clearance, apparent volume of distribution, non-linear disposition. Membrane limited models. Relationship between Physiologically based models and usual compartment models.

Non-compartmental analysis: Non compartmental analysis based on statistical moment theory. Bioavailability, clearance, half-life, absorption kinetics, apparent volume of distribution etc., Steady state.

Unit III

Non-Linear Pharmacokinetics: Michaelis Menten Kinetics, Estimation of Km and Vm, Clearance, Half Life, Volume of distribution, steady state, bioavailability etc., Urinary excretion process and other non-linear elimination process. Problems in quantifying non-linear pharmacokinetics.

Multiple Dosing: IV, IV infusion, First order absorption and determination of PK parameters from multiple dosing data

Unit IV

Kinetics of Pharmacologic response:

a) Kinetics of directly reversible pharmacologic response.

b) Kinetics of indirect pharmacologic response.

c) Kinetics of irreversible pharmacologic response.

Applications of PK principles: Multiple dosing, Dose adjustments in Renal failure, Hemo dialysis, Methods for determination of Individual Patient parameters. Assessing Bio Availability of Drug Delivery systems.

Modelling in Pharmacodynamics: Classical Pharmacodynamics,Non-Classical Pharmacodynamics.

Books recommended:

1) Hedaya, Basic pharmacokinetics.

2) Milo Gibaldi, Pharmacokinetics.

3)J.C.Wagner, Fundamentals of Clinical Pharmacokinetics.

4) Bert.N.Ladu, Fundamentals of drug metabolism and disposition.

COURSE OUTCOMES:

After successful completion of the course student will be able to:

1. Understand the concept of ADME of drug in human body.

2. Determine the various pharmacokinetic parameters from either plasma concentration or urinary excretion data for drug

3. Apply the various regulations related to developing BA -BE study protocol for the new drug molecule.
4. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
5. Understand the concept of dissolution and application of in vitro in vivo correlation in drug product development.
CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	2	1	2	3	2	1	3	2	1	3
CO2	1	2	3	2	1	2	2	1	1	2	3	3
CO3	3	1	2	1	2	3	3	2	3	2	1	1
CO4	2	2	1	1	1	3	2	3	1	2	2	1
CO5	3	3	2	1	2	1	2	1	3	1	1	3

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 206	**Human Values and Professional Ethics-II**	06	04
Sessional Marks : 20		**End Semester Examination Marks : 80**	

Objectives:

1. To instill Moral and Social Values and Loyalty
2. To appreciate the rights of others
3. To inculcate the sense of social responsibility.
4. To develop a firm ethical base
5. To make the students realize the significance of ethics in professional environment.

Course Content:

Unit I

Value Educattion- Defination- relevance to present day- Concept of Human Values- self introspection-Self esteem- Family Values – Components, Structure and responsibilities of family-Neutralization of anger- Adjustability- Treats of famiy life – Status Of women in family and society- Caring for needy and elderly – Time allotment for sharing ideas and concerns.

Unit II

Medical ethics- Views of Charaka, Sushruta and Hippocratus on moral responsibility of medical practitioners. Code of ethics for medical and Health care professionals. Euthanasia, Ethical obligation to animals, Ethics issues in relation to health care professionals and patients. Social justice in health care, Human cloning, Problems of abortion. Ethical issues in genetic engineering and Ethical issues raised by new biological technology or knowledge.

Unit III

Business ethics- Ethical standards of business- Immoral and illegal practices and their solutions. Characteristics of ethical problems in management, ethical theories, causes of unethical behavior, ethical abuses and work ethics.

Unit IV

Environment ethics- Ethical theory, man and nature- Ecological crisis, Pest control, Pollution and waste, Climate change, Energy and population, Justie and Environmental health.

Unit V

Social ethics- Organ trade, Human trafficking, Human rights violation and social disparities, Feminist ethics, Surrogacy/ pregnancy. Ethics of media- Impact of Newspaper, Television, Movies and Internet.

Recommended Books

1. John S Mackenjie: A manual of ethics.
2. The Ethics of Management" by Larue Tone Hosmer, Richard .D. Irwin Inc.
3. Management Ethics-integrity at work" by Joseph A. Petrick and John F. Quinn, Response Books: New Delhi.
4. Ethics in management" by S.A.Sherlekar, Himalaya Publishing House.
5. Harold H. Titus: Ethics for Today.
6. Maitra, S.K: Hindu Ethics.
7. William Lilly: Introduction to Ethics
8. Sinha: A Manual of Ethics
9. Manu: Manu Dharma Sastra or the Institute of Manu : Comprising the Indian System of Duties: Religious and Civil (ed.) G.C. Haughton.
10. Susruta Samhita: Tr. Kaviraj Kunjalal ,KunjalalBrishagratha, Chowkamba Sanskrit series, Vol I,II and III, Varanasi, Vol 1 OO, 16-20, 21-32 and 74- 77 only.
11. Caraka Samhita: Tr. Dr. Ram Karan Sarma and Vaidya Bhagavan Dash, Chowkambha Sanskrit Series Office , Varanasi Vol 100, 16-20,21-32 and 74-77 only.
12. Ethics: Theory and Contemporary Issues., Barbara Mackinnon Wadsworth/ Thomson Learning , 2001.
13. Analysing Moral Issues, Judith A. Boss, Mayfield Publishing Company ,1999.
14. An Introduction to Applied ethics (Ed.) John H.Piet and Ayodhya Prasad, Cosmo Publications.

15. Text Book for Intermediate logic, Ethics and Human Values550355, board of intermediate Education & Telugu Academic Hyderabad.

COURSE OUTCOMES:

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

1. Identify and analyze an ethical issue in the subject matter under investigation or in a relevant field
2. Learn about morals, values & work ethics.
3. Develop commitment
4. Learn about the different professional roles.
5. Ethical, social and environmental awareness
6. Professional rights and responsibilities act in morally desirable ways, towards moral commitment and responsible conduct
7. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3	2	3	2	1	2	3	2	3	3	1
CO2	2	2	2	1	2	3	2	1	3	2	2	3
CO3	2	2	2	1	2	3	2	3	1	2	3	2
CO4	1	2	3	2	1	2	3	2	1	2	2	1
CO5	2	2	2	1	2	3	2	1	2	3	2	2

8.

Course Code	**Course Title**	**No of Hours Per week**	**No of Credits**
MPH 207	**Comprehensive Viva**	00	02
Sessional Marks : 00		**End Semester Examination Marks : 50**	

COURSE OUTCOMES:

1. Understand various formulation aspects of tablets and capsulesand also provide knowledge about selection of excipients in the preparation of same.
2. Acquire knowledge on various quality assurance systems, processes and current regulatory guidelines related to manufacturing and distribution.
3. Identify and analyze an ethical issue in the subject matter under investigation or in a relevant field
4. Understand the concepts of bioavailability and bioequivalence of drug products and their significance.
5. Understand the concept of dissolution and application of in vitro in vivo correlation in drug product development.

CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	3	2	1	2	3	1	3	1	2	3
CO2	2	1	1	1	2	3	2	3	2	1	1	2
CO3	1	2	1	1	2	3	1	1	2	3	1	2
CO4	3	2	1	2	1	2	3	1	2	3	1	3
CO5	1	1	3	3	2	1	2	3	1	2	3	1

THIRD SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 301	**Mid-Term Evaluation of Research project**	00	08
Sessional Marks : 00		**End Semester Examination Marks : 200**	

COURSE OBJECTIVE

After successful completion of this course students will be able to:

1. Work in team and undertake a project in the area of Pharmacy
2. Apply concepts of pharmaceutical sciences for executing the project
3. Apply appropriate research methodology while formulating a project
4. Define specifications, synthesize, analyse, develop and evaluate a project
5. Present, exhibit and document the project work
6. Develop a project report

COURSE OUTCOME

1. Final Year Projects represent the culmination of study towards the Master of Pharmaceutical sciences degree.
2. Projects offer the opportunity to apply and extend material learned throughout the program.
3. Assessment is by means of a seminar presentation, submission of a thesis, and a public demonstration of work undertaken.
4. In contrast to the majority of courses studied elsewhere in the program, projects are undertaken individually or in small groups.
5. This necessarily introduces the dimension of workload management into the program to enable completion of a large, relatively unstructured "assignment" over the course of the semester.

6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	1	2	3	2	1	2	3	1	2	3	3
CO2	3	1	2	2	3	1	3	2	1	2	3	2
CO3	1	2	1	2	1	2	2	3	1	1	3	2
CO4	3	3	2	1	2	1	1	2	2	2	1	3
CO5	1	2	2	2	1	1	1	3	3	2	3	1

FOURTH SEMESTER

Course Code	Course Title	No of Hours Per week	No of Credits
MPH 401	**Project thesis submission & presentation and Project Viva voce**	00	12
Sessional Marks : 00		**End Semester Examination Marks : 300**	

COURSE OBJECTIVE

After successful completion of this course students will be able to:

1. Work in team and undertake a project in the area of Pharmacy
2. Apply concepts of pharmaceutical sciences for executing the project
3. Apply appropriate research methodology while formulating a project
4. Define specifications, synthesize, analyse, develop and evaluate a project
5. Present, exhibit and document the project work
6. Develop a project report

COURSE OUTCOME

1. Final Year Projects represent the culmination of study towards the Master of Pharmaceutical sciences degree.
2. Projects offer the opportunity to apply and extend material learned throughout the program.
3. Assessment is by means of a seminar presentation, submission of a thesis, and a public demonstration of work undertaken.
4. In contrast to the majority of courses studied elsewhere in the program, projects are undertaken individually or in small groups.
5. This necessarily introduces the dimension of workload management into the program to enable completion of a large, relatively unstructured "assignment" over the course of the semester.
6. CO-PO Mapping

Course	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	2	3	2	1	2	3	2	1	2	3	2	3
CO2	2	1	2	3	2	1	2	3	2	1	2	3
CO3	1	2	3	2	1	2	1	2	1	2	3	2
CO4	2	3	2	1	2	3	3	2	1	1	2	3
CO5	3	2	3	2	1	2	3	2	3	2	3	2