**SHRI SHANKARACHARYA TECHNICAL CAMPUS**
**SHRI SHANKARACHARYA GROUP OF INSTITUTION**
**Faculty of Pharmaceutical Sciences**
**(An Autonomous Institution)**
**SCHEME OF TEACHING AND EXAMINATION (Effective from 2020 – 2021 Batch)**
**Courses of Study and Scheme of Examination of Pharmacy**
**M Pharm (I Semester) (Common for All Specializations)**

| Sl. No. | Board of Study | Subject Code | Subject | Periods per week | | | Scheme of Exam | | | Total Marks | Credit L+(T+P)/2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Theory/Practical | | | | |
| | | | | L | T | P | ESE | CT | TA | | |
| 1. | Pharmacy | **PH208101** | Advanced Research Methods | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 2. | Pharmacy | **PH208102** | Pharmacology | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 3. | Pharmacy | **PH208103** | Drug Regulatory Affairs and Quality Assurance | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 4. | Pharmacy | **PH208104** | Formulation Development | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 5. | Pharmacy | **PH208191** | Advanced Research Methods Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 6. | Pharmacy | **PH208192** | Pharmacology Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 7. | Pharmacy | **PH208193** | Formulation Development Lab | - | - | 6 | 100 | - | 40 | 140 | 3 |
| **Total** | | | | **14** | **2** | **8** | **660** | **100** | **240** | **1000** | **29** |

L-Lecture T- Tutorial P-Practical
CT- Class Test TA- Teachers Assessment ESE- End Semester Exam

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**SCHEME OF TEACHING AND EXAMINATION (Effective from 2020 – 2021 Batch)**
**Courses of Study and Scheme of Examination of Pharmacy**
**M Pharm (Pharmaceutics)-II Semester**

| Sl. No. | Board of Study | Subject Code | Subject | Periods per week | | | Scheme of Exam | | | Total Marks | Credit L+(T+P)/2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Theory/Practical | | | | |
| | | | | L | T | P | ESE | CT | TA | | |
| 1. | Pharmacy | **PH208201(33)** | Pharmaceutics – I | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 2. | Pharmacy | **PH208202(33)** | Pharmaceutics – II | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 3. | Pharmacy | **PH208203(33)** | Pharmaceutics – III | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 4. | Pharmacy | **PH208204(33)** | Pharmaceutics – IV | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 5. | Pharmacy | **PH208291(33)** | Pharmaceutics – I Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 6. | Pharmacy | **PH208292(33)** | Pharmaceutics – II Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 7. | Pharmacy | **PH208293(33)** | Pharmaceutics – III Lab | - | - | 6 | 100 | - | 40 | 140 | 3 |
| **Total** | | | | **16** | **4** | **18** | **700** | **80** | **220** | **1000** | **29** |

L-Lecture T- Tutorial P-Practical
CT- Class Test TA- Teachers Assessment ESE- End Semester Exam

**SHRI SHANKARACHARYA TECHNICAL CAMPUS**
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**Courses of Study and Scheme of Examination of Pharmacy**

## M Pharm (Pharmacology) - II Semester

| Sl. No. | Board of Study | Subject Code | Subject | Periods per week | | | Scheme of Exam | | | Total Marks | Credit L+(T+P)/2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Theory/Practical | | | | |
| | | | | L | T | P | ESE | CT | TA | | |
| 1. | Pharmacy | **PH208201(34)** | Pharmacology –I (General Pharmacology) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 2. | Pharmacy | **PH208202(34)** | Pharmacology – II (Pharmacological Screening Methods) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 3. | Pharmacy | **PH208203(34)** | Pharmacology – III (Molecular Pharmacology) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 4. | Pharmacy | **PH208204(34)** | Pharmacology – IV (Clinical Pharmacology & Toxicology) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 5. | Pharmacy | **PH208291(34)** | Pharmacology – I Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 6. | Pharmacy | **PH208292(34)** | Pharmacology – II Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 7. | Pharmacy | **PH208293(34)** | Pharmacology – III Lab | - | - | 6 | 100 | - | 40 | 140 | 3 |
| **Total** | | | | **16** | **4** | **18** | **700** | **80** | **220** | **1000** | **29** |

L – Lecture, T-Tutorial, P-Practical, Duration of Theory Paper 3Hours
ESE – End Semester Examination, CT – Class Test, TA – Teacher Assessment

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**SCHEME OF TEACHING AND EXAMINATION (Effective from 2020 – 2021 Batch)**
**Courses of Study and Scheme of Examination of Pharmacy**
## M Pharm (Pharmaceutical Chemistry) - II Semester

| Sl. No. | Board of Study | Subject Code | Subject | Periods per week | | | Scheme of Exam | | | Total Marks | Credit L+(T+P)/2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | Theory/Practical | | | | |
| | | | | L | T | P | ESE | CT | TA | | |
| 1. | Pharmacy | **PH208201(35)** | Pharmaceutical Chemistry-I (Advanced Medicinal Chemistry) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 2. | Pharmacy | **PH208202(35)** | Pharmaceutical Chemistry-II(Advanced Organic Chemistry) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 3. | Pharmacy | **PH208203(35)** | Pharmaceutical Chemistry-III (Natural Products) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 4. | Pharmacy | **PH208204(35)** | Pharmaceutical Chemistry-IV (Drug Design) | 4 | 1 | - | 100 | 20 | 20 | 140 | 5 |
| 5. | Pharmacy | **PH208291(35)** | Pharmaceutical Chemistry-I Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 6. | Pharmacy | **PH208292(35)** | Pharmaceutical Chemistry-II Lab | - | - | 6 | 100 | - | 50 | 150 | 3 |
| 7. | Pharmacy | **PH208293(35)** | Pharmaceutical Chemistry-III Lab | - | - | 6 | 100 | - | 40 | 140 | 3 |
| **Total** | | | | **16** | **4** | **18** | **700** | **80** | **220** | **1000** | **29** |

L – Lecture, T-Tutorial, P-Practical, Duration of Theory Paper 3Hours
ESE – End Semester Examination, CT – Class Test, TA – Teacher Assessment

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharmacy First Year (1st/ 2nd semester)**

| Subject Code – PH208101 | Advance Research Methods (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| After completion of course student is able to know about chemicals and excipients-<br>The analysis of various drugs in single and combination dosage forms<br>Theoretical and practical skills of the instruments | On successful completion of the course, the student will be able to:<br><br>**CO1:-**Understand general principles, theory and structure elucidation by using various spectroscopies UV, IR, NMR.<br>**CO2:-** Understand the basic concept and instrumentation of Chromatographic techniques<br>**CO3:-**Understand the Instrumentation and identification of compounds by thermal and calorimetric analysis technique<br>**CO4:-** Understand principles and techniques involved in electrophoresis, RIA and ELISA |

**Unit - 1 :**

Spectroscopic Method – Introduction, application structure elucidation using UV, IR, NMR, Mass spectrometry with examples.

**Unit – 2 :**

Separation Techniques – Theory, instrumentation and application of GLC, HPLC, HPTLC, Chiral chromatography, ion pair chromatography.

**Unit – 3 :**

Thermal Analysis – Theory, instrumentation and application of thermo-gravimentric analysis, differential thermal thermal analysis.

**Unit – 4 :**

Calorimetric Analysis – Theory, instrumentation, chemical application and structural elucidation, differential scanning calorimetric (DSC), Isothermal titration.

**Unit – 5 :**

Immunochemical techniques – Immunelectrophoresis, immunoprecipation, ELISA, radioimmunoassay.

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharmacy First Year (1st/ 2nd semester)**

| Subject Code – PH208191 | Advance Research Methods (Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

**List of experiments**

1. Determination of $\alpha_{max}$ and Linearity of methylene blue by spectroscopic method.
2. To determine the absorption curve of aromatic hydrocarbons and the analysis of binary mixture.
3. Estimation of Aspirin by colorimetry.
4. Assay of Paracetamol tablet by UVspectroscopy.
5. Determination of the active constituents in a medicinal preparation by derivative spectroscopy.
6. Estimation of Paracetamol by HPLC.
7. Identification of given sample by paper chromatography.
8. Identification of drug's by TLC.
9. To determine the purity of commercial benzoic acid using compressed discs(IR).
10. Interpretation of given sample by IR spectra.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Spectroscopy of organic compounds | P. S. Kalsi | Second | Wiley eastern |
| 2 | Practical Pharmaceutical Chemistry | Beckett and Stenlake | Fourth | CBS Publishers |
| 3 | Textbook of Pharmaceutical Analysis | KA. Connors | Third | John Wiley & Sons |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Spectrometric Identification of organic compounds | Robert M Silverstein | Sixth | John Wiley & Sons |
| 2 | Principles of Instrumental Analysis | Doglas A Skoog, F. James Holler | Fifth | Eastern press |

| | | October 2020 | 1.00 | Applicable for AY 2020-21Onwards |
|---|---|---|---|---|
| Chairman(AC) | Chairman(BoS) | Date of Release | Version | |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharmacy First Year (1st/ 2nd semester)**

| Subject Code – PH208102 | Pharmacology (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of the course the student shall be able to :<br>• Describe the various newer screening methods involved in the drug discovery process<br>• Explain the mechanism of drug actions at cellular and molecular level<br>• Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases | On successful completion of the course, the student will be able to:<br>**CO1:-** The students would appreciate the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications<br>**CO2:-** They would have learnt to describe the various screening methods involved in the drug discovery process.<br>They would appreciate to correlate the preclinical data to humans<br>**CO3:-** The students would appreciate the knowledge gained on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.<br>**CO4:-** The students would have understood the fundamental knowledge on the structure and functions of cellular components.<br>**CO5:-** They would have learnt the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases ,Know the applications of statistics in clinical data management |

**Unit – 1 :**

Drug dependence, tolerance, abuse drug allergy and resistance.

**Unit – 2 :**

Genetics, gene cloning, gene delivery and recombinant DNA.

**Unit – 3:**

Molecular pharmacology, receptor theories, receptor isolation radio- ligand binding studies, Signal transduction mechanism of the cell.

**Unit – 4 :**

Therapeutics regimens – therapeutics response and toxicity, dosage regimens, clinical trial studies, ADME – Pharmacokinetics, Drug – drug interaction and bioassay.

**Unit – 5:**

Biological screening of new compounds and New drug discovery.

| Subject Code – PH208192 | Pharmacology (Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 140 | 3 Hrs |

| List of experiments |
|---|
| 1. To Study the maintenance of common laboratoryanimals.<br>2. Bioassay of the more important biogenic agents by variousmethods.<br>3. Pharmacological Screening methods used for CNS, Local anesthetics, Endocrine and In-vitro microbialscreening.<br>4. Protocol design of ClinicalTrials. |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Essentials of Medical Pharmacology | KD.Tripathi | Six | Jey Pee Pub. |
| 2 | Robbins & Cortan Pathologic Basis of Disease | Robbins Pathology | Nine | Elsevier |
| 3 | Essentials of Medical Pharmacology | KD.Tripathi | Six | Jey Pee Pub. |
| 4. | Handbook of Experimental Pharmacology | S.K. Kulkarni | First | Vallabh Prakashan |
| 5. | Principles of toxicology | Karen E. Stine, Thomas M. Brown | Third | CRC Press |

**ReferenceBooks:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | The Pharmacological Basis of Therapeutics | Goodman andGillman's | Second | Mcgraw Hill |
| 2 | Principles of Pharmacology, The Pathophysiologic basis of drug Therapy | Armen H, TashjianJr, EhrinJ,Armstrong, April W, Armstrong | First | Wolters, Kluwer-Lippincott Williams & WilkinsPublishers |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharmacy First Year (1st/ 2nd semester)**

| Subject Code – PH208103 | Drug Regulatory Affairs and Quality Assurance (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Course will impart advanced knowledge and skills required to learn<br>• the concept of generic drug and their development, various regulatory filings in different countries<br>• Concepts of quality, quality management and its implementation<br>• Documentation of BMR, MFR, DMF and relevant process related documents | On successful completion of the course, the student will be able to:<br>**CO1**- Understand Concept of innovator and generic drugs, drug development process, Regulatory guidance's and guidelines for filing and approval process<br>**CO2**- Understand the various documents pertaining to drugs in pharmaceutical industry<br>**CO3**- Evaluate current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices and Good Regulatory Practices.<br>**CO4**- Organize SOPs for Good Pharmaceutical Practices Implement Good Pharmaceutical Practices in the Industries and Prepare for the Audit and validation of document in Pharmaceutical Industries.<br>**CO5**- Support the SOP guideline of different dosage form level. |

**Unit – 1 :**

Requirement of GMP, CGMP, GLP, USFDA, WHO guidelines and ISO 9000 series. Drug and cosmetics acts and rules. Drug regulatory affairs.

**Unit – 2 :**

Documentation – Protocols, forms and maintenance of record in Pharmaceuticals industry.

**Unit – 3 :**

Preparation of documentation of new drug approval and export registration, processing and its application intellectual property rights (patent, copyright and trade marks)
Sewage disposal and pollution control.

**Unit – 4 :**

Concept in validation of manufacturing, analytical and process, validation and its application.

**Unit – 5 :**

Basic concept of quality control and quality assurance system, source and control of quality variation of raw material, containers, closures personnel, environmental etc.

**Unit – 6 :**

In process quality control test, IPQC problem in pharmaceutical industries, ICH guidelines.

**Unit – 7 :**

Sampling plans, Sampling and characteristics curves, Master formula generation and maintenance, standard operating procedure (SOP) for different dosage forms.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Theory and Practice of Industrial Pharmacy | Lachmann and Libermann | Fourth | CBS Publishers & Distributors |
| 2 | Good manufacturing practices for Pharmaceuticals: A plan for total quality control | Sidney H. Willig | Second | Marcel Dekker |
| 3 | Pharmaceutical Process Validation | Fra. R. Berry and Robert A. Nash. | - | CRC Press |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Remington‟s Pharmaceutical Sciences. | Remington | Nineteenth | John Wiley & Sons |
| 2 | Applied production and operations management | Evans, Anderson, Sweeney and Williams. | - | South-Western |

| Subject Code – PH208104 | Formulation Development (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Course would provide knowledge to the students with respect to<br>1. The principles or basics involved in the dosage form design.<br>2. How to use the physicochemical properties of the drug/ excipients and pharmacokinetics principles in the development of pharmaceutical dosage forms.<br>3. Knowledge as well as hands on training with respect to the principles of formulation<br>4. Biopharmaceutical and pharmacokinetics aspects which help to design a dosage form for patient's need. | On successful completion of the course, the student will be able to:<br>**CO1**- Understand the basics involved in the dosage form design and formulation and manufacturing aspects of various dosage forms in Industrial Pharmacy. (**Level 2)**<br>**CO2**- Investigate with respect to composition of dosage forms, excipients, evaluation tests, storage conditions, packaging, GMP and novel drug delivery systems (**Level 6)**<br>**CO3**- Understand Pharmaceutical dosage forms for quality and stability kinetics and compare with standards prescribed in the pharmacopoeia (**Level 2)**<br>**CO4**- Develop complete package information of pharmaceutical formulation, pilot plant and scale up issues, manufacture, quality control, storage (**Level 6)**<br>**CO5-** Execute knowledge of controlled and novel drug delivery system in industry. (**Level 3)** |

**Unit – 1:**

Stability, solubility, Pka, Dissolution rate, Partition Coefficient. In Vitro and In Vivo evaluation techniques, product formulation and CGMP.

**Unit –2:**

Designing of Pharmaceuticals - Tablets formulation, special tablets and preparation of components for compression. Characterization of granulation, Coating of tablets, evaluation of tablets. Equipment and processing problem in tablets.

**Unit – 3:**

Topical and rectal absorption of drug, formulations and evaluations.

**Unit – 4:**

Formulation consideration of oral liquids, suspension, emulsion, development of various products.

**Unit – 5:**

Formulation consideration of parenteral ophthalmic, depot products, large volume and small volume parenteral, environmental control and quality assurance in parenteral drug manufacturing.

**Unit – 6:**

Stability in pharmaceuticals and study of stability kinetics.

**Unit – 7:**

Introduction to controlled and novel drug delivery system, Sustained release dosage form, prodrug concept, Nanoparticals, Liposomes, Resealed erythrocytes, Transdermal and other Novel drug delivery systems.

**Unit – 8:**

Types of container and closures, packaging and stability assessment. Optimization techniques in pharmaceutical formulations and processing. Pilot plant and scale up techniques.

| Subject Code – PH208193 | Formulation Development(Lab) | L = | T = | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 140 | 3 Hrs |

| List of experiments |
|---|
| 1. To prepare and evaluate aspirin tablets by wet granulation method.<br>2. To evaluate and compare at least three marketed Paracetamol tablets.<br>3. To study the effect of various binders on the hardness and dissolution rate of ascorbic acid tablets, at different concentration.<br>4. To prepare 10gm of sustained release granules of ascorbic acid by Microencapsulation method.<br>5. To perform the pre-formulation studies of the given sample of ascorbic acid.<br>6. To study the dissolution profile of marketed sustained release products of aspirin.<br>7. To prepare and evaluate partially flocculated suspension of Paracetamol by using electrolyte.<br>8. To prepare and evaluate suspension of aspirin.<br>9. To study the effect of various suspending agents on sedimentation rate at different concentration. |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Physical Pharmacy | A. Martin, J.C. Swarbrick | Third | Lippincott Williams and Wilkins; |
| 2 | Theory and Practice of Industrial Pharmacy | Lachmann and Libermann | Fourth | CBS Publishers & Distributors |
| 3 | Modern Pharmaceutics | G. S. Banker | Second | Marcel Dekker Inc |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Controlled Drug Delivery System, | J.R. Robinson and V.H.S.L. Lee. | Second | Marcel Dekker, Inc., New York |
| 2 | Pharmaceutical Dosage Forms: Tablets | Editors- Herbert Lieberman, Leon Lachman, Joseph B. Schwartz (Editor) | Second | CRC Press |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208201(33) | Pharmaceutics–I (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of this course it is expected that students will be able to understand the process of formulation, development and evaluation of dosage forms. | On successful completion of the course, the student will be able to:<br>**CO1:-** Describe recent advancements in tablet technology, Parenteral and microencapsulation.<br>**CO2:-**. Formulate parenterals and antibiotics.<br>**CO3:-**.Compare disperse system and molecular dispersions.<br>**CO4:-** Design stability studies.<br>**CO5:-**Examine the data through statistical methods. |

**Unit -1:**

Recent advances in tablet technology. Parenteral and Microencapsulation. Process automation in pharmaceutical manufacturing, role of GMP, Quality assurance and validation.

**Unit -2:**

Formulation and development of vitamins and antibiotic products.

**Unit -3:**

Disperse system, Molecular dispersion, solubilization theory methods of solubility enhancement, factor enfluencing solubility.

**Unit - 4:**

Coarse dispersion – Physical stability of suspension and emulsion, role of Zeta potential in stability of coarse dispersion, theory of emulsification, micro and multiple emulsion, rheology of suspension and emulsion, rheology of suspensions and emulsions. Drug kinetics in coarse disperse systems, drug diffusion in coarse dispersesystems.

**Unit -5:**

Stability indicating assays, Advances in pharmaceutical packaging, Advances in polimer sciences and application in pharmacy.

**Unit -6:**

Collection ans classification of experimental data and its statistical treatment, Probability definition and laws of probability, Regression and correction, method of least squares, correlation coefficient and multiple regression, test of significance and t-test, Statistical quality control process control, control chart, acceptance sampling plans.

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208291(33) | Pharmaceutics–I(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

**List of experiments**

1. Preparation and evaluation of solid dispersion of aspirin/ other drug by fusionmethod.
2. Preparation and evaluation of solid dispersion of aspirin/other drug by solvent evaporation method.
3. Preparation and evaluation of multipleemulsions.
4. Microencapsulation of aspirin/other drug by emulsion solvent evaporationmethod.
5. Preparation and evaluation of antacidsuspension.
6. Preparation of liquid paraffin emulsion I.P. and determination of effect of homogenization time on globule sizedistribution.
7. Preparation and evaluation of floating tablets ofaspirin.
8. Preparation and evaluation of hydrodynamically balanced system (HBS) tablet of Riboflavin.
9. Preparation and evaluation ofmicro emulsion.
10. Preparation and evaluation of buccal tablets and study on the effect of binding agents on disintegration.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | The theory and practice of Industrial pharmacy | L. Lachman, H. A. Liberman | Third | Lea & Febiger |
| 2 | Modern Pharmaceutics | G. S. Banker | Third | Marcel Dekker Inc |
| 3 | Physical Pharmacy | A. Martin, J.C. Swarbrick | Third | Lippincott Williams and Wilkins |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Controlled Drug Delivery System | J.R. Robinson and V.H.S.L. Lee. | Second | Marcel Dekker, Inc., New York |
| 2 | Pharmaceutical Dosage Forms: Tablets | Editors- Herbert Lieberman , Leon Lachman , Joseph B. Schwartz | Second | CRC Press |
| 3 | Remington‟s Pharmaceutical Sciences. | Remington | Nineteenth | John Wiley & Sons |

| | | October 2020 | 1.00 | Applicable for AY 2020-21Onwards |
|---|---|---|---|---|
| Chairman(AC) | Chairman(BoS) | Date of Release | Version | |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208202(33) | Pharmaceutics-II (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| On completion of course student will be able to formulate and evaluate oral, occular, parenteral, transdermal, prodrug controlled release drug delivery systems. | **On successful completion of the course, the student will be able to:**<br><br>**CO1-** Design and construct control drug delivery systems.<br>**CO2-** Select drugs and polymers for the development of delivery system<br>**CO3-** Formulate and judge control drug delivery systems<br>**CO4-** Differentiate biochemical and molecular approach to controlled drug delivery. |

**Unit -1:**

Fundamentals of controlled release drug delivery influence of drug properties and routes of drug administration on the design of sustained and controlled release systems.

**Unit -2:**

Pharmacokinetic / Pharmacodynamic basis of drug delivery, Dosing considerations and bioavailability assessment, Regulatory assessment.

**Unit -3:**

Design and fabrication of Oral controlled release drug delivery systems.

**Unit - 4:**

Parenteral products and Ocular drug delivery systems.

**Unit -5:**

Implantable products, Transdermal therapeutic system.

**Unit -6:**

Prodrugs as sustained chemical delivery system, Biochemical and Molecular approach to Controlled Drug delivery.

# Shri Shankaracharya Technical Campus

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Faculty of Pharmaceutical Sciences

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208292(33) | Pharmaceutics- II(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

**List of experiments**

1. Preparation and evaluation of ophthalmic preparation.
2. Preparation of ethyl cellulose film as a rate controlling membrane for Paracetamol Transdermalpatch.
3. Preparation of matrix embedded system of drug in hydrophobic polymer and its release rate.
4. Comparative study of *in-vitro* release of a drug of sustained release tablets by using HPMC and EC.
5. Preparation and evaluation of 0.3 % gentamycin eye solution.
6. Preparation and evaluation of colon delivery tablets ofaspirin.
7. Preparation and evaluation of microcapsules of Isoniazide and Diclofenac sodium.
8. Preparation and evaluation of microspheres of Paracetamol by emulsification method.
9. Preparation and evaluation of liposomes of diclofenac sodium.
10. Preparation and evaluation of niosomes of Isoniazide by hand shaking method.
11. Preparation and evaluation of osmoticpump.
12. Preparation and evaluation of microspheres of ascorbic acid by solvent evaporation method.
13. To study the effect of two different polymers on release pattern of sustained release tablets of Paracetamol in basic buffer.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Remingtons Pharmaceutical Sciences. | Remington | Nineteenth | John Wiley & Sons |
| 2 | Modern Pharmaceutics | G. S. Banker | Third | Marcel Dekker Inc |
| 3 | Physical Pharmacy | A. Martin, J.C. Swarbrick | Third | Lippincott Williams and Wilkins |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Controlled Drug Delivery System | J.R. Robinson and V.H.S.L. Lee. | Second | Marcel Dekker, Inc., New York |
| 2 | Pharmaceutical Dosage Forms: Tablets | Editors- Herbert Lieberman , Leon Lachman , Joseph B. Schwartz | Second | CRC Press |
| 3 | Novel Drug Delivery Systems | Yie W. Chien | Second | Marcel Dekker, Inc., New York. |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208203(33) | Pharmaceutics –III (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| After completion of course student is able to know,<br>Understand the basic concepts in Biopharmaceutics and Pharmacokinetics and their significance.<br>Use of plasma drug concentration-time data to calculate the pharmacokinetic parameters to describe the kinetics of drug absorption, distribution, metabolism, excretion, elimination.<br>To understand the concepts of bioavailability and bioequivalence of drug products and their significance.<br>Understand various pharmacokinetic parameters, their significance & applications. | On successful completion of the course, the student will be able to:<br>**CO1:-** Appraise the basic concepts in biopharmaceutics and pharmacokinetics.<br>**CO2:-** Investigate the raw data and derive the pharmacokinetic models and parameters that best describe the process of drug absorption, distribution, metabolism and elimination.<br>**CO3:-** Implement biopharmaceutic studies involving drug product equivalency.<br>**CO4:-** Describe dosage regimens of the drugs using pharmacokinetic and biopharmaceutic parameters.<br>**CO5:-**Investigate plasma drug concentration measurement by the application of the compartment model. |

**Unit -1:**

Transport of drugs through membranes and barriers other than GI Tract, Buccal absorption, Salivary excretion of drugs, excreting of drugs via sweat, excretion of drugs in to milk, penetration of drugs into eye, transfer across placenta, passage of drugs into and out of cerebrospinal andbrain.

**Unit -2:**

Measurement and Interpretation of in-vivo rates of dissolution, intrinsic rates of dissolution, dissolution of drugs from solid dosage forms, various modern methods and models for testing dissolution rate, factor and kinetics of dissolution.

**Unit -3:**

Bioavailability and bioequivalence, Bioequivalence and its determination, study design for the assessment of bioavailability and bioequivalence, factors influencing bioavailability and bioequivalence, Correlation of in- vitro Dissolution and in- vivo bioavailability, Statistical concept in estimation of bioavailability and bioequivalence.

**Unit - 4:**

Consideration of one, two and multiple compartment model on Intravenous administration, Intravenous infusion and first order absorption of single dose, Kinetics of reversible pharmacological effects – Direct and Indirect.

**Unit - 5:**

Clinical pharmacokinetics concept, absorption, Distribution and read clearance and elimination disposition and absorption kinetics, intravenous dose contain infusion, extra vascular dose, metabolite kinetics.

**Unit - 6:**

Physiological pharmacokinetic model, Concept, physiologic pharmacokinetic model with binding block flow – Limited versus diffusion limited model, application and limitation of physiologic pharmacokinetic models, mean residence time (MRT) Statistical moment theory, mean absorption time (MAT), mean residence time (MRT), Statistical moments theory, mean absorption time (MAT), Mean dissolution time (MDT).

**Unit -7:** Non-linear pharmacokinetics, Recognition of non linearity, one- two compartment open model with Michalis Menton kinetic, Determination of Km & Vm, non-linear tissue binding constants.

| Subject Code – PH208293(33) | Pharmaceutics–III(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

**List of experiments**

1. Determination of partition coefficient and effect of pH on partition coefficient.
2. Study on protein binding.
3. Dissolution studies on marketed enteric coated tablets.
4. Evaluation of pharmacodynamics of antihypertensive drugs.
5. *In-vitro* dissolution studies on marketed erythromycin tablets.
6. *In-vitro* dissolution test of marketed sustained release capsules.
7. Comparative study on dissolution rate of Paracetamol tablet by different dissolution apparatus.
8. Determination of various pharmacokinetic parameters of a given drug after single dose oral administration by using urinary excretion method.
9. Study on the effect of various dietary factors on the bioavailability of given drug, administered orally, using urinary excretion data.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Biopharmaceutics and Pharmacokinetics | V. Venkateswarlu | Second | B.S. Publisher |
| 2 | Biopharmaceutics and Pharmacokinetics-A Treatise | D. M. Brahmankar and Sunil B.Jaiswal | Third | Vallabh Prakashan |
| 3 | Applied biopharmaceutics and pharmacokinetics | Leon Shargel and Andrew B.C.YU | Fourth | Prentice-Hall International edition |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Biopharmaceutics and Clinical Pharmacokinetics-An introduction | Rebort F Notari | Fourth | Marcel Dekker |
| 2 | Remington's Pharmaceutical Sciences | John E. Hoover | Thirteen | Mack Publishing Company |
| 3 | Biopharmaceutics and Clinical Pharmacokinetics | Milo Gibaldi | Second | Lea & Febiger |

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**M. Pharm (Pharmaceutics) First Year (1st/ 2nd semester)**

| Subject Code – PH208204(33) | Pharmaceutics–IV (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of this course it is expected that students will be able understand,<br>1. About Industrial packaging area design and Current good manufacturing practices.<br>2. They also learn about packaging components, polymers and metals used in packaging.<br>They also understand about the storage conditions of different formulations and their stability evaluations. | On successful completion of the course, the student will be able to:<br>**CO1:-** Describe the criteria for selection and evaluation of packaging material<br>**CO2:-** Examine of suitable packaging material (container-closure) for the preparation.<br>**CO3:-** Defend packaging compliance and labelling of different Pharmaceutical product and materials of packaging available for liquid, powders and tablets.<br>**CO4:-** Understand the importance of documentation standardization and regulatory requirement in packaging.<br>**CO5:-** Describe several recent pharmaceutical packaging trends that are impacting packaging industry |

**Unit - 1:**

Package protection and its functions, Materials and pack selection - Factors, mechanical and physiochemical properties, Influence of Packaging components on dosage from stability and drug plastic consideration,

**Unit - 2:**

Various materials for containers and closures, classification, types, additives, processing, allowance and norms, Closures, Safety closures, tampers – Evidentpacking.

**Unit - 3:**

Drug package insert, Compliance, packaging, labeling for various pharmaceutical products.

**Unit - 4:**

Packaging of tablets, capsules, powder, ointments, Parenteral, ophthalmic.

**Unit – 5:**

Standardization of packaging material, bar code, colour codes, evaluation of package, standard for packaging, quality assurance systems, quality control consideration, regulatory requirements.

**Unit – 6:**

Trends in security packaging for monitoring effective storage condition for drug, Equipment for auto packaging, Environmental consideration in disposal.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | A text book of pharmaceutical packaging technology | D. A. Dean | Third | Tyler n francis |
| 2 | Packaging of Pharmaceuticals and Healthcare Products | Paine, Frank A., Lockhart, H | Second | UK |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Pharmaceutical Product Development | N. K. Jain | Second | Marcel Dekker Inc. |
| 2 | The theory and practice of Industrial pharmacy | L. Lachman, H. A. Liberman | Fourth | Lippincott Williams & Wilkins |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208201(35) | Pharmaceutical Chemistry-I (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| After course completion, the student shall able to understand.<br>• The strategies of scale up process microbial transformation.<br>Regulation governing the manufacturing of biological products | On successful completion of the course, the student will be able to:<br>**CO1:** Described microbial transformation technology in the production of certain drugs.<br>**CO2:** Develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient.<br>**CO3:** Explain Stereochemistry and drug action.<br>**CO4:** Explain Mechanism of action of antibiotics. |

**UNIT 1.**

Microbial transformation technology in the production of certain drugs. Microbial conversions of drugs like steroids, prostaglandins and antibiotics. These should include some biotechnology-oriented chapters like enzymes immobilizationtechniques.

**UNIT 2.**

Synthesis of following drugs describing reaction conditions mechanism and strategies involved

a) AntiviralagentsandagentsunderdevelopmentofHIVinfection.
b) Antineoplasticagents.
c) Antihypertensiveagents.
d) Prostaglandins, leukotrienes and othereicosanoids.
e) Cetrizine, Fexofenadine, Linezolide, Risperidone, Ziprasidone, Diazepam, Dapsone, Ethinylestradiol, Vit. B,Diphenhydramine.

**UNIT 3.**Stereochemistry and drug action. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

**UNIT 4.**Steroidal receptor, natural hormones and currently used synthetic derivatives, SAR, comparison of activity, transformation of phytosterols into steroidal drugs

**UNIT 5.**Mechanism of action Penicillins, Cephalosporins, Nocardicins and Monobactums, Carbapenems, β-lactamase inhibitors and other β-lactum agents.

**UNIT 6.**Amino glycosides, macrolides, linomycins and polypeptide antibiotics.

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208291(35) | Pharmaceutical Chemistry– I(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

| List of experiments | |
|---|---|
| I. | Estimation of elements and functional groups in organic compounds. |
| II. | Isolation, characterization like melting point, molecular weight determination, functional group analysis, chromatographic technique for identification of isolated compounds and interpretation of UV and IR data. |
| III. | Suitable synthesis and the evaluation of drugs based on theory topics. |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Organic Chemistry of Natural Products Vol I and II | Gurdeep and Chatwal. | 4th | Himalaya Publishing House Pvt. Ltd |
| 2 | Organic Chemistry of Natural Products Vol I and II | O.P. Agarwal. | 3rd | Krishna Publishing House Pvt. Ltd |
| 3 | Organic Chemistry Vol I and II | I.L. Finar | 3rd | Pearson |
| 4 | Text book of Organic Medicinal and Pharmaceutical Chemistry | Wilson and Gisvold's | 12th | Lippincott *Williams* and Wilkins |
| 5 | Principles of Medicinal Chemistry | William Foye. | 7th | Lippincott *Williams* and Wilkins |
| 6 | A Practical Book on Medicinal Chemistry I | Dr.Meghna Seta, Mrs.MonikaKakadiya | 1st | Everest Publishing House |
| 7 | Advanced Practical Medicinal Chemistry | AshutoshKar | 3rd | New Age International (P) Ltd. |
| 8 | Organic Medicinal Chemistry Practice | Anees Ahmad Siddiqui | 2nd | CBS |
| 9 | Principles of Laboratory Techniques and Methods | MeenaSrivastava | 3rd | CBS |

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**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | A Biomedical basis – Medicinal chemistry | Thomas Nogrady | | Wiley |
| 2 | Medicinal Chemistry by Burger | Burger | | Wiley |
| **3** | A Practical Handbook of Medical Chemistry | Owman John Eddowes | | Palala Press |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208202(35) | Pharmaceutical Chemistry-II (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| After course completion, the student shall able to comprehend<br>Basic concept of Advanced organic chemistry with their applications<br>Different synthetic approach for drug development.<br>Photochemical reactions with mechanism<br>The concept of heterocyclic ring system in drug development<br>The concept of different name reaction with their mechanism. | On successful completion of the course, the student will be able to:<br>**CO1:** To make effective use of advanced methods in synthesis of drugs.<br>**CO2:** To apply all the types of reactions in manufacturing of drugs and drug intermediates<br>**CO3:** To synthesize novel drugs using advanced synthetic methodologies<br>**CO4:** Significance of heterocyclic ring system in drug synthesis.<br>**CO5:** To acquire knowledge in the field of name reactions with mechanism. |

**UNIT 1.**

**Techniques in drug development and synthesis will be deals at advanced level.**

a) Chemical bonding (localized, delocalized and Bonding weaker thancovalent).
b) Reactionintermediates(carbocations,carbanions,freeradicals,carbenesandnitrenes).
c) Varioustypesofmechanismsandmethodsofdeterminingthem.
d) Acids andBases.
e) Effect of structure onReactivity.

**UNIT 2.**

a) Substitution reactions (aliphatic nucleophilic, aromatic electrophilic, aliphatic electrophilic, aromatic nucleophilic and freeradical).
b) Addition reactions (both carbon-carbon and carbon-heteroatom multiplebonds).
c) Elimination reactions and Rearrangementreactions.
d) Oxidationreductionreactionsandthereagentsusedforsuchreactions.
e) Protection and deprotection of variousgroups.

**UNIT 3.**

**Synthetic methodologies for obtaining drugs**

a) Disconnectionapproach.
b) Synthones for carbon-carbon bondformation.
c) Difunctionalcompounds.
d) Selective functional group interconversions(FGI).
e) Retrosyntheticanalysis.

**UNIT 4.**

Synthetic approaches for attaching heterocyclic ring systems in drug molecules having five membered and six membered heteroaromatic rings and fused ring systems. Biological importance of heterocycles.

**UNIT 5.**

**Photochemical &Pericyclic reactions-** Basic theory, orbital symmetry rules and their applications. Mechanism, Types of pericyclic reactions cyclo addition, elctrocyclic reaction, sigmatrophic rearrangement.

**UNIT 6.**

**A study of the following reactions of synthetic importance-** Birch reduction, Mannich reaction, Meerwin-Pondroff's reduction, Oppeneaur oxidation, Beckmann rearrangement, Grignard reaction, Hoffman rearrangement, Ozonolysis., Reformatskyreaction,Michael reaction.

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208292(35) | Pharmaceutical Chemistry– II (Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

| List of experiments |
|---|
| **I. Synthesis of the following heterocycliccompounds**<br>Benzimidazole, Benzotriazole, 2,3diphenylquinoxaline, Oxadiazole, Thiadiazole, Isatin.<br>**II. To perform the following reactions of syntheticimportance**<br>Birch reduction, Clemmenson reduction, Meerwin-Pondroff's reduction, Grignard reaction, Oppeneaur oxidation, Benzyllic acid rearrangement, Beckmann rearrangement, Photochemicalreaction |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Advanced Organic chemistry, Reaction, mechanisms and structure", g March, john Wiley and sons, New York. | Jerry March | Seventh | Wiley |
| 2 | Mechanismandstructureinorganicchemistry, NewYork. | ESGould,HoldRinchat and Winston | Fourth | Wiley |
| 3 | Organicreactionmechanisms, | VK Ahluwalia and RK Parashar, | Fourth | Narosa Publishers. |
| 9 | Principles of Laboratory Techniques and Methods | MeenaSrivastava | 3rd | CBS |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Organic Chemistry" Vol I and II. | I.L Finar | Sixth | ELBS |
| 2 | Organic synthesis-the disconnection approach, WilyIndia | S. Warren | Second | Wiley |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208203(35) | Natural Products/ Pharmaceutical Chemistry-III (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| At completion of this course it is expected that students will be able to understand- Different types of natural compounds and their chemistry and medicinal importance. The importance of natural compounds as lead molecules for new drug discovery. General methods of structural elucidation of compounds of natural origin. | On successful completion of the course, the student will be able to:<br>**CO1**: - To attain detailed knowledge about molecular basis of medicinal compounds from natural origin.<br>**CO2**: - To acknowledge synthon approach and combinatorial chemistry in medicinal compounds.<br>**CO3**: - To illustrate and employ knowledge of natural compounds as lead for new pharmaceuticals and their synthesis.<br>**CO4**: - To attain knowledge regarding isolation, purification and general methods of structural elucidation of medicinal compounds from natural origin. |

**UNIT 1.Molecular basis of drug action**

a) Receptor: Drug Receptor Interaction: Basic ligand concept, agonist, antagonist, partial agonist, inverse agonist, receptor Theories - Occupancy, Rate & Activation Theories, receptor Binding Assays, determination of B-max and Kd by transforming data with Hill plot and Scatchered plot., above concepts with special reference to Opioid, Histaminergic, Adrenergic and GABA nergicreceptors.

b) Enzyme Inhibition – Enzyme structure: primary, secondary, tertiary and quaternary, enzyme kinetics, enzyme Inhibitors - reversible, irreversible, Kcat inhibitors. Transition state analogs, enzyme Inhibitors as drugs - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, DNA PolymeraseInhibitors, HIV - Protease / Reverse Transcriptase, Integrase and Cytochrome P-450Inhibitors.

c) Drugbindingtonucleicacid,Antimalarial,anticancer,antiviral.

**UNIT 2.Synthon approach-** Definition of terms disconnection, synthon, functional group interconversion (FGI), Basic rules in Disconnection, Use of synthon approach in synthesis of following compounds: Trimethoprim, Terfenadine, lbuprofen, Propanolol, Fentanyl, Ciprofloxacin, Cimetidine Piroxicam, Rosiglitazone, Diclofenac, Captopryl, Nifedipine, Losartan.

**UNIT 3.CombinatorialChemistry-**Introduction, combinatorial approaches, chemical peptide and small molecule libraries, applications, methodology, combinatorial organic synthesis, assays and screening of combinatorial libraries, introduction to High Throughputs Screening (HTS).

**UNIT 4.Biosynthesis of vitamin A, C & E.**

**UNIT 5.Natural products as leads for new pharmaceuticals-** Cannabinoids, asperlicin, etoposide, teniposide, echinocandins, teprotide, khellin, cromoglycate.

**UNIT 6.The natural products obtained by terrestrial & microbial sources by spectral data.**

a) **Alkaloids-** General introduction and classification, isolation and purification methods, general methods employed for determining the structure of alkaloids, constitution of morphine, reserpine andquinine.

b) **Flavonoid-** Detailed chemical account of rutin andquercetin.

c) **Triterpenoids-** A general chemical treatment and structural elucidation of terpenoids.

d) **Coumarins-** General methods of isolation and purification and structural determination of Xanthotoxin andpsoralene.

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**M. Pharm (Pharmaceutical Chemistry) First Year (1st/ 2nd semester)**

| Subject Code – PH208293(35) | Pharmaceutical Chemistry–III(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

| List of experiments |
|---|
| I. Isolation and quantification of alkaloids.<br>II. Isolation and quantification of glycosides.<br>III. Isolation and quantification of phenolic compound and tannins.<br>IV. Isolation and quantification of caffeine from tea.<br>V. Isolation of vitamin C.<br>VI. Isolation of citric acid from citrus fruits.<br>VII. Isolation of flavonoid from crude drug. |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Organic Chemistry of Natural Products | Gurdeep and Chatwall | Vol I and II | Himalaya Publishing House. |
| 2 | 10. Organic Chemistry of Natural Products | O.P. Agarwal | Vol I and II | KrishanPrakashan. |
| 3 | Natural Product Chemistry, | Nakanishi Gggolo | – | University Science Books, California. |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Modern Methods of Plant Analysis | Peech and M.V.Tracey | – | Springer — Verlag, Berlin, Heidelberg |
| 2 | Recent advances in Phytochemistry | ScikelRuneckles | Vol. I to IV | Springer Science & Business Media. |

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| Subject Code – PH208204(35) | Drug Design/ Pharmaceutical Chemistry-IV (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| The objective is to make the students to understand conceptualize and use of the different molecular modeling techniques. | On successful completion of the course, the student will be able to:<br>**CO1:-** Know the history and role of CADD in drug discovery**.**<br>**CO2:-**Various strategies to design and develop new drug like molecules.<br>**CO3:-** Understand different CADD techniques and their applications.<br>**CO4:-**Work with molecular modeling software's to design new drug molecules with the *in-silico* virtual screening protocols. |

**UNIT 1.**

Historical perspective, Drug Discovery Strategies in Direct Drug Design (Structure based) and Indirect drug design, Target selection and lead identification, Natural product sources, Fermentation / Microbial sources, Synthetic, Introduction to Pharmacogenomics.

**UNIT 2.**

**Drug Design-** Synthesis of compounds in accordance with the molecular structure, biological activity concept with special references to analgesics, neuromuscular blocking agents, anti- fertility drugs and compounds containing bridge head nitrogen atom and bactericidal & bacteriostatic agents (sulphonamides, mercury compounds and antiseptics).

**UNIT 3.**

**QSAR:** Parameters, Lipophilicity, electronic, Stearic factors, Quantitative Models, Hansch analysis, Free Wilson Analysis, Mixed approach, Other QSAR Approaches, Applications of Hansch Analysis, Free Wilson Analysis.

**UNIT 4.**

**Enzymes, Peptides in Drug Design.**

**UNIT 5.**

**Molecular Modeling in Drug Design-** Introduction to computer aided drug design and molecular modeling: concepts and methods, molecular mechanics force fields (potential energy function), energy minimization methods, steepest, descent. conjugate gradients, Newton methods (non mathematical), conformational analysis systematic search, Monte Carlo simulations, molecular dynamics simulations, ligand design based on 3D structure of receptor/enzyme. Indirect drug design analog approach, Pharmacophore mapping, Template forcing, excluded volume & shape analysis, artificial intelligence methods.

**UNIT 6.**

An overall treatment of various approaches to drug design including the method of variation, e.g. Fibonacci search, Topliss tree, Craigs plot, Simplex methods, and Cluster analysis.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Computer aided drug design | Anees Ahmad Siddiqui | - | CBS Publishers |
| 2 | Drug Design and discovery | Dr. V.M Kulkurnai Dr K.G Bothra | - | Nirali Publications |
| 3 | Computer Aided Drug Design - CADD | DebarshiKarMahapatra, | - | Everst publishing house |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Computational and structural approaches to drug design | Jon Duckett | Second | WROX |
| 2 | Introduction to Quantitative Drug Design | Y.C. Martin, | - | CRC Press, Taylor & Francis group. |

# Shri Shankaracharya Technical Campus

Shri Shankaracharya Group of Institutions

Faculty of Pharmaceutical Sciences

(An Autonomous Institute affiliated to Chhattisgarh Swami Vivekanand Technical University, Bhilai)

**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208201(34) | Pharmacology –I (General Pharmacology) (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of the course the student shall be able to :<br>-Discuss the pathophysiology and pharmacotherapy of certaindiseases<br>-Explain the mechanism of drug actions at cellular and molecularlevel<br>-Understand the adverse effects, contraindications and clinical uses of drugs used in treatment ofdiseases | On successful completion of the course, the student will be able to:<br>**CO1:-** The students would appreciate the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications.<br>**CO2:-**They would have elaborately learnt the recent advances in the drugs used for the treatment of various diseases.<br>**CO3:-** They would have discussed the pathophysiology and pharmacotherapy of certain diseases.<br>**CO4:-**They would have understood the underlying mechanism of drug actions at cellular and molecular level.<br>**CO5:-** They would have learnt the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases. |

**UNIT-I Drugs acting on ANS**

- Cholinergic drugs and cholinergic blockingdrugs
- Ganglionic stimulants, ganglionicblockers
- Neuromuscularblockers
- Adrenergic (or) Sympathomimeticdrugs
- Antiadrenergic (or) sympatholyticdrugs

**UNIT-II Drugs acting on CNS**

General anesthetics, Anxiolytics & hypnotic drugs, Antiepileptics, Analgesics, CNS stimulants, NSAID's, Antigout drugs, Antipsychotic drugs, Antidepressants and Anti Parkinsonian drugs Drugs acting on peripheral nervous system: Localanesthetics

**UNIT-III Drugs acting on CVS**

Cardiotonics, Antiarrythmic drugs, Antianginal drugs, Antihypertensives ,Diuretics

**UNIT-IV Drugs acting on Digestive system**

Drugs used in gastric ulcer, purgative, antiemetic, antidiarrhoeal

**UNIT-V Drugs acting on Respiratory System**

Bronchodilators, Expectorants and Antitussive agents

**UNIT-VI Chemotherapy**

Basic principles of chemotherapy; chemotherapy of bacterial infections (antibacterial and antibiotics) ; chemotherapy of tuberculosis and leprosy; chemotherapy of viral and fungal

infections, malaria, amoebiasis, cancer and AIDS.

**UNIT-VII Hormones and Hormone Antagonists**

a) Adenohypophyseal hormones and their hypothalamic releasingfactors.
b) Hormones of Posteriorpituitary
c) Thyroid and Antithyroiddrugs
d) Estrogens and Progestins, Antifertilityagents
e) Androgens
f) Adrenocorticotropic hormones; Adrenocortical steroids and their synthetic analogs; Inhibitors of the synthesis and actions of adrenocortical hormones.
g) Insulin, oral hypoglycemic agents and the Pharmacology of pancreatichormones.
h) Agents affecting Calcification and boneturnover:
Calcium phosphate, parathyroid hormones, vitamin D, Calcitonin and other compounds.
i) Vasopressin and other agents affecting the renal conservation ofwater.

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208291(34) | Pharmacology–I (Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

**List of experiments**

1. To study standard techniques for injection of drugs, collection of blood samples and feeding ofanimals.
2. To study the effect of Phenobarbital on righting reflex inmice.
3. To study the anxiolytic (antianxiety) effect of diazepam in mice using elevated plus-mazeapparatus.
4. To study the antianxiety effect of diazepam in mice using Rota rodapparatus.
5. To study the anticonvulsant property of diazepam against pentylenetetrazol inducedclonic convulsions inmice.
6. To Study the analgesic effect of morphine in mice using hot platemethod.
7. To study the analgesic effect of morphine in mice using tail-flickmethod.
8. To study the effect of physostigmine and atropine on ciliary movement in frog buccalcavity.
9. To study the antisecretory and ulcerprotective effect of cimetidine in pylorus ligatedrats.
10. To study the effect of adrenaline and acetylcholine on perfused frogheart.
11. To study the effect of drugs on the coronary blood flow and heart rate of isolated ratheart.
12. To study the effect of chlorpromazine on the locomotor activity of mice usingactophotometer.
13. To study the anti inflammatory property of indomethacin against carrageen induced pawoedema.
14. To study the local anesthetic effects of drug using foot withdrawal reflex in laboratoryanimals.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Essentials of MedicalPharmacology | KD.Tripathi | Six | JeyPee Pub. |
| 2 | Robbins &Cortan Pathologic Basis of Disease | Robbins Pathology | Nine | Elsevier |
| 3 | The Pharmacological Basis of Therapeutics | Goodman andGillman‘s | Second | Mcgraw Hill |
| 4 | Principles of Pharmacology, The Pathophysiologic basis of drug Therapy | Armen H, TashjianJr, EhrinJ,Armstrong, April W, Armstrong | First | Wolters, Kluwer-Lippincott Williams & WilkinsPublishers |
| 5 | Principles and Practice of Medicine | Nicki R. Colledge, Brian R. Walker, Stuart H. Ralston;Davidson’s | 21st edition | ELBS/Churchill Livingstone |

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**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | The Pharmacological Basis of Therapeutics | Goodman andGillman's | Second | Mcgraw Hill |
| 2 | Principles of Pharmacology, The Pathophysiologic basis of drug Therapy | Armen H, TashjianJr, EhrinJ,Armstrong, April W, Armstrong | First | Wolters, Kluwer-Lippincott Williams & WilkinsPublishers |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208202(34) | Pharmacology-II (Pharmacological Screening Methods) (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of the course, the student shall be able to,<br>-Explain the various types of toxicitystudies.<br>-Appreciate the importance of ethical and regulatory requirements for toxicity studies.<br>-Demonstrate the practical skills required to conduct the preclinical toxicity studies. | On successful completion of the course, the student will be able to:<br>**CO1:-**<br>The students would appreciate the knowledge gained on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development.<br>**CO2:-**<br>They would have understood the maintenance of laboratory animals as per the guidelines, basic knowledge of various *in-vitro* and *in-vivo* preclinical evaluation processes.<br>**CO3:-**<br>They would have appraised the regulations and ethical requirement for the usage of experimental animals.<br>**CO4:-**<br>They would have learnt to describe the various animals used in the drug discovery process and good laboratory practices in maintenance and handling of experimental animals<br>**CO5:-**<br>They would have learnt to describe the various screening methods involved in the drug discovery process.<br>They would appreciate to correlate the preclinical data to humans. |

**UNIT-I Regulations for Laboratory Animals care and Ethical Requirements**

Guidelines and regulatory agencies- CPCSEA, OECD, USFDA, ICH, FHSA, WHO

**UNIT-II Principles of biological standardization:**

a. Statistical treatment of model problems in evaluation ofdrugs.
b. Methods of biological assay, principles of biological assays with certainexamples.
c. Development of new bioassaymethods.

**UNIT-III Preclinical and clinical models employed in the screening of new drugs belonging to following categories**

: Antipsychotic agents, antianxiety agents; nootropic drugs; antidepressant drugs; antiparkinsonian agents; opioid analgesics; anti-inflammatory drugs.

**UNIT-IV Preclinical and clinical models employed in the screening of new drugs belonging to following categories.**

Infarction; antiatherosclerotic drugs; antimalarials; anthelmintics; antidiabetics; models for antiepileptics; local anesthetics; activity on the GI tract, transgenic animals and other genetically prone animal models.

**UNIT-V Alternatives to animal screening procedures**

Alternatives to animal screening procedures, cell-line, patch-clamp techniques, in-vitro models, molecular biology techniques.

High throughput screening, human genomics.

**UNIT-VI New approaches in drug discovery:**

a. Combinatorial chemistry.
b. Pharmacogenomics.
c. Proteonomics.
d. Arraytechnology.

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**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208292(34) | Pharmacology- II(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

| List of experiments |
|---|
| 1. To study dose response curve and determine $pD_2$ Value of acetylcholine by using the rectus abdominis muscle offrog.<br>2. To study dose response curve and determine $pD_2$ Value of adrenaline by using the rabbitileum.<br>3. To calculate pA value for atropine using acetylcholine as an agonist employing guineapig ileum.<br>4. Bio-assay of acetylcholine by comparative method using rectus abdominis muscle offrog.<br>5. Bio-assay of acetylcholine by three point bioassay method using rectus abdominis muscle offrog.<br>6. Bio-assay of acetylcholine by four point bioassay method using rectus abdominis muscle offrog.<br>7. Bioassay of Histamine by matching method using guinea pigileum.<br>8. Bioassay of Histamine by three point bioassay method using guinea pigileum.<br>9. To record the CRC of 5-hydroxytryptamine using rat fundusstrip.<br>10. To record the CRC of oxytocin using rat uteruspreparation.<br>11. To record the concentration response curve of acetylcholine and its modification by atropine using colonpreparation.<br>12. To record the CRC of 5-hydroxytryptamine using rat fundus strippreparation.<br>13. To determine the $LD_{50}$ of sampledrug.<br>14. Bio equivalence studies onanimals. |

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Principles of toxicology | Karen E. Stine, Thomas M.Brown | Third | CRC Press |
| 2 | Animal Models in Toxicology | Lower andBryan | Third | CRC Press |
| 3 | Drug discovery and Evaluation | VogelH.G. | First | Springer |
| 4 | Practical Manual of Experimental and Clinical Pharmacology | BikashMedhi, Ajay Prakash | First | Jaypee brothers' medical publishers Pvt.Ltd |
| 5 | Handbook of Experimental Pharmacology | S.K. Kulkarni | First | VallabhPrakashan |
| 6 | Screening Methods in Pharmacology | RobertA.Turner | First | Elsevier |
| 7 | Rodents for Pharmacological Experiments | Dr.Tapan Kumarchatterjee | Fifth | Pharmamed Press |

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**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Screening Methods in Pharmacology | RobertA.Turner | First | Elsevier |
| 2 | Rodents for Pharmacological Experiments | Dr.Tapan Kumarchatterjee | Fifth | Pharma med Press |
| 3. | OECD testguidelines | | | |
| 4. | Schedule Y Guideline | Drugs and cosmetics (second amendment) rules | 2005 | Ministry of health and family welfare (department of health)New Delhi |
| 5 | Drug discovery and Evaluation | VogelH.G. | First | Springer |
| 6 | Text book of quantitative chemicalanalysis | Jeffery, Basset, Mendham Denney | First | Wiley |

| Subject Code – PH208203(34) | Pharmacology-III (Molecular Pharmacology) (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of the course, the student shall be able to,<br>-Explain the receptor signal transductionprocesses.<br>-Explain the molecular pathways affected bydrugs.<br>-Appreciate the applicability of molecular pharmacology and biomarkers in drug discoveryprocess.<br>-Demonstrate molecular biology techniques as applicable for pharmacology. | On successful completion of the course, the student will be able to:<br>**CO1:-**<br>The students would have understood the fundamental knowledge on the structure and functions of cellular components.<br>**CO2:-**<br>They would appreciate the interaction of these components with drugs. This would enable them to apply the knowledge in drug discovery process.<br>**CO3:-**<br>They would have learnt to explain the receptor signal transduction processes. They would have learnt to explain the molecular pathways affected by drugs.<br>**CO4:-**<br>They would appreciate the applicability of molecular pharmacology and biomarkers in drug discovery process.<br>**CO5:-**<br>They would have learnt to demonstrate molecular biology techniques as applicable for pharmacology. |

**UNIT-I Molecular Aspects of Drug Action**

Receptors, ion channels and their modulators i.e. calcium, potassium, sodium and chloride channels, enzymes and carrier proteins, mechanism of signaltransduction.

**UNIT-II Recent advances in following receptors**

Angiotensin receptors, Excitatory amino acid receptors, Kinin receptors, Adrenoceptors, Low molecular weight heparins and GP II/IIIa receptor antagonists, Imidazole receptors, Cholinergic receptors, Dopamine receptors, Serotonin receptors, Hormone receptors, GABA and Benzodiazepine receptors, Opiod receptors, Purinergic receptors, Glutamate receptors.

**UNIT III Gene therapy**

a. Gene transfer technologies (viral and non viralvectors).
b. Clinical application of gene therapy.
c. Disease targets for genetherapy.
d. Pharmacodynamics, pharmacokinetics of peptide and protein drugs and Immunogenicity of proteintherapeutics.

**UNIT-IV Renin-Angiotensin System**

Its physiological role, essential hypertension, Interrelationship between rennin angiotensin system and sympathetic nervous system – Pharmacology of Drugs acting on Renin-angiotensin system.

**UNIT-V Endogenous Bioactive Molecules**

Cytokines, neuropeptides and their modulators,neurosteroids, nitric oxide, phosphodiestrase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

**UNIT-VI Immunoassay**

a. General principles of immunoassay: Theoretical basis, optimization of immunoassay, heterogeneous Immunoassay system, homogeneous immunoassaysystems.
b. Production of Immunoassay reagents. Introduction, receptors or binders, unlabelled ligands calibrators, labeled ligands and receptors, separation techniques,buffers.
c. Immunoassay methods evaluation: Protocol outline, objectives and preparation, evaluation of precision, standard tracer, sensitivity, evaluation of accuracy, antibody characteristics monitoring, reaction conditions, clinicalevaluation

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**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208293(34) | Pharmacology–III(Lab) | L = 0 | T = 0 | P = 6 | Credits = 3 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | -- | 50 | 150 | 3 Hrs |

**List of experiments**

1. To determine the concentration of antibody by indirect ELISA or capture ELISAmethod.
2. To perform antigen antibody reaction by various immunoassay basedmethod.
3. To isolate DNA from animal tissues using CTAB (cetyltrimethyl ammonium bromide)method.
4. Estimation of protein by Lowry's method/BiuretMethod.
5. To isolate RNA fromYeast.
6. Isolation of protein sample using gel electrophoresistechnique.
7. To perform electrophoresis of DNA isolated from varioussources.
8. To study cell culture preparation and maintenance: Chick embryo fibroblast Lymphocyteculture.

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | The Cell, A Molecular Approach | Geoffrey MCooper | Seven | Sinauer Associates Inc |
| 2 | Pharmacogenomics: The Search for Individualized Therapies | J. Licinio and M - L.Wong | First | Wiley |
| 3 | Current protocols in molecular biology | Frederick. M.Ausubel | First | Wiley |
| 4 | Human molecular genetics | Tomstracham& Andrew P.Read | Fifth | Garland Science |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Molecular Pharmacology: From DNA to Drug Discovery | John Dickenson | First | Wiley |
| 2 | Current porotocols in molecular biology vol I to VI edited | by Frederick M.Ausuvel | First | Wiley |
| 3 | Fundamentals of BiochemicalPharmacology | Bacq Z.M | First | Elsevier |
| 4 | Bioinformatics: Genes, proteins & Computers | ChristineOrengo | First | Taylor & Francis |

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**SCHEME OF EXAMINATION AND SYLLABUS (Effective from 2020-2021 Batch)**

**M. Pharm (Pharmacology) First Year (1st / 2nd semester)**

| Subject Code – PH208204(34) | Pharmacology-IV (Clinical Pharmacology and Toxicology) (Theory) | L = 4 | T = 1 | P = 0 | Credits = 5 |
|---|---|---|---|---|---|
| Evaluation Scheme | ESE | CT | TA | Total | ESE Duration |
| | 100 | 20 | 20 | 140 | 3 Hrs |

| COURSE OBJECTIVES | COURSE OUTCOMES |
|---|---|
| Upon completion of the course, the student shall be able to,<br>-Explain the regulatory requirements for conducting clinicaltrial.<br>-Demonstrate the types of clinical trialdesigns.<br>-Explain the responsibilities of key players involved in clinicaltrials.<br>-Execute safety monitoring, reporting and close-outactivities.<br>-Explain the principles ofPharmacovigilance.<br>-Detect new adverse drug reactions and theirassessment.<br>Perform the adverse drug reaction | On successful completion of the course, the student will be able to:<br>**CO1:-** The students would appreciate the knowledge on the clinical research.<br>**CO2:-** They would get a better understanding in the regulatory requirements for conducting clinical trial.<br>**CO3:-**They would have understand the types of clinical trial designs.<br>**CO4:-** They would have studied the responsibilities of key players involved in clinical trials.<br>**CO5:-** They would have an understand on the safety monitoring, reporting and close-out activities. They would have studied the principles of Pharmacovigilance. |

**UNIT -I Principles of Pharmacokinetics**

- Clinical Pharmacokinetics: Dose – response in man, Influence of renal and hepatic disease on pharmacokinetics, Therapeutic drug monitoring, Populationpharmacokinetics.
- Adverse drug reactions: Definition and classification, epidemiology, predisposing factors, mechanism of ADR & different types ofADR.
- Pharmacovigilance&Pharmacoepidemiology: Current method of Pharmcovigilance, Ethical oversight, consent and confidentiality, The ICH step process, Periodic safety update reports, Statistical method of evaluating pharmacovigilance data, Pharmacovigilance& riskmanagement.

**UNIT-II Drug therapy in**

Geriatrics, Pediatrics, Pregnancy & lactation

**UNIT-III Pathophysiology and Drug therapy of the following disorders**

CNS disorders: Schizophrenia, anxiety, depression, epilepsy, Parkinson's, Alzheimer's diseases, migraine CVS disorders: hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction Infectious disorders: Gastrointestinal, respiratory and urinary infections, Endocarditis and Meningitis

**UNIT-IV Pathophysiology and Drug therapy of the following disorders:**

**Endocrine disorders**: Diabetes mellitus, Hypo / Hyperthyroidism, Cushing's syndrome, Addison's disease, sexually transmitteddiseases

**Autoimmune and metabolic disorder**:-Rheumatic fever, Pain management Rheumatoid arthritis, Osteoarthritis, gout and Hyperuricemia, Diabetes mellitus(DM).

**Respiratory Diseases**-: Pneumonia, Flu (Influenza), Bronchitis, Chronic Obstructive Pulmonary disease (COPD), Asthma

**Neoplastic disorder**:-Leukemia; General Principal of cancer chemotherapy.

**UNIT-V Clinical evaluation of drugs**

Testing of Acute, Subacute and Chronic toxicity, Undue toxicity of drug Determination of $LD_{50}$ and $ED_{50}$

OECD guidelines for toxicity testing

**UNIT-VIToxicity**

a) Physicochemical, Biochemical and genetic basis of toxicity, principles of toxicokinectics, mutagenesis andcarcinogenesis.

b) Behavioral, Inhalation, cellular and sub-cellular toxicity hypersensitivity and immune response, range findingtests

**Text Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Textbook of Clinical Trials | David Machin, Simon Day and Sylvan Green | First | John Wiley andSons |
| 2 | Clinical Data Management | R K Rondels, S A Varley, C F Webbs | Second | WileyPublications |

**Reference Books:**

| S. No. | Title | Authors | Edition | Publisher |
|---|---|---|---|---|
| 1 | Handbook of clinical Research | Julia Lloyd and Ann Raven | First | Churchill Livingstone. |
| 2 | Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India | Central Drugs Standard Control Organization | First | New Delhi: Ministry ofHealth |
| 3. | International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use | ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice | First | ICH |