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. 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- The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments	On successful completion of the course, the student will be able to: **CO1:-**Understand general principles, theory and structure elucidation by using various spectroscopies UV, IR, NMR. **CO2:-** Understand the basic concept and instrumentation of Chromatographic techniques **CO3:-**Understand the Instrumentation and identification of compounds by thermal and calorimetric analysis technique **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.

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 α_{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

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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 : • Describe the various newer screening methods involved in the drug discovery process • Explain the mechanism of drug actions at cellular and molecular level • 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: **CO1:-** The students would appreciate the basic knowledge in the field of pharmacology pertaining to the drugs and its therapeutic applications **CO2:-** They would have learnt to describe the various screening methods involved in the drug discovery process. They would appreciate to correlate the preclinical data to humans **CO3:-** The students would appreciate the knowledge gained on preclinical evaluation of drugs and recent experimental techniques in the drug discovery and development. **CO4:-** The students would have understood the fundamental knowledge on the structure and functions of cellular components. **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. 2. Bioassay of the more important biogenic agents by variousmethods. 3. Pharmacological Screening methods used for CNS, Local anesthetics, Endocrine and In-vitro microbialscreening. 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 • the concept of generic drug and their development, various regulatory filings in different countries • Concepts of quality, quality management and its implementation • Documentation of BMR, MFR, DMF and relevant process related documents	On successful completion of the course, the student will be able to: **CO1-** Understand Concept of innovator and generic drugs, drug development process, Regulatory guidance's and guidelines for filing and approval process **CO2-** Understand the various documents pertaining to drugs in pharmaceutical industry **CO3-** Evaluate current Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, Good Documentation Practices and Good Regulatory Practices. **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. **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 1. The principles or basics involved in the dosage form design. 2. How to use the physicochemical properties of the drug/ excipients and pharmacokinetics principles in the development of pharmaceutical dosage forms. 3. Knowledge as well as hands on training with respect to the principles of formulation 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: **CO1-** Understand the basics involved in the dosage form design and formulation and manufacturing aspects of various dosage forms in Industrial Pharmacy. (**Level 2)** **CO2-** Investigate with respect to composition of dosage forms, excipients, evaluation tests, storage conditions, packaging, GMP and novel drug delivery systems (**Level 6)** **CO3-** Understand Pharmaceutical dosage forms for quality and stability kinetics and compare with standards prescribed in the pharmacopoeia (**Level 2)** **CO4-** Develop complete package information of pharmaceutical formulation, pilot plant and scale up issues, manufacture, quality control, storage (**Level 6)** **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.

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

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