# Course Curriculum & Syllabi-2020

## School of Pharmaceutical Education and Research, Berhampur University

## Introduction

### About the School of Pharmaceutical Education and Research

School of Pharmaceutical Education and Research (SPER) was established in the year 2008 as a self financing body under Berhampur University. It started functioning under the supervision of Prof. (Dr.) N. K. Tripathy, Dept of Zoology and since then it has been working to generate technical human resource in the field of Pharmacy. The department is currently functioning with efficient teaching and non teaching staff under the directorship Prof. (Dr.) Gitanjali Mishra with a goal to update the pharmacy profession in Education and Research and other allied areas to meet the clarion call of health for all.

## Aim

SPER aims to impart quality education in the area of Pharmaceutical Sciences, promote traditional research activities keeping pace with the progress and change in approaches in research in Global perspective.

## Faculty Members

1. Mrs. Smitapadma Mohanty, Lecturer
2. Dr. Suraj Sahoo, Lecturer
3. Mrs. Ipsa Padhy, Lecturer
4. Ms. Padmini Kanhar, Lecturer

## Facilities

School of Pharmaceutical Education & Research, Berhampur University has independent building with following infrastructure facilities.

1. Electric supply
2. Potable Water facility
3. Separate toilet for girls & boys
4. Two Classrooms
5. Three ventilated laboratories with instruments & apparatus
6. Director Room
7. Faculties Room
8. Office Room
9. Computer Lab

## Programs offered

SPER, Berhampur University offers following P. G. courses:

| COURSE | DURATION | INTAKE |
|---|---|---|
| M. Pharmacy Pharmaceutics | 2 years, (04 semesters) | 15 |
| M. Pharmacy Pharmaceutical Analysis and Quality Assurance | 2 years, (04 semesters) | 15 |

## Objective of course curriculum

The emphasis at the curricular level is to give a broad coverage of branches of Pharmaceutical Sciences in keeping with the interdisciplinary nature of the subject today. A Post-Graduate in pharmacy will be able to think logically and solve the problems, will develop an ability to conduct, analyze and interpret data of pharmaceuticals in various sectors (e.g. Drug discovery, Formulation & Development, Production, Quality control & Quality assurance etc) as per the needs of pharmaceutical industries and society. They will develop an ability to visualize and work on multidisciplinary tasks. They will be able to demonstrate necessary skills (e.g. working independently, time management and

organizational skills).They will demonstrate an adaptable, flexible and effective approach towards organizational development.

## General Course Framework & Structure

### Pharmaceutics

| Sem | Course No. | Course Name | Credit Hrs | Credit Points | Marks /Exam Hrs | | Total Marks |
|---|---|---|---|---|---|---|---|
| | | | | | Mid Sem | End Sem | |
| I | PHAC C101 | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C102 | Regulatory Affairs | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C103 | Drug Delivery System | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C104 | Modern Pharmaceutics | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC P105 | Pharmaceutics Practical I | 12 | 6 | 50/6 | 100/6 | 150 |
| | PHAC S106 | Seminar/Assignment | 7 | 4 | - | 100 | 100 |
| | Total | | 35 | 26 | | | 650 |
| | | | | | | | |
| II | PHAC C201 | Molecular Pharmaceutics (Nano Tech and Targeted DDS) | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C202 | Advanced Biopharmaceutics and Pharmacokinetics | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C203 | Advanced Pharmaceutical Technology | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHAC C204 | Cosmetics and cosmeceuticals | 4 | 4 | 25/1 | 75/3 | 100 |

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|---|---|---|---|---|---|---|---|
| | PHAC P205 | Pharmaceutics Practical II | 12 | 6 | 50/6 | 100/6 | 150 |
| | PHAC S206 | Seminar/Assignment | 7 | 4 | - | 100 | 100 |
| | Total | | 35 | 26 | | | 650 |

## Pharmaceutical Analysis and Quality Assurance

| Sem | Course No. | Course Name | Credit Hrs | Credit Points | Marks /Exam Hrs | | Total Marks |
|---|---|---|---|---|---|---|---|
| | | | | | Mid Sem | End Sem | |
| I | PHQA C101 | Modern Pharmaceutical Analytical Techniques | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C102 | Regulatory Affairs | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C103 | Advanced Pharmaceutical Analysis | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C104 | Quality Control and Quality Assurance | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA P105 | Pharmaceutical Analysis & Quality Assurance Practical I | 12 | 6 | 50/6 | 100/6 | 150 |
| | PHQA S106 | Seminar/Assignment | 7 | 4 | - | 100 | 100 |
| | Total | | 35 | 26 | | | 650 |
| | | | | | | | |
| II | PHQA C201 | Advanced Instrumental Analysis | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C202 | Pharmaceutical Validation | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C203 | Audits and Regulatory Compliance | 4 | 4 | 25/1 | 75/3 | 100 |
| | PHQA C204 | Pharmaceutical | 4 | 4 | 25/1 | 75/3 | 100 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | Manufacturing Technology | | | | | |

| Sem | Course No. | Course Name | Credit Hrs | Credit Points | Total Marks |
|---|---|---|---|---|---|
| | PHQA P205 | Pharmaceutical Analysis & Quality Assurance Practical II | 12 | 6 | 50/6 | 100/6 | 150 |
| | PHQA S206 | Seminar/Assignment | 7 | 4 | - | 100 | 100 |
| | Total | | 35 | 26 | | | 650 |

| | | | | | |
|---|---|---|---|---|---|
| III | PHAR C301 | Research Work (research topic proposal, its finalization and progress) | 26 | 13 | 325 |
| | PHAR S302 | Presentation/seminar | 3 | 3 | 75 |
| | PHAR D303 | Discussions / Viva-voce | 4 | 4 | 100 |
| Total | | | 33 | 20 | 500 |
| | | | | | |
| IV | PHAR C401 | Research Work (experimental outcomes, results, discussions, final conclusion, further work etc.) | 31 | 16 | 400 |
| | PHAR S402 | Presentation/seminar | 1 | 1 | 25 |
| | PHAR D403 | Discussions / Viva-voce | 3 | 3 | 75 |
| | Total | | 35 | 20 | 500 |
| | Co-curricular Activities (Attending Conference, Scientific Presentations and other Scholarly Activities) | | - | 02 | 100 |
| Grand Total | | | 138 | 94 | 2400 |

**Pharmaceutics/ Pharmaceutical Analysis and Quality Assurance**

## Instructions

- Apart from list mentioned for practicals, other related topics for experiments can be taken into consideration as per academic requirements.
- Regarding Seminar/Assignment, individual student will be allotted different topics from syllabus in consultation and under the supervision of concerned faculty for which student has to submit an assignment and to present seminar.
- Seminar Presentations shall be based on the Topics selected for Dissertation/ progress on research work.

# DETAILS OF SYLLABUS

**FIRST SEMESTER**

Course No. **PHAC C101/PHQA C101** Course Name: **Modern Pharmaceutical Analytical Techniques**

Semester: **I** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Course Coordinator: Dr. Suraj Sahoo, 9776607835, surajsahoo.sper@buodisha.edu.in

Mrs. Ipsa Padhy, 8917638492, ipsa.padhy88@gmail.com

Objective:

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

Brief description on course and expectations

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1. | **UV-Visible spectroscopy:** Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.<br>**IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational | 12 |

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|---|---|---|
| | frequencies and Applications of IR spectroscopy, Data Interpretation.<br>**Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.<br>**Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications. | |
| 2. | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance. Applications of NMR spectroscopy.<br>**Mass Spectroscopy:** Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and applications of Mass spectroscopy. | 12 |
| 3. | **Chromatography:** Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following: a. Thin Layer chromatography b. High Performance Thin Layer Chromatography c. Ion exchange chromatography d. Column chromatography e. Gas chromatography f. High Performance Liquid chromatography g. Ultra High Performance Liquid chromatography h. Affinity chromatography i. Gel Chromatography | 12 |
| 4. | **Electrophoresis:** Principle, Instrumentation, Working conditions, factors affecting separation and applications of the | 12 |

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|---|---|---|
| | following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing<br>X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction | |
| 5. | **Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry.<br>Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications. | 12<br>**ONLINE** |
| Total | | 60 |

**Textbooks and reading materials**


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edition, P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

Course No. **PHAC C102/ PHQA C102** Course Name: **Regulatory Affairs**

Semester: **I** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Course Coordinator: Mrs. Smitapadma Mohanty, 9937771551, smitamohanty.sper@buodisha.edu.in
Ms. Padmini Kanhar, 8895958273, pdmnkanhar@gmail.com

Objective:

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

- The Concepts of innovator and generic drugs, drug development process.
- The Regulatory guidance's and guidelines for filing and approval process.
- Preparation of Dossiers and their submission to regulatory agencies in different countries.
- Post approval regulatory requirement fo actives nd drug products.
- Submission of global documents in CTD/ eCTD formats.
- Clinical trials requirements for approvals for conducting clinical trials.

Brief description on course and expectations:

Course designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different

phases of clinical trials and submitting regulatory documents: filling process of IND, NDA and ANDA.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Documentation in Pharmaceutical industry:** Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development: Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), ANDA regulatory approval process, NDA approval process, BE and drug product assessment, post marketing surveillance. | 12 |
| 2 | **Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs. W.H.O. Certification scheme on the quality of pharmaceutical products. | 12 |
| 3 | **Post approval regulatory affairs:** Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH – Guidelines of ICH-Q, SEM. Regulatory requirements of EU, MHR, TGA and ROW countries. | 12 **ONLINE** |
| 4 | **Non Clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier(IMPD) and investigator brochure(IB). | 12 **ONLINE** |
| 5 | **Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee. Formulation and working procedures informed consent process. Pharmacovigillance safety monitoring in clinical trials. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Generic Drug Product Development, Solid Oral Dosage Forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmceuticl Sciences, Vol.185, Informa Health care Publishers.
3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceuticl sciences, Vol.190.
4. Guidebook for drug regulatory submission/ Sandy Weinberg. By John Wiley and Sons.Inc.
5. FDA regulatory affairs: A guide for prescription drugs, medical devices and biologics/edited By Douglas J. Pisano, David Mantus.
6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
7. www.ich.org/wwwww.fda.gov/
8. e europa.edu/index_en.htm
9. http:://w.tga.gov.au/tga-basics


Course No. **PHAC C103** Course Name: **Drug Delivery System**

Semester: **I** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm


Course Coordinator: Mrs. Smitapadma Mohanty, 9937771551, smitamohanty.sper@buodisha.edu.in

Ms. Padmini Kanhar, 8895958273, pdmnkanhar@gmail.com


Objective:

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

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

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Sustained Release (SR) and Controlled Release (CR) formulations:** Introduction and basic concepts, advantages/ disadvantages, factors influencing, Physicochemical and biological approaches for SR/CR formulation, Mechanism of drug delivery from SR/CR formulation. Polymers: introduction, definition, classification, properties and application. | 12 |
| 2 | **Rate Controlled Drug Delivery Systems:** Principles & Fundamentals, Types, Activation; Modulated Drug Delivery Systems; Mechanically activated, pH activated, Enzyme activated and Osmotic activated drug delivery system. | 12 |
| 3 | **Gastro-Retentive Drug Delivery Systems:** Principle, concepts advantages and disadvantages, Modulation of GI transit time approaches to extend GI transit. Buccal Drug Delivery Systems: Principle of muco adhesion, advantages and disadvantages, Mechanism of drug permeation, Methods of formulation and its evaluations. | 12 |
| 4 | **Ocular Drug Delivery Systems:** Barriers for drug permeation, Method to overcome barriers.<br>**Transdermal Drug Delivery Sytems:** Structure of skin and barriers, Penetration enhancers, Transdermal Drug Delivery Systems, Formulation and evaluation. | 12 |
| 5 | **Protein and Peptide Delivery:** Barriers for protein delivery. Formulation and Evaluation of delivery systems of proteins and other macromolecules.<br>**Vaccine delivery systems:** Vaccines, uptake of antigens, single | 12<br>**ONLINE** |

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|---|---|---|
| | shot vaccines, mucosal and transdermal delivery of vaccines. | |
| Total | | 60 |

**Textbooks and reading materials**


1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2. Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker,Inc., New York, 1992.
3. Encyclopedia of controlled delivery, Editor-Edith Mathiowitz Published by WileyInterscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.
4. N.K. **J**ain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors
5. New Delhi, First edition 1997 (reprint in 2001).
6. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.


**JOURNALS**

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of controlled release( Elsevier Sciences) desirable
4. Drug Development and Industrial Pharmacy (Marcel & Decker) desirable

Course No. **PHAC C104** Course Name: **Modern Pharmaceutics**

Semester: **I** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm


Course Coordinator: Mrs. Smitapadma Mohanty, 9937771551, smitamohanty.sper@buodisha.edu.in

Ms. Padmini Kanhar, 8895958273, pdmnkanhar@gmail.com

Objective:

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

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

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Preformulation Studies:** pKa and solubility partition coefficient, crystal morphology, polymorphism, powder flow, dissolution, compatibility studies, Compression properties and protocol for pre-formulation studies. | 12 |
| 2 | **Drug Stability:** Solution stability, solid state stability, parameters for physical stability, protocol for physical stability testing, accelerated stability studies and shelf life assessment. | 12 |
| 3 | **Validation:** Introduction to Pharmaceutical Validation, Scope & merits of Validation, Validation and calibration of Master plan, ICH & WHO guidelines for calibration and validation of equipments, Validation of specific dosage form, types of Validation. | 12 |
| 4 | **cGMP & Industrial Management:** Objectives and policies of current good manufacturing practices, layout of buildings, services, equipments and their maintenance. Production management: Production organization, materials management, inventory management and control, production and planning control. Concept of Total Quality Management. | 12 **ONLINE** |

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|---|---|---|
| 5 | **Study of consolidation parameters:** Diffusion parameters, Dissolution parameters and pharmacokinetic parameters, Heckel plots, Similarity factors – f2 and f1, Higuchi and Peppas plot, Linearity concept of significance, Standard deviation, Chi square test, students T-test, ANOVA test. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Pharmaceutical Dosage forms: Parenteral medications Vol 1-2; By Leon Lachmn.
5. Modern Pharmaceutics; By Gillbert and S.Banker.
6. Remington's Pharmaceutical Sciences.
7. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
8. Physical Pharmacy; By Alfred martin
9. Bentley's Textbook of Pharmaceutics – by Rawlins.
10. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, Secondedition; By Sidney H.Willig.


Course No. **PHAC P105** Course Name: **Pharmaceutics practical -I**

Semester: **I** Credits: **06** Core/Elective: **Core**

Hours/Weak: 12 Hrs.

Pre-requisite: B.Pharm

Practical Details

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component formulations by UV spectrophotometry.

3. Experiments based on FTIR
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry.
8. To perform In-vitro dissolution profile of CR/SR marketed formulations
9. Formulation and evaluation of sustained release matrix tablets
10. Formulation and evaluation of osmotically controlled DDS.
11. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS
12. Formulation and evaluation of Muco adhesive tablets.
13. Formulation and evaluation of transdermal patches.
14. To carry out preformulation studies of tablets. Accelerated stability studies of various formulations or drugs with respect to temperature, effect of buffers / pH dependent.
15. To study Micromeritic properties of powders and granulation.
16. To study the effect of particle size on dissolution of tablet.
17. To study Micromeritic properties of powders and granulation.
18. To study the effect of particle size on dissolution of a tablet.
19. To study the effect of binders on dissolution of tablet.
20. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

Course No. **PHQA C103** Course Name: **Advanced Pharmaceutical Analysis**

Semester: **I** Credits: **0 4** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

After completion of the course students shall able to know,

- Appropriate analytical skills required for the analytical method development.

- Principles of various reagents used in functional group analysis that renders necessary support in research methodology and demonstrates its application in the practical related problems.
- Analysis of impurities in drugs, residual solvents and stability studies of drugs and biological products

Brief description on course and expectations:

This subject deals with the various aspects of Impurity, Impurities in new drug products, in residual solvents, Elemental impurities, Impurity profiling and characterization of degradents, Stability testing of phytopharmaceuticals and their protocol preparation. It also covers the biological testing of various vaccines and their principle and procedure.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1. | **Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines<br>Impurities in new drug products: Rationale for the reporting and control of degradation products, reporting degradation products content of batches, listing of degradation products in specifications, qualification of degradation products<br>Impurities in residual solvents: General principles, classification of residual solvents, Analytical procedures, limits of residual solvents, reporting levels of residual solvents | 12 |
| 2. | **Elemental impurities:** Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis<br>Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, | 12 |

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| | commitment etc. Important mechanistic and stability related information provided by results of study of factors like temperature, pH, buffering species ionic strength and dielectric constant etc. on the reaction rates with practical considerations. | |
| 3. | **Impurity profiling and degradent characterization:** Method development, Stability studies and concepts of validation accelerated stability testing & shelf life calculation, WHO and ICH stability testing guidelines, Stability zones, steps in development, practical considerations. Basics of impurity profiling and degradent characterization with special emphasis. Photostability testing guidelines, ICH stability guidelines for biological products | 12 |
| 4. | **Stability testing of phytopharmaceuticals:** Regulatory requirements, protocols, HPTLC/HPLC finger printing, interactions and complexity. | 12 |
| 5. | **Biological tests and assays of the following:** a. Adsorbed Tetanus vaccine b. Adsorbed Diphtheria vaccine c. Human anti haemophilic vaccine d. Rabies vaccine e. Tetanus Anti toxin f. Tetanus Anti serum g. Oxytocin h. Heparin sodium IP i. Antivenom. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)<br>**Immunoassays (IA):** Basic principles, Production of antibodies, Separation of bound and unbound drug, Radioimmunoassay, Optical IA, Enzyme IA, Fluoro IA, Luminiscence IA, Quantification and applications of IA. | 12<br>**ONLINE** |
| Total | | 60 |

**Textbooks and reading materials**


1. Vogel‘s textbook of quantitative chemical analysis - Jeffery J Bassett, J. Mendham, R. C. Denney, 5th edition, ELBS, 1991.
2. Practical Pharmaceutical Chemistry - Beckett and Stenlake, Vol II, 4th Edition, CBS publishers, New Delhi, 1997.

3. Textbook of Pharmaceutical Analysis - K A Connors, 3rd Edition, John Wiley & Sons, 1982. 103
4. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Inter science Publication, 1961.
5. Quantitative Analysis of Drugs in Pharmaceutical formulation – P D Sethi, 3rd Edition, CBS Publishers New Delhi, 1997.
6. Pharmaceutical Analysis- Modern methods - J W Munson – Part B, Volume 11, Marcel Dekker Series.
7. The Quantitative analysis of Drugs - D C Carratt, 3rd edition, CBS Publishers, NewDelhi, 1964.
8. Indian Pharmacopoeia Vol I , II & III 2007, 2010, 2014.
9. Methods of sampling and microbiological examination of water, first revision, BIS
10. Practical HPLC method development – Snyder, Kirkland, Glajch, 2nd edition, John Wiley & Sons.
11. Analytical Profiles of drug substances – Klaus Florey, Volume 1 – 20, Elsevier, 2005
12. Analytical Profiles of drug substances and Excipients – Harry G Brittan, Volume 21 – 30, Elsevier, 2005.
13. The analysis of drugs in biological fluids - Joseph Chamberlain, 2nd edition, CRC press, London.
14. ICH Guidelines for impurity profiles and stability studies.

Course No. **PHQA C104** Course Name: **Quality Control and Quality Assurance**

Semester: **I** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Course Coordinator: Dr. Suraj Sahoo, 9776607835, surajsahoo.sper@buodisha.edu.in

Mrs. Ipsa Padhy, 8917638492, ipsa.padhy88@gmail.com

Objective:

At the completion of this subject it is expected that the student shall be able to know

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

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1. | **Concept and Evolution of Quality Control and Quality Assurance:** Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Q-series guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non clinical testing, control on animal house, report preparation and documentation. | 12 |
| 2. | **cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering:** Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice. CPCSEA guidelines. | 12 |
| 3. | **Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3):** Purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following formulation in Pharma industry according to | 12 |

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|---|---|---|
| | Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenterals, ophthalmic and surgical products (How to refer pharmacopoeias), Quality control test for containers, closures and secondary packing materials. | |
| 4. | **Documentation in pharmaceutical industry:** Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain, retention and retrieval etc. Standard operating procedures (How to write), Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specification and test procedures, Protocols and reports. Distribution records. Electronic data. | 12 **ONLINE** |
| 5. | **Manufacturing operations and controls:** Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Quality Assurance Guide by organization of Pharmaceutical Procedures of India, 3rd revised edition, Volume I & II, Mumbai, 1996.
2. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol. 69, Marcel Dekker Series, 1995.
3. Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
4. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
5. The International Pharmacopoeia – vol I, II, III, IV & V - General Methods of Analysis and Quality specification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO, Geneva, 2005.

6. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
7. ICH guidelines
8. ISO 9000 and total quality management 115
9. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
10. QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
11. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
12. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.
13. Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

Course No. **PHQA P105** Course Name: **Pharmaceutical Analysis & Quality Assurance Practical - I**

Semester: **I** Credits: **06** Core/Elective: **Core**

Hours/Week: 12 Hrs

Pre-requisite: B.Pharm

Practical Details

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Assay of official compounds by different titrations
4. Assay of official compounds by instrumental techniques.
5. Quantitative determination of hydroxyl group.
6. Quantitative determination of amino group
7. Colorimetric determination of drugs by using different reagents

8. Calibration of glasswares
9. Calibration of pH meter
10. Calibration of UV-Visible spectrophotometer
11. Cleaning validation of any one equipment
12. Analysis of Pharmacopoeial compounds in bulk and in their formulations (tablet/ capsules/ semisolids) by UV Vis spectrophotometer
13. Simultaneous estimation of multi-drug component containing formulations by UV spectrophotometry
14. Development of Stability study protocol
15. In process and finished product quality control tests for tablets, capsules, parenterals and semisolid dosage forms.
16. To study the effect of pH on the solubility of drugs, (1 experiment)
17. Accelerated stability studies (1 experiment)
18. Improved solubility of drugs using surfactant systems (1 experiment)
19. Improved solubility of drugs using co-solvency method (1 experiment)
20. Determination of Pka and Log p of drugs.

**SECOND SEMESTER**

**PHARMACEUTICS**

Course No. **PHAC C201** Course Name: **Molecular Pharmaceutics (Nano Tech and Targeted DDS)**

Semester: **II** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

Upon completion of the course student shall be able to understand

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

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Targeted Drug Delivery Systems:** Concepts, Events and biological process involved in drug targeting. Tumor targeting and Brain specific delivery. | 12 |
| 2 | **Targeting Methods:** Introduction preparation and evaluation. Nano particles & Liposomes: types, prepation and evaluation. | 12 |
| 3 | **Micro Capsules/Micro Spheres:** Types, preparation and evaluation, Monoclonal Antibodies; preparation and application, preparation and application of Niosomes, Aquasomes, Electrosomes. | 12 |
| 4 | **Pulmonary Drug Delivery Systems:** Aerosols, propellents, Containers types, preparation and evaluation, Intra Nasal route Delivery systems; Types, preparation and evaluation. | 12 |
| 5 | **Nucleic acid based therapeutic delivery system:** Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potential target diseases for gene therapy (inherited disorder and cancer). Gene expression systems (viral and non-viral gene transfer). Liposomal gene delivery systems. | 12 **ONLINE** |
| Total | | 60 |

**Textbooks and reading materials**

1. Y W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc, New York, 1992.

2. S.P. Vyas and R.K. Khar, Controlled Drug Delivery- Concepts and advances, Vallabh Prakashan, New Delhi, 1st edition, 2002.
3. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, 1st edition, 1997 (reprint in 2001).
4. Controlled Drug Delivery systems by Joseph R. Robinson and Vincent ILL. Lee.
5. Drug Targeting and delivery edited by H.E. Junginger.
6. Specialized Drug Delivery Systems edited by Praveen Tyle, Pub. and Marcel Dekker Inc.

Course No. **PHAC C202** Course Name: **Advanced Biopharmaceutics and Pharmacokinetics**

Semester: **II** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

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

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drug product equivalency.

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, $p^H$-partition theory of drug absorption. | 12 |

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|---|---|---|
| | Formulation and physicochemical factors: Dissolution rate, Dissolution process, Noyes–Whitney equation and drug dissolution, factors affecting the dissolution rate. Gastrointestinal absorption: role of the dosage form: Solution (elixir, syrup and solution) as a dosage form, Suspension as a dosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods, Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. | |
| 2 | **Biopharmaceutic considerations in drug product design and In Vitro Drug Product Performance:** Introduction, biopharmaceutic factors affecting drug bioavailaility, rate-limiting steps in drug absorption, physicochemical nature of the drug formulation factors affecting drug product performance, in vitro: dissolution and drug release testing, compendial methods of dissolution, alternative methods of dissolution testing, meeting dissolution requirements, problems of variable control in dissolution testing performance of drug products. In vitro-in vivo correlation, drug product stability. | 12 |
| 3 | **Pharmacokinetics:** Basic considerations, pharmacokinetic models, compartmental modeling: One compartment model-IV bolus, IV infusion, extravascular. Multi compartment model: Two compartment- model in brief, non-linear pharmacokinetics: cause of non-linearity, Michaelis-Menten equation, estimation of $k_{max}$ and $v_{max}$. Drug interactions: Introduction, the effect of protein-binding interactions, the effect of tissue-binding interactions, drug interactions linked to transporters. | 12 |
| 4 | **Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:** Drug product performance, purpose of bioavailability studies, relative and absolute availability. Methods for assessing bioavailability, bioequivalence studies, design and evaluation of bioequivalence studies, study designs, crossover | 12<br>**ONLINE** |

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|---|---|---|
| | study designs, evaluation of data. Clinical significance of bioequivalence studies. | |
| 5 | **Application of Pharmacokinetics:** Modified release drug products, Targeted drug delivery system.<br>**Time dependent pharmacokinetics:** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Feiger, 1991.
2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D.M. Brahmankar and Sunil B. Jaiswal, Vallab Prakashan, Pitampura, Delhi.
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. Land YuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Book.
5. Pharmacokinetics by Milo Gibaldi and D. Perrier 2nd edition, Marcel Dekker Inc, New York, 1982.
6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia, 1970.
7. Clinical Pharmacokinetics, Concepts and Applications, 3rd edition by Malcolm Rowland and Thom~N. Tozer, Lea and Febiger, Philadelphia, 1995.
8. Dissolution, Bioavailability and Bioeuivalence, Abdou. H.M, Mack Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4th edition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner and M. Pemarowwski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.

11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. G. Boylan, Marcel Dekker Inc, New York, 1996.
12. Basic Pharmacokinetics, 1st edition, Sunil S Jambhekar and Philip J Breen, Pharmaceutical press, RPS Publishing, 2009.
13. Absorption and Drug Development- Solubility, Permeability, and Charge state, Alex Avdeef John Wiley & Sons, Inc, 2003.

Course No. **PHAC C203** Course Name: **Advanced Pharmaceutical Technology**

Semester: **II** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

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

- Recent advances in dosage form regarding formulation aspects.
- Manage the scale up process in pharmaceutical industry.

Brief description on course and expectations:

This course is designed to impart knowledge and skills necessary to train the students to be on advances in dosage form regarding formulation, scale up, and process validation.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Formulation Development:** Recent advances in formulation aspects of tablet production process, unit operation improvements, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, Recent advances in formulation aspects and manufacturing of monophasic dosage forms, suspensions, semi- | 12 |

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|---|---|---|
| | solid dosage forms and aerosol. | |
| 2 | **Validation:** General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaning validation and vender qualification. | 12 |
| 3 | **Aseptic processing operation and parenteral dosage form development:** Introduction, Contamination control, Microbial environmental monitoring, Microbiological testing of water, Microbiological air testing, Characterization of aseptic process, Media and incubation conditions, Theoretical evaluation of aseptic operations. | 12 |
| 4 | **Scale-up Techniques:** Effect of scale up on formulation, process parameters like mixing, granulation, drying, compression, coating, packaging, stability, selection and evaluation of suitable equipments. | 12 |
| 5 | **Process Validation:** Importance, validation of mixing, granulation, drying, compression, tablet coating, liquid filling and sealing, sterilization, water process systems, environmental control. | 12 **ONLINE** |
| Total | | 60 |

**Textbooks and reading materials**


1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker, NY. Pharmaceutical production facilities, design and applications, by GC Cole, Taylor and Francis.
2. The theory & Practice of Industrial Pharmacy, L. Lachman, H.A. Lieberman, Varghese Publ. Bombay.
3. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.
4. Pharmaceutical dosage forms, Tablets, Vol 1, 2, by Lachman, Lieberman, Marcel Dekker, NY.

5. Pharmaceutical dosage forms, Parenteral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
6. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007, Vallabh Prakashan, Delhi.

Course No. **PHAC C204** Course Name: **Cosmetics and cosmeceuticals**

Semester: **II** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

- Upon completion of the course, the students shall be able to understand
- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market.
- Various key ingredients and basic science to develop cosmetics and cosmeceuticals. Scientific knowledge to develop cosmetic and cosmeceuticals with desired safety, stability and efficacy.

Brief description on course and expectations:

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

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Cosmetics – Regulatory:** Definition of cosmetic products as per Indian regulation. Indian regulatory requirements for labeling of cosmetics. Regulatory provisions relating to import of cosmetics. Misbranded and spurious cosmetics. Regulatory provisions | 12 |

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|---|---|---|
| | relating to manufacture of cosmetics- Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties. | |
| 2 | **Cosmetics - Biological aspects:** Structure of skin, Structure of hair and hair growth cycle. Common problems associated with oral cavity. Cleansing and care needs for face, eye lids, lips, hands, feet, nail, scalp, neck, body and under-arm. | 12 |
| 3 | **Formulation Building blocks:** Building blocks for different product formulations of cosmetics/ comeceuticals. Surfactants-Classification and application. Emollients, rheological additives: classification and application. Antimicrobial used as preservatives, their merits and demerits. Factors affecting microbial preservative efficacy. Building blocks for formulation of a moisturizing cream, vanishing cream, cold cream, shampoo and toothpaste. | 12 |
| 4 | **Design of cosmeceutical products:** Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne, sun-protection, pigmentation, prickly heat, wrinkles, body odor, dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations. | 12 |
| 5 | **Herbal Cosmetics:** Herbal ingredients used in Hair care, skin care and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics. | 12<br>**ONLINE** |
| Total | | 60 |

**Textbooks and reading materials**

- Harry's Cosmeticology 8th edition

- Cosmetics- Formulation, manufacture and quality control, PP. Sharma, 4th edition
- Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition.
- Cosmetic and Toiletries recent suppliers catalogue.
- CTFA directory.

Course No. **PHAC P205** Course Name: **Pharmaceutics practical -II**

Semester: **II** Credits: **06** Core/Elective: **Core**

Hours/Weak: 12 Hrs.

Pre-requisite: B.Pharm

Practical Details

1. Study on diffusion of drugs through various polymers.
2. To study the effect of temperature change, non solvent addition, incompatible polymer addition in Microcapsules preparation.
3. Preparation and evaluation of alginate Beads.
4. Formulation and evaluation of gelatine/albumin Microspheres.
5. Formulation and evaluation of Liposomes.
6. Formulation and evaluation of Niosomes.
7. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
8. Dissolution study of an enteric coated tablet.
9. Comparison of dissolution of two different marketed products/brands.
10. Calculation of various pharmacokinetic parameters.
11. Formulations and evaluation of tablets.
12. Formulations and evaluation of liquid orals.
13. Formulation and evaluation of reconstituted dry syrups.
14. Preparation of matrix tablets using various polymers.
15. Development and evaluation of Creams.

16. Development and evaluation of Hair care products.
17. Formulation and evaluation Toothpaste.
18. Formulation and evaluation of Skin care products.
19. To address dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff.
20. To incorporate herbal and chemical actives to develop products.

**Pharmaceutical Analysis and Quality Assurance**

Course No. **PHQA C201** Course Name: **Advanced Instrumental Analysis**

Semester: **II** Credits: **04** Core/Elective: **Core**

Pre-requisite: B.Pharm

Objective:

To know

- Interpretation of the NMR, Mass and IR spectra of various organic compounds
- Theoretical and practical skills of the hyphenated instruments
- Identification of organic compound

Brief description on course and expectations:

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. After completion of course student will come to know about Instruments like LC-MS, GC-MS, and hyphenated techniques.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **HPLC:** Principle, instrumentation, pharmaceutical applications, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, gradient HPLC, HPLC solvents, trouble shooting, | 12 |

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|---|---|---|
| | sample preparation, method development, New developments in HPLC-role and principles of ultra, nano liquid chromatography in pharmaceutical analysis.. HPLC in Chiral analysis of pharmaceuticals. Preparative HPLC, practical aspects of preparative HPLC | |
| 2 | **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.<br>Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification.<br>High performance Thin Layer chromatography: Principles, instrumentation, pharmaceutical applications | 12 |
| 3 | **Super critical fluid chromatography:** Principles, instrumentation, pharmaceutical applications. Capillary electrophoresis: Overview of CE in pharmaceutical analysis, basic configuration, principles of CE, methods and modes of CE. General considerations and method development in CE, CE-MS hyphenation | 12<br>**ONLINE** |
| 4 | **Mass spectrometry:** Principle, theory, instrumentation of mass spectrometry, different types of ionization like electron impact, chemical, field, and FAB, ESI, APPI mass fragmentation and its rules, meta stable ions, isotopic peaks and applications of mass spectrometry. LC-MS hyphenation and DART MS analysis. Mass analysers (Quadrpole, Time of flight, FT-ICR, and ion trap) instruments. MS/MS systems (Tandem: QqQ, TOF-TOF; LTQ-FT, LTQ-Orbitrap. | 12 |
| 5 | **NMR spectroscopy:** Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Nuclear magnetic double | 12 |

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|---|---|---|
| | resonance, Brief outline of principles of FT-NMR with reference to 13CNMR: Spin spin and spin lattice relaxation phenomenon. 13C NMR, 1-D and 2-D NMR, NOESY and COSY techniques, Interpretation and Applications of NMR spectroscopy. LC-NMR hyphenations. | |
| Total | | 60 |

**Textbooks and reading materials**


1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.
8. Organic Spectroscopy by Donald L. Paviya, 5th Edition.


Course No. **PHQA C202** Course Name: **Pharmaceutical Validation**

Semester: **II** Credits: **04** Core / Elective: **Core**

Pre-requisite: B.Pharm

Objective:

To know

- The concepts of calibration, qualification and validation
- The qualification of various equipments and instruments

- Process validation of different dosage forms
- Validation of analytical method for estimation of drugs
- Cleaning validation of equipments employed in the manufacture of pharmaceuticals

Brief description on course and expectations:

The main purpose of the subject is to understand about validation and how it can be applied to industry and thus improve the quality of the products, the subject covers the complete information and after completion of course student will come to know about validation, types, methodology and application.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Introduction to validation:** Definition of Calibration, Qualification and Validation, Scope, frequency and importance. Difference between calibration and validation. Calibration of weights and measures. Advantages of Validation, scope of Validation, Organization for Validation, Validation Master plan, Types of Validation, Validation process and Validation Master Plan.<br>**Qualification:** User requirement specification, Design qualification, Factory Acceptance Test (FAT)/Site Acceptance Test (SAT), Installation qualification, Operational qualification, Performance qualification, Re-Qualification (Maintaining status-Calibration Preventive Maintenance). | 12 |
| 2 | **Qualification of manufacturing equipment:** Dry Powder, Mixers, Fluid Bed and Tray dryers, Tablet Compression (Machine), Dry heat sterilization, Autoclaves, Membrane filtration, Capsule filling machine.<br>**Qualification of analytical instruments:** UV-Visible spectrophotometer, FTIR, GC, HPLC, LC-MS. | 12 |

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| | **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus<br>**Validation of Utility systems**: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen. | |
| 3 | **Process Validation:** Concept, Process and documentation of Process Validation. Prospective, Concurrent & Retrospective Validation, Re validation criteria, Process Validation of various formulations (Coated tablets, Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDA guidelines on Process Validation- A life cycle approach.<br>Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP | 12 |
| 4 | **Cleaning Validation:** Cleaning Method development, Validation of analytical method used in cleaning, Cleaning of Equipment, Cleaning of Facilities. Cleaning in place (CIP). Validation of facilities in sterile and non-sterile plant.<br>**Computerized system validation:** Electronic records and digital signature - 21 CFR Part 11 and GAMP | 12 |
| 5 | **General Principles of Intellectual Property:** Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramification and financial implications. Filing a patent applications; patent application forms and guidelines. Types<br>patent applications-provisional and non provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; | 12<br>**ONLINE** |

| | | |
|---|---|---|
| | Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices | |
| Total | | 60 |

**Textbooks and reading materials**


1. B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco,
5. Michael Levin, Pharmaceutical Process Scale-Up, Drugs and Pharm. Sci. Series, Vol. 157,2nd Ed., Marcel Dekker Inc., N.Y.
6. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
7. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
8. Validation of Pharmaceutical Processes: Sterile Products, Frederick J. Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker
9. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y.C. Lee, Yue. Zhang, Wiley Interscience.
10. Huber L. Validation and Qualification in Analytical Laboratories. Informa Healthcare.
11. Wingate G. Validating Corporate Computer Systems: Good IT Practice for Pharmaceutical Manufacturers. Interpharm Press.
12. LeBlanc DA. Validated Cleaning Technologies for Pharmaceutical Manufacturing. Interpharm Press.

Course No. **PHQA C203** Course Name: **Audits and Regulatory Compliance**

Semester: **II** Credits: **04** Core / Elective: **Core**

Pre-requisite: B.Pharm

Objective:

To know

- To understand the importance of auditing
- To understand the methodology of auditing
- To carry out the audit process
- To prepare the auditing report
- To prepare the check list for auditing

Brief description on course and expectations:

This course deals with the understanding and process for auditing in pharmaceutical industries. After completion of course student will come to know the methodology involved in the auditing process of different in pharmaceutical industries.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Introduction:** Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies | 12 |
| 2 | **Role of quality systems and audits in pharmaceutical manufacturing environment:** cGMP Regulations, Quality assurance functions, Quality systems approach, Management responsibilities, Resource, Manufacturing operations, Evaluation activities, Transitioning to quality system approach, Audit checklist for drug industries. | 12 |
| 3 | **Auditing of vendors and production department:** Bulk Pharmaceutical Chemicals and packaging material Vendor audit, | 12 **ONLINE** |

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|---|---|---|
| | Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging. | |
| 4 | **Auditing of Microbiological laboratory:** Auditing the manufacturing process, Product and process information, General areas of interest in the building raw materials, Water, Packaging materials. | 12 |
| 5 | **Auditing of Quality Assurance and engineering department:** Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London New York, Washington D.C.
2. Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3. Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4. Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005)


Course No. **PHQA C204** Course Name: **Pharmaceutical Manufacturing Technology**

Semester: **II** Credits: **04** Core / Elective: **Core**

Pre-requisite: B.Pharm

Objective:

To know

- The common practice in the pharmaceutical industry developments, plant layout and production planning
- Will be familiar with the principles and practices of aseptic process technology, non sterile manufacturing technology and packaging technology.
- Have a better understanding of principles and implementation of Quality by design (QbD) and process analytical technology (PAT) in pharmaceutical manufacturi

Brief description on course and expectations:

This course is designed to impart knowledge and skills necessary to train the students with the industrial activities during Pharmaceutical Manufacturing. After completion of course student will come to know about Production planning, Quality by design (QbD) and process analytical technology (PAT) etc.

| Chapter | Contents | Hours/ Semester |
|---|---|---|
| 1 | **Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing.<br>**Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout.<br>**Production planning:** General principles, production systems, calculation of standard cost, process planning, routing, dispatching of records, production control. | 12 |
| 2 | **Aseptic process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume).<br>**Advanced sterile product manufacturing technology:** Area planning & environmental control, wall and floor treatment, | 12 |

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|---|---|---|
| | fixtures and machineries, personnel flow, utilities & utilities equipment location, engineering and maintenance.<br>**Process Automation in Pharmaceutical Industry:** With specific reference to manufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP) Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS).<br>Lyophilization technology: Principles, process, equipment. | |
| 3 | **Non sterile manufacturing process technology:** Manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets (compressed & coated), Capsules (Hard & Soft).<br>**Advance non-sterile solid product manufacturing technology:** Process Automation in Pharmaceutical Industry with specific reference to manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipments, continuous and batch mixing, rapid mixing granulators, spheronizers and marumerisers, and other specialized granulation and drying equipments. Problems encountered. Coating technology: Process, equipments, particle coating, fluidized bed coating, application techniques. Problems encountered. | 12 |
| 4 | **Containers and closures for pharmaceuticals:** Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit | 12<br>**ONLINE** |

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|---|---|---|
| | worthiness of package, Stability aspects of packaging.<br>Evaluation of stability of packaging material | |
| 5 | **Quality by design (QbD) and process analytical technology (PAT):** Current approach and its limitations. Why QbD is required, Advantages, Elements of QbD, Terminology: QTPP. CMA, CQA, CPP, RLD, Design space, Design of Experiments, Risk Assessment and mitigation/minimization. Quality by Design, Formulations by Design, QbD for drug products, QbD for Drug Substances, QbD for Excipients, Analytical QbD. FDA initiative on process analytical technology. PAT as a driver for improving quality and reducing costs: quality by design (QbD), QA, QC and GAMP. PAT guidance, standards and regulatory requirements. | 12 |
| Total | | 60 |

**Textbooks and reading materials**


1. Lachman L, Lieberman HA, Kanig JL. The theory and practice of industrial pharmacy, 3rded., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed., B.I. Publications Pvt. Ltd, Noida, 2006.
3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nded., CBS Publishers & distributors, New Delhi, 2005.
4. Banker GS, Rhodes CT. Modern Pharmaceutics, 4thed., Marcel Dekker Inc, New York, 2005.
5. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
6. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.
7. British Pharmacopoeia. British Pharmacopoeia Commission Office, London, 2008.
8. United States Pharmacopoeia. United States Pharmacopeial Convention Inc, USA, 2003.

9. Dean D A, Evans E R and Hall I H. Pharmaceutical Packaging Technology. London, Taylor & Francis, 1stEdition. UK.
10. Edward J Bauer. Pharmaceutical Packaging Handbook. 2009. Informa Health care USA Inc. New york.
11. Shaybe Cox Gad. Pharmaceutical Manufacturing Handbook. John Willey and Sons, New Jersey, 2008.

Course No. **PHQA P205** Course Name: **Pharmaceutical Analysis & Quality Assurance Practical -II**

Semester: **II** Credits: **06** Core/Elective: **Core**

Hours/Week : 12

Pre-requisite: B.Pharm

Practical Details

1. Comparison of absorption spectra by UV and Wood ward – Fiesure rule
2. Identification of organic compounds using suitable analytical instruments
3. Bio molecules separation utilizing various sample preparation techniques and Quantitative analysis of components by gel electrophoresis
4. Protocol preparation and performance of analytical/Bioanalytical method validation.
5. Protocol preparation for the conduct of BA/BE studies according to guidelines.
6. In process and finished product quality control tests for tablets, capsules, parenterals and creams
7. Quality control tests for Primary and secondary packing materials
8. Assay of raw materials as per official monographs
9. Preparation of Master Formula Record.
10. Determination of acid value and saponification value.
11. Qualification of few Pharma equipment
12. Validation of an analytical method for a drug
13. Validation of a processing area
14. Qualification of at least two analytical instruments
15. Cleaning validation of one equipment

16. Check list for Bulk Pharmaceutical Chemicals vendors
17. Check list for tableting production.
18. Check list for sterile production area
19. Check list for Water for injection.
20. Design of plant layout: Sterile and non-sterile

**III & IV Semester**

Topics selection for Dissertation/Project work under the supervision of concerned guide is to be approved by the department.

(Based on the Literature Review, Drug Profile, Data generated, interpretation of data etc. of the Research work, a seminar shall be presented by every student in the Department prior to evaluation by Internal and External examiners during the End-Sem. Exam.)

Assessment and Expectations from students by Sessional, End semester exams, attendance and punctuality