BERHAMPUR UNIVERITY

Syllabus for Master of Pharmacy (M.Pharm.)
2 years programme

School of Pharmaceutical Education and Research, SPER
Berhampur University
Berhampur-760007
Odisha

2021-2022

Programme Outcome:

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.

Courses offered:

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

COURSE	Code	DURATION	INTAKE
M. Pharmacy Pharmaceutics	PHAC	2 years (04 semesters)	15
M. Pharmacy Pharmaceutical Analysis and Quality Assurance	PHQA	2 years (04 semesters)	15

Course of study for M. Pharm. (Pharmaceutics):

FIRST SEMESTER							
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Internal Mark/hrs	External Mark/hrs	Total Marks
1	PHAC C101	Modern Pharmaceutical Analytical Techniques	4	4	25/1	75/3	100
2	PHAC C102	Regulatory Affairs	4	4	25/1	75/3	100
3	PHAC C103	Drug Delivery System	4	4	25/1	75/3	100
4	PHAC C104	Modern Pharmaceutics	4	4	25/1	75/3	100
5	PHAC P105	Pharmaceutics Practical I	12	6	50/6	100/6	150
6	PHAC S106	Seminar/Assignment	7	4	-	100	100
Total			35	26	150	500	650
SECOND SEMESTER							
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Internal Mark/hrs	External Mark/hrs	Total Marks
1	PHAC C201	Molecular Pharmaceutics (Nano Tech and Targeted DDS)	4	4	25/1	75/3	100
2	PHAC C202	Advanced Biopharmaceutics and Pharmacokinetics	4	4	25/1	75/3	100
3	PHAC C203	Advanced Pharmaceutical Technology	4	4	25/1	75/3	100
4	PHAC C204	Cosmetics and cosmeceuticals	4	4	25/1	75/3	100
5	PHAC P205	Pharmaceutics Practical II	12	6	50/6	100/6	150
6	PHAC S206	Seminar/Assignment	7	4	-	100	100
Total			35	26	150	500	650

Course of study for M. Pharm. (Pharmaceutical Analysis and Quality Assurance):

FIRST SEMESTER							
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Internal Mark/hrs	External Mark/hrs	Total Marks
1	PHQA C101	Modern Pharmaceutical Analytical Techniques	4	4	25/1	75/3	100
2	PHQA C102	Regulatory Affairs	4	4	25/1	75/3	100
3	PHQA C103	Advanced Pharmaceutical Analysis	4	4	25/1	75/3	100
4	PHQA C104	Quality Control and Quality Assurance	4	4	25/1	75/3	100
5	PHQA P105	Pharmaceutical Analysis & Quality Assurance Practical I	12	6	50/6	100/6	150
6	PHQA S106	Seminar/Assignment	7	4	-	100	100
Total			35	26	150	500	650
SECOND SEMESTER							
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Internal Mark/hrs	External Mark/hrs	Total Marks
1	PHQA C201	Advanced Instrumental Analysis	4	4	25/1	75/3	100
2	PHQA C202	Pharmaceutical Validation	4	4	25/1	75/3	100
3	PHQA C203	Audits and Regulatory Compliance	4	4	25/1	75/3	100
4	PHQA C204	Pharmaceutical Manufacturing Technology	4	4	25/1	75/3	100
5	PHQA P205	Pharmaceutical Analysis & Quality Assurance Practical II	12	6	50/6	100/6	150
6	PHQA S206	Seminar/Assignment	7	4	-	100	100
Total			35	26	150	500	650

Course of study for M. Pharm. (Common for all the specialization)*:

THIRD SEMESTER					
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Marks
1	PHAR C301	Research Work (research topic proposal, its finalization and progress)	26	13	325
		Presentation/seminar	3	3	75
		Discussions / Viva-voce	4	4	100
Total			33	20	500
FOUTH SEMESTER					
Sl.No.	Course Code	Course	Credit hrs	Credit Points	Marks
1	PHAR C401	Research Work (experimental outcomes, results, discussions, final conclusion, further work etc.)	31	16	400
		Presentation/seminar	1	1	25
		Discussions / Viva-voce	3	3	75
Total			35	20	500
Co-curricular Activities (Attending Conference, Scientific Presentations and other Scholarly Activities)			-	04	100
Grand Total			138	96	2400

* Non-University Examination.

- Apart from the list mentioned for practical. Other experiments in related topics will also carry out as per requirements.
- Individual student will be allotted different topics from the syllabus for assignment and presentation. This will be supervised by the concern faculty.
- Seminar Presentations shall be based on the Topics selected for Dissertation.

FIRST SEMESTER

Course: Modern Pharmaceutical Analytical Techniques	Course Code. PHAC C101/PHQA C101	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Concept of spectroscopy.		
Course outcome: - Analysis of various drugs in single and combination dosage forms. - Theoretical and practical skills of the instruments		

Unit	Contents	Hours
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. **IR spectroscopy:** Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation. **Spectroflourimetry:** Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by flourimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer. **Flame emission spectroscopy and Atomic absorption spectroscopy:** Principle, Instrumentation, Interferences and Applications.	12
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. **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 following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing 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.	12

5.	**Potentiometry:** Principle, working, Ion selective Electrodes and Application of potentiometry. 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
Total		60

Text books 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: Regulatory Affairs	**Course Code.** PHAC C102/ PHQA C102	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Basic regulation and guideline according to GMP.		
Course outcome: - The Regulatory guidance's and guidelines for filing and approval process. - Preparation of Dossiers and their submission to regulatory agencies in different countries. - Clinical trials requirements for approvals for conducting clinical trials.		

Unit	Contents	Hours
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
4	**Non Clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier(IMPD) and investigator brochure(IB).	12
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

Text books 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.
3. Martin, Drugs and the Pharmceuticl Sciences, Vol.185, Informa Health care Publishers.
4. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceuticl sciences, Vol.190.
5. Guidebook for drug regulatory submission/ Sandy Weinberg. By John Wiley and Sons.Inc.
6. FDA regulatory affairs: A guide for prescription drugs, medical devices and biologics/edited By Douglas J. Pisano, David Mantus.
7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
8. www.ich.org/wwwww.fda.gov/
9. http:://w.tga.gov.au/tga-basics

Course: Drug Delivery System	**Course Code.** PHAC C103	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Concept on drug delivery system.		
Course outcome: - The various approaches for development of novel drug delivery systems. - The criteria for selection of drugs and polymers for the development of delivering system.		

Unit	Contents	Hours
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. **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. **Vaccine delivery systems:** Vaccines, uptake of antigens, single Shot vaccines, mucosal and transdermal delivery of vaccines.	12
Total		60

Text books 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 4. Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.
4. N.K. Jain, Controlled and Novel Drug Delivery, CBS Publishers and Distributors, New Delhi, First edition 1997 (reprint in 2001).
5. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
JOURNALS
6. Indian Journal of Pharmaceutical Sciences (IPA)
7. Indian drugs (IDMA)
8. Journal of controlled release(Elsevier Sciences) desirable
9. Drug Development and Industrial Pharmacy(Marcel & Decker) desirable.

Course: Modern Pharmaceutics	**Course Code. PHAC C104**	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Concept pre-formulation.		
Course outcome: - 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 packaging of dosage forms. Brief description on course and expectations.		

Unit	Contents	Hours
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 andcalibration 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
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

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

Course: Pharmaceutics practical -I	**Course Code. PHAC P105**	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Knowledge about handling of instruments.		
Course outcome: - Practical experience in handling basic instrument. - Preparation of sample and handling of data.		
Experiment		**Hours/week 12**
1. Analysis of pharmacopoeial compounds and their formulations by UV-Vis spectrophotometer Simultaneous estimation of multi component formulations by UV spectrophotometry. 2. Experiments based on FTIR 3. Experiments based on HPLC 4. Experiments based on Gas Chromatography 5. Estimation of riboflavin/quinine sulphate by fluorimetry 6. Estimation of sodium/potassium by flame photometry. 7. To perform In-vitro dissolution profile of CR/SR marketed formulations 8. Formulation and evaluation of sustained release matrix tablets 9. Formulation and evaluation of osmotically controlled DDS. 10. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS 11. Formulation and evaluation of Muco adhesive tablets. 12. Formulation and evaluation of transdermal patches. 13. To carry out preformulation studies of tablets. Accelerated stability studies of various formulations or drugs with respect to temperature, effect of buffers / pH dependent. 14. To study Micromeritic properties of powders and granulation. 15. To study the effect of particle size on dissolution of tablet.		

16. To study Micromeritic properties of powders and granulation.
17. To study the effect of particle size on dissolution of a tablet.
18. To study the effect of binders on dissolution of tablet.
19. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors.

Course: Advanced Pharmaceutical Analysis	**Course Code. PHQA C103**	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: ICH guideline and concept of impurities.		
Course outcome: - Knowledge about impurities present in drug substance, drug product, solvent, etc. - Importance of impurities profiling.		

Unit	Contents	Hours
1.	**Impurity and stability studies:** Definition, classification of impurities in drug Substance or Active Pharmaceutical Ingredients and quantification of impurities as per ICH guidelines. 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 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. Stability testing protocols: Selection of batches, container orientation, test parameters, sampling frequency, specification, storage conditions, recording of results, concept of stability, 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.	12
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) **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
Total		60

Text books 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. Text book 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, New Delhi, 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.
ICH Guidelines for impurity profiles and stability studies.

Course: Quality Control and Quality Assurance	**Course Code. PHQA C104**	
Semester: I	**Credits:** 04	**Core course**
Pre-requisite: Overview of ICH guidelines.		
Course outcome: • To learn the cGMP aspects in a pharmaceutical industry • To understand the scope of quality certifications applicable to Pharmaceutical industries • Knowledge in the various aspects of quality control and quality assurance aspects of pharmaceutical industries.		

Unit	Contents	Hours
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 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.	12
4.	**Documentationin 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
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

Text books 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.
Quality Assurance of Pharmaceuticals- A compedium of Guide lines and Related materials Vol I & II, 2nd edition, WHO Publications, 1999.
3. How to Practice GMP's – P P Sharma, Vandana Publications, Agra, 1991.
4. 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.
5. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
ICH guidelines ISO 9000 and total quality management 115
6. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
QA Manual – D.H. Shah, 1st edition, Business Horizons, 2000.
7. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
8. 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.
9.Sarker DK. Quality Systems and Controls for Pharmaceuticals. John Wiley & Sons; 2008.

Course: Pharmaceutical Analysis & Quality Assurance Practical I	Course Code. PHQA P105	
Semester: I	**Credits:** 06	**Core course**
Pre-requisite: Principle of different analytical instruments.		
Course outcome: - Knowledge of handling instruments and analysis of data. - Experience in quality control test. - Formulation of drugs and their analysis.		
Experiments		**Hours/week 12**
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: Molecular Pharmaceutics (Nano Tech and Targeted DDS)	**Course Code. PHAC C201**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Concept of Microsphere and Nanotechnology.		
Course outcome: - 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.		

Unit	Contents	Hours
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 Deliverysystems; 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
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: Advanced Biopharmaceutics and Pharmacokinetics	Course Code. PHAC C202	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Physiological characteristics of GI track, PK-PD study.		

Course outcome:

- The basic concepts of biopharmaceutics and pharmacokinetics.
- Use of raw data to derive the pharmacokinetic models and parameters of drug absorption, distribution, metabolism and elimination.
- Skills in dose calculations and dose adjustments of drug.

Unit	Contents	Hours
1	**Drug Absorption from the Gastrointestinal Tract:** Gastrointestinal tract, Mechanism of drug absorption, Factors affecting drug absorption, pH-partition theory of drug absorption. 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.	12
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 study designs, evaluation of data. Clinical significance of bioequivalence studies.	12
5	**Application of Pharmacokinetics:** Modified release drug products, Targeted drug delivery system. **Time dependent pharmacokinetics:** Introduction, classification, physiologically induced time dependency: Chronopharmacokinetics and Chronotherapeutics.	12
Total		60

Text books 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: Advanced Pharmaceutical Technology	**Course Code. PHAC C203**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Pre-formulation study.		
Course outcome: - Recent advances in dosage form regarding formulation aspects. - Manage the scale up process in pharmaceutical industry.		

Unit	Contents	Hours
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-solid dosage forms and aerosol.	12
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
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,
7. Pharmaceutical production and Management, 2007, Vallabh Prakashan, Delhi.

Course: Cosmetics and cosmeceuticals	**Course Code. PHAC C204**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Key ingredients used in cosmetics and cosmeceuticals.		
Course outcome: Various key ingredients and basic science to develop cosmetics and cosmeceuticals. Scientific knowledge to develop cosmetic and cosmeceuticals with desired safety, stability and efficacy.		

Unit	Contents	Hours
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 relating to manufacture of cosmetics- Conditions for obtaining license, prohibition of manufacture and sale of certain cosmetics, loan license, offences and penalties.	12
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
Total		60

Text books and reading materials:

1. Harry's Cosmeticology 8th edition
2. Cosmetics- Formulation, manufacture and quality control, PP. Sharma, 4th edition
3. Handbook of cosmetic science and Technology A.O.Barel, M.Paye and H.I. Maibach. 3 rd edition.
4. Cosmetic and Toiletries recent suppliers catalogue.
5. CTFA directory.

Course: Pharmaceutics practical -II	**Course Code. PHAC P205**	
Semester: II	**Credits:** 06	**Core course**
Pre-requisite: Preparation and evaluation of Microparticles.		
Course outcome: - Experience in evaluation of Liposomes - Preparation and evaluation of Tablet and different cosmetic products.		
Experiment	Hours/Weak: 12 Hrs	
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.		

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Course: Advanced Instrumental Analysis	Course Code. PHQA C201	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Fundamental knowledge of spectroscopy and chromatography.		
Course outcome: - Interpretation of the NMR, Mass and IR spectra of various organic compounds. - Theoretical and practical skills of the hyphenated instruments. - Identification of organic compound.		

Unit	Contents	Hours
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, 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	12
2	**Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases. Gas chromatography: Principles, instrumentation, derivatization, head space sampling, columns for GC, detectors, quantification. 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
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 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.	12
Total		60

Text books 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: Pharmaceutical Validation	**Course Code. PHQA C202**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Concept of validation, qualification and calibration.		
Course outcome: • The concepts of calibration, qualification and validation. • Process and validation of different dosage forms. • Validation of analytical method for estimation of drugs.		

Unit	Contents	Hours
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. **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. **Qualification of analytical instruments:** UV-Visible spectrophotometer, FTIR, GC, HPLC, LC-MS. **Qualification of laboratory equipments:** Hardness tester, Friability test apparatus, tap density tester, Disintegration tester, Dissolution test apparatus **Validation of Utility systems**: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.	12
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. 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. **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 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; Patent infringement meaning and scope. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.	12
Total		60

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

Course: Audits and Regulatory Compliance	**Course Code. PHQA C203**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: cGMP regulations, auditing of different departments.		
Course outcome: To understand the importance of auditing and understand the methodology of auditing. Preparation of auditing report.		

Unit	**Contents**	**Hours**
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, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging.	12
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

Text books and reading materials:

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

Course: Pharmaceutical Manufacturing Technology	**Course Code. PHQA C204**	
Semester: II	**Credits:** 04	**Core course**
Pre-requisite: Knowledge of Pharmaceutical industry development, concept of quality by design.		

Course outcome:

- 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 manufacture.

Unit	Contents	Hours
1	**Pharmaceutical industry developments:** Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing. **Plant layout:** Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. **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). **Advanced sterile product manufacturing technology:** Area planning & environmental control, wall and floor treatment, fixtures and machineries, personnel flow, utilities & utilities equipment location, engineering and maintenance. **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). Lyophilization technology: Principles, process, equipment.	12
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). **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 worthiness of package, Stability aspects of packaging. Evaluation of stability of packaging material	12
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

Text books 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, 1st Edition. 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: Pharmaceutical Analysis & Quality Assurance Practical II	**Course Code. PHQA P205**	
Semester: II	**Credits:** 06	**Core course**
Pre-requisite: Principle of analytical instruments.		
Course outcome: - Experiment knowledge in handling of instruments. - Knowledge of quality control testing.		
Experiment		Hours/Week : 12
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.		

THIRD AND FOUTH SEMESTER (FOR ALL THE SPECIALIZATION)

(Non University examination)

Course: Research Work (Literature survey)	**Course Code. PHARC301**	
Semester: III	**Credits:** 20	**Core course**
Pre-requisite: Literature study.		
Course outcome: - Knowledge to carry out research work. - Knowledge of literature review. - Presentation of research work. - Group discussion and viva.		
Contents		**Hours:33**
The research topic will be selected from recent advancement in Pharmaceutical field under the supervision of concerned guide approve by the Department. The student will present their literature/research work in present of internal and external expert. The student will have a group discussion and viva-voce in their literature/research work in present of internal and external expert.		

Course: Research Work (Experimental work).	**Course Code. PHARC401**	
Semester: IV	**Credits:** 20	**Core course**
Pre-requisite: Literature study.		
Course outcome: - Knowledge to carry out research work. - Knowledge of literature review. - Presentation of research work. - Group discussion and viva.		
Contents		**Hours: 35**
Based on the literature survey carried out in semester III the student will carry out experimental work under the supervision of concerned guide approve by the Department. The student will present their experimental outcomes, results and discussion in present of internal and external expert. The student will have a group discussion and viva-voce in their experimental work in present of internal and external expert.		
Co-curricular Activities (Attending Conference, Scientific Presentations and other Scholarly Activities)		**Credit: 04**