ANDHRA UNIVERSITY

AU COLLEGE OF PHARMACEUTICAL SCIENCES

# MASTER OF PHARMACY

Regulations and Syllabus Four semester pattern

With effect from 2013-14

**1. General Regulations:**

1.1 The degree of Master of Pharmacy of the Andhra University will be conferred on a candidate who has satisfied the following conditions:

The candidate must have passed the B.Pharm. degree examination of this University or B.Pharm. degree examinations of any other University recognized by the Academic Council as equivalent thereto in First or Second class; and must have qualified in any entrance examination, if prescribed.

1.2 The candidate should have undergone a regular course of study as prescribed hereunder extending over a period of four semesters, ordinarily consecutive, and satisfied the academic requirements as prescribed hereinafter. The course of instruction and periods of study shall be as given in the scheme of instruction and in the syllabus mentioned in the Annexures – I & II.

1.3 The subjects of specializations for Master of Pharmacy Course shall be as follows:

I. Pharmaceutical Analysis and Quality Assurance

II. Pharmaceutical Chemistry

III. Pharmaceutical Technology

IV. Pharmaceutical Biotechnology

V. Pharmacology

VI. Pharmacognosy and Phytochemistry

VII. Pharmaceutical Management and Regulatory Affairs

VIII. Pharmaceutical Analysis and Quality Control

IX. Pharmaceutics

X. Industrial Pharmacy

XI. Pharmacy Practice

1.4 Every candidate shall put the attendance for not less than 75% of the total number of working days in each semester to be eligible to sit for the semester end examination. If a student represents the University officially at games, sports or other officially organized extra-curricular activities, it will be deemed that he/she has attended the college on the days he/she is absent for this purpose.

**2. Regulations for Evaluation:**

2.1 Evaluation of performance of all candidates who pursue the above courses shall be as per the scheme of examination enclosed. The course shall be on the basis of the semester end examinations. In theory, 20% of the marks are earmarked for sessional (internal; there have to be two examinations of each theory and consider the average marks of two examinations) examination and 80% marks are earmarked for the semester end examination. In practical, 20% of the marks are earmarked for continuous evaluation and record, and 80% are earmarked for the semester end examination. The marks certificate issued to the candidate by the University shall show separately the sessional marks in practicals and the semester end examination marks.

2.2 Regulations concerning semester-end examinations of the first two semesters:

a) There shall be one semester end examination in each theory course based on the question paper set by an external paper setter and there shall be double valuation. There shall be one semester end examination in each practical course as per the scheme of examination and valuation shall be done jointly by two examiners, one external and one internal.

b) In order to eligible to be appointed as an internal examiner for the semester end examination in the respective specialization, a teacher shall have M. Pharm. or Ph.D. in the respective specialization with at least three years of M.Pharm teaching experience for the course concerned.

c) If the disparity between the marks awarded by the both the examiners is 20% or less, the average mark shall be taken as the marks awarded in the paper. If the disparity happens to be more than 20, reference to a third examiner will be made whose valuation shall be final.

**3. Results:**

3.1 A candidate shall be declared to have passed the examination held at the end of each semester if obtains not less than 40% in the each theory and 50% in each practical, seminar, comprehensive viva, thesis and thesis viva-voce and 50% in the aggregate of all examinations including internal assessment marks in practical.

3.2 A candidate who has successfully completed the examination in a course by securing not less than 50% of marks shall not be permitted to retake the examination in that course.

3.3 A candidate who fails to secure 50% of marks on the aggregate but secures 50% or more in some courses and between 40-49% in the other courses, he/she shall be required to retake the semester and supplementary examination in one or more of the courses in which he/she secures less than 50% of marks as per his/her choice to

satisfy the requirement of 50% aggregate.

3.4 Candidates who secure not less than 70% of the total marks including the sessional marks in practicals in all the examinations of the four semesters taken together shall be declared to have passed in First Class with Distinction. Candidates who secure not less than 60% shall be declared to have passed in First Class. All the remaining successful candidates shall be declared to have passed in Second Class (50%). However, any candidate who has not passed all the papers relating to an examination of any semester at First appearance shall not be declared to have passed in First Class with Distinction nor eligible for the award of any medals or prizes and is not eligible to receive a rank certificate.

**4. M. Pharm. III & IV Semester Evaluation Pattern:**

4.1 Evaluation of the M.Pharm III Semester Mid-term project review and seminar on selected research topic will be done by the research guide and external examiner within the college.

4.2 A candidate shall submit four copies of his/her thesis either printed or typed, embodying the results of research work done by him under direction of an approved research director following the specific guidelines as stipulated under Section 5. All the candidates must submit their thesis within the prescribed date as per the academic calendar.

4.3 The thesis submitted by the candidate shall be examined by a Board of Examiners consisting of an External Examiner and the research director and shall have to be approved after holding a viva voce examination to test the knowledge of the candidate in the subject. The thesis will be evaluated independently by the external

examiner and research director and in case the difference between examiners is more than 20%, the thesis shall be sent to a second external examiner whose award shall be the final. The viva-voce examination will be jointly conducted both by the external examiner and research director. A candidate can re-submit the thesis in a revised form after further work, if required to do so.

4.4 A candidate desires of improving his/her class shall take either or both of the first two semesters as a whole.

5. Guidelines for writing the thesis

The thesis should have the following pages in order:

5.1 Title page highlighting the title, name of the candidate, reg. no., guide name, college name and month and year of submission.

5.2 The inner title page containing the same details on white background.

5.3 Certificate from the Head of the institution

5.4 Certificate from the Research Director

5.5 Certificate from the ethical committees for approval of study, if any

5.6 Declaration by the student

5.7 Acknowledgements

5.8 Index highlighting chapter titles and sections titles

5.9 Index for tables, figures and plates, if any

5.10 Abbreviations and symbols

5.11Materials used in the investigation with their procurement details like name of the company, batch number etc.

5.12 Equipment used in the study with the model number and other details

5.13 The thesis should contain the following chapters:

a) Aim and objectives of the investigation b) Introduction and

literature survey

c) Description: Methods and Materials, etc. d) Experimental work

e) Results and discussion

f) Summary and conclusions

g) References (The references may be included at the end of each chapter or at the end of the thesis according to the convenience)

The thesis should be typed in a suitable font like times new roman, bookman old style in 12 font size with 1.5 line spacing from the beginning of the thesis including titles to the chapters and sections. Bold font may be used wherever necessary. The students are expected to follow scientific grammar for writing *in vivo* etc. which should be in italics.

The citation of references should be done carefully by citing the complete reference i.e. name of all the authors. Usage of et al. is not allowed in the citation of reference. The students are expected to give the primary references rather than secondary or higher levels of references. The presentation of reference must be in Vancouver style.

The examiners of thesis evaluation are expected to verify all this and appropriate corrections are to be made before conducting the viva-voce examination.

6. The eligibility of a teacher for guiding the M.Pharm III and IV semester project is as follows:

6.1 The teacher must have M.Pharm/Ph.D. in the respective specialization with an experience of minimum 3 years of Post Graduate teaching in the respective specialization.

6.2 The eligibility of such teachers qualified for guiding M.Pharm projects must be ratified by the Board of Studies before commencement of M.Pharm guidance.

6.3 The recognised M.Pharm guides are not eligible to guide more than 6 students in one academic year including joint guidance.

7. Regulations for pursuing M.Pharm III and IV Semester project

7.1 Students desirous of pursuing M.Pharm III and IV semester projects outside college are required to get the approval from the college before one month from the commencement of the project work. The research work can be carried out in a GMP compliant industry (as approved by WHO, USFDA etc.) and Central research laboratories like IICT, CDRI, NIH etc. or DSIR and Drug Control Administration recognized laboratories. A certificate to that effect must be incorporated in the M.Pharm thesis indicating the duration of stay. If the duration of stay is less than nine months the remaining period of stay in the college should be certified by the research supervisor and the Principal.

7.2 All the students should present a seminar on the objectives of their work, work plan, etc. within one month from the commencement of the project. The students should attend a mid-term review seminar in the presence of a committee consisting of one external examiner, research director. The suggestions made by the committee are to be taken into consideration for further work and should be presented in the thesis.

7.3 No code names or numbers are allowed to be written in the thesis for the materials used in the project.

## II. PHARMACEUTICAL TECHNOLOGY (S.No III as per AU syllabus)

I/II I Semester

| Course No. | | No. of hours/week | | Max. Marks | Questions to be answered in the semester end examination |
|---|---|---|---|---|---|
| | | Theory | Practical | | |
| 3101 | Biostatistics Theory (Common for all specializations) | 5 | | 100 | 5 out of 7 |
| 3102 | Biopharmaceutics and Pharmacokinetics Theory | 5 | - | 100 | 5 out of 7 |
| 3103 | Biopharmaceutics and Pharmacokinetics Practical | -- | 10 | 100 | |
| 3104 | Advanced Physical Pharmaceutics Theory | 5 | -- | 100 | 5 out of 7 |
| 3105 | Advanced Physical Pharmaceutics Practical | -- | 10 | 100 | |
| 3106 | Comprehensive viva | | | 50 | |
| | **Total** | | | **550** | |

I/II II Semester

| | | | | | |
|---|---|---|---|---|---|
| 3207 | Modern Analytical Techniques Theory Common for all specializations | 5 | | 100 | 5 out of 7 |
| 3208 | Quality Assurance and Drug Regulatory Affairs Theory Common for all specializations | 5 | -- | 100 | 5 out of 7 |
| 3209 | Novel Drug Delivery Systems Theory | 5 | -- | 100 | 5 out of 7 |
| 3210 | Product Formulation and Development Theory | 5 | -- | 100 | 5 out of 7 |
| 3211 | Product Formulation and Development Practical | -- | 10 | 100 | |
| 3212 | Comprehensive Viva | | | 50 | |
| | Total | | | 550 | |

II/II III Semester

| | | | | |
|---|---|---|---|---|
| 3312 | Seminar on the objectives and work plan of the proposed project to be completed within one month from the commencement of the project | | | 50 |
| 3313 | Mid-term project review at the end of third semester | | | 50 |
| 3314 | Seminar on Selected research topic | | | 100 |
| | Total | | | 200 |

II/II IV Semester

| | | | | |
|---|---|---|---|---|
| 3415 | Thesis Evaluation | | | 100 |
| 3416 | Thesis Viva-voce | | | 100 |
| | Total | | | 200 |
| | Grand total | | | 1500 |

## 3 PHARMACEUTICAL TECHNOLOGY

### Course no.3101: Bio Statistics (Paper Common for All Specialisations)

Course Nos.: 1101, 2101, 3101, 4101, 5101, 6101, 7101, 8101, 9101, 10101 and 11101

Tests of significance: Testing hypotheses- principle and applications of Z, t-, F- ratio and chi- square tests in pharmaceutical and medical research.

Analysis of Variance: 1-way, 2-way and 3-way classification.

Non-parametric tests: sign test, Wilcoxon signed rank test, Wilcoxon rank sum test, Kruskal

Wallis test, run test and median tests.

Design of Experiments: Principles of randomization, replication and local control; CRD, RBD, LSD- their applications and analysis of data; Factorial Experiments-Principles and applications; Probit analysis-Dose-effect relationships, calculation of $LD_{50}$, $ED_{50}$

Regression and correlation: Method of least squares, Correlation Coefficient, rank correlation and multiple regressions.

### Course No.3102: Biopharmaceutics and Pharmacokinetics
### Theory

1. **Drug Absorption, Distribution, Biotransformation and Excretion:** Absorption of drugs, Significane of metabolisms involved in the absorption and bio transformation of drugs. Effects of Physico-Chemical, Pharmaceutical and Biological Factors on absorption, distribution, metabolism and excretion. Renal and Non renal Excretion, concept of clearance
   10 hr

2. **Bioavailability and Bioequivalence of Drug Products:** Factors-Assessment-Experimental designs and protocol for bioavailability and bioequivalence studies as per CDSCO, Schedule Y guidelines and GCP guidelines, in-vitro and in-vivo

correlation of bioavailability, methods to enhance bioavailability. Statistical considerations in comparative bioavailability studies. 8 hr

3. **Drug Interactions:** Interaction of drugs with food, Classification of food drug interactions, models for estimation of pharmacokinetic parameters in food drug interaction studies. Effect of alcohol, smoking on drugs. Drug- Drug Interactions: factors contributing to drug interaction s, Mechanisms of drug interactions with emphasis on pharmacokinetic interactions. 8 hr

4. **Pharmacokinetics:** Basic consideration, pharmacokinetic models, Pharmacokinetic Parameters, Compartment modeling: One compartment model- IV bolus, IV infusion, Extra• vascular; Multi Compartment models; Two compartment model- IV bolus, IV infusion, Extra• vascular. Application of pharmacokinetics in new drug development and designing of dosage forms and novel drug delivery systems. Kinetics of multiple dosing- dosage regimens-loading and maintenance doses of sustained release and continuous blood levels. Concepts of software used in the pharmacokinetic analysis Win Nonlin® and Kinetica. 10 hr

5. **Non-linear and Clinical Pharmacokinetics:** Concepts of linear and non-linear pharmacokinetics, Michaelis-Menten Kinetics characteristics. Basic kinetic parameters, possible causes of non-induction, non-linear binding, non-linearity of pharmacological responses. 7 hr

6. **Time Dependent Pharmacokinetics:** Introduction, classification, physiologically i nduced time dependency, Chronopharmacokinetics. 6 hr

7. **Non Compartmental Analysis based on Statistical Moment Theory:** Statistical Moments, Bioavailability, Clearance, half- life, Absorption kinetics, Apparent volume of distribution, fraction metabolites, Predicting Steady State Concentrations, Predicting time to steady state. 7 hr

8. **Clinical Pharmacokinetics:** Altered Kinetics in Paediatrics, Geriatrics, Kinetics in GI, Liver, Cardiac, Renal and Pulmonary Disease State.

**Books:**

1. Pharmacokinetics, Milo Gibaldi, 2nd Ed.
2. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel, 5th Ed.
3. Biopharmaceutics and Clinical Pharmacokinetics, Robert E. Notari, 4th Ed.
4. Modern Pharmaceutics, Gilbert S. Banker, Christopher T. Rhodes, 4th Ed.
5. Clinical Pharmacokinetics and Pharmacodynamics – Concepts and Applications, Malcolm

   Rowland and Thomas N. Tozer, 4th Ed.
6. Drug Disposition and Pharmacokinetics, Stephen H. Curry, 3rd Ed.
7. Current concepts in the Pharmaceutical Sciences-Biopharmaceutics, James Swarbrick
8. Current concepts in the Pharmaceutical Sciences-Dosage Form Design and Bioavailability, James Swarbrick

**Course No.3103: Biopharmaceutics and Pharmacokinetics-Practical**

1. Effect of particle size on the drug dissolution using drugs like aspirin, salicylic acid, nitrofurantoin
2. Effect of surfactant on the drug dissolution using drugs like sulfamethoxazole, nefidipine.
3. Effect of ointment base on drug diffusion using agar plate method and diffusion membrane.
4. Determination of protein binding effect on drugs by using dialysis sac method using protein bound drugs.
5. Improvement in the dissolution of drugs by solid dispersion, cyclodextrin complexation etc.
6. To study the effect of sink condition on dissolution of drugs using discriminatory dissolution medium
7. To study the effect of permeation enhancers on drug diffusion using Franz-diffusion cell using suitable biomembranes.
8. Calculation of pharmacokinetic parameters using reported data.
9. Calculation of bioavailability and bioequivalence from the given data using different approaches.
10. In vitro-in vivo correlations using experimental data.
11. Preparation of experimental protocols for carrying out pharmacokinetic, pharmacodynamic, bioavailability and bioequivalence studies using suitable experimental designs for the given data.

**Course No.3104: Advanced Physical Pharmaceutics Theory**

1. Solubilisation of drugs in aqueous media:

Solubility, ideal solubility, activity coefficient, Hildebrand solubility approach, solubility parameter, estimating solubility and dissolution rate, apparent solubility enhancement from different solid phases, pH control, salt formation, buffers, cosolvents, dependence of solubilisation on solute properties, dependence of solubilisation on cosolvent properties, multiple cosolvents, surfactants, complexation, self-association and stacking complexation, inclusion complexes, combination of pH and complexation **8 hours**

2. Solubilising excipients in pharmaceutical formulations:

Introduction, oral formulations(water soluble organic solvents, surfactants, water insoluble organic solvents, water insoluble solids, cyclodextrins, microemulsion oral formulations); injectable formulations (water soluble organic solvents, surfactants, cyclodextrins, phospholipids, emulsions), oily injectable formulations and transdermal formulations. **8 hours**

3. Granulation and tablet characteristics: Granule formation and structure, particle size measurement and interpretation, shape determination, surface area, densities and packings, granule strength and friability, electrostatic properties, flow properties, ease of consolidation and mechanisms; control of tablet characteristics, such as , size and shape, tablet thickness, hardness, friability, disintegration, weight variation and content uniformity. **8 hours**

4. Compression: properties of tablets influenced by compression(elastic deformation, plastic deformation, brittle fracture, micro squashing, density and porosity, hardness and strength, specific surface, disintegration, dissolution;) measurement of compressional force, energy expenditure, transmission of force. Consolidation, role of moisture, compression and consolidation under high loads, effect of friction, force distribution, development of radial force die wall lubrication, Heckle plots, energy involved in compaction, force-displacement curves, instrumentation of tablet machines, single station presses, multistation presses and signal processing. **8 hours**

5. Stability: physical, chemical and microbiological stability, quantitation of rate of degradation(zero order kinetics, first order kinetics, shelf life calculation), factors influencing reaction rate(temperature, pH, ionic strength, dielectric constant), methods of stabilizing dosage forms. **8 hours**
6. Stability testing: ICH guidelines for stability testing, selection of batches and

container closure systems, matrixing and bracketing design, storage conditions and testing frequency, climatic zones concept, stability testing in different stages of drug product life cycle, specific stability tests for various dosage forms. Photo stability studies, expiration dating, overages calculation. **8 hours**

7. Polymers: Definitions, molecular weight averages, determination of molecular weight from solution viscosity, polymers as thickening agents, polymers in solutions, preparing polymer solutions, thermodynamics of polymer solutions, gel formation, coacervation and microencapsulation, Pharmaceutical application of polymers. **8 hours**

8. Hydrogels (over view, synthesis, structure and properties, swelling ratio and water content, use in drug delivery, mucoadhesive hydrogels, sensitivity to pH changes, Polyethylene oxides), lipids(physical and chemical properties, applications in drug delivery), Biodegradable polymers as drug carriers (overview, factors affecting selection of polymer, factors affecting drug release, degradation mechanisms, polyesters, polyanhydrides). **8 hours**

Text Books:


1. Encyclopedia of Pharmaceutical Technology, edited by James swarbrick, Third Edition, Informa Healthcare publishers.
2. Pharmaceutical Dosage Forms, Tablets, Volume II, edited by Herbert A. Lieberman and Leon Lachman; Marcel Dekker, Inc.
3. The Theory and Practice of Industrial Pharmacy, Fourth Edition, edited by Roop K Khar, S P Vyas, Farhan J Ahmad, Gaurav K Jain; CBS Publishers and Distributors Pvt. Ltd.
4. Martin's Physical Pharmacy and Pharmaceutical Sciences, Fifth Edition, edited by Patrick J. Sinko, BI Publications Pvt. Ltd.


**Course No. 3105: Advanced Physical Pharmaceutics - Practical**

1. Estimation of aspirin in Disprin Tablets
2. Stability studies on commercial tablets containing drugs like aspirin over two months at room temperature, 37°C and 45°C.
3. Stability studies on suspensions containing drugs like aspirin over 20 days at room temperature, 37°C and 45°C.
4. Determination of molecular weight by viscosity method, by Mark- Houwink equation for gelatin, methyl cellulose and polyvinyl alcohol.
5. Effect of temperature on the decomposition of bromophenol blue at three temperatures and two pH values
6. Effect of pH on the decomposition of aspirin.
7. Preparation of granules, drying by conventional dryer and fluidized bed dryer and comparing the granules by their flow properties.
8. Preparation of tablets by two different sets of granules with different flow properties; and finding the effect of variability in flow rate of granules on the weight variation of resultant tablets using drugs like Metronidazole.
9. Drawing the coacervation curve on a three component system graph (gelatin, sodium sulphate and water) for gelatin, sodium sulphate system.
10. Determination of bloom strength of gelatin.
11. Preparation of liquid paraffin emulsion in a colloid mill; determining the effect of duration of milling (up to 10 minutes), on the heat developed in the emulsion (temperature) and on the extent of micronization (globule size analysis).
12. Visiting a pharmaceutical industry and observing the modern equipment used in production and quality control.
13. Carrying out accelerated stability studies of disperse systems using freeze thaw technique and centrifugation techniques and prediction of shelf life.

**Course no.3207: Modern Analytical Techniques (Paper common for all Specialisations)**

A study of the principals, instrumentation and applications in pharmaceutical research of the following

Chromatography: HPLC and GC

Spectroscopy: IR, FTIR, NMR, Mass spectrometry, $^{13}$CNMR,

Differential thermal analysis (DTA), Differential scanning calorimetry, X-ray diffraction analysis.

Radiometric techniques

## 3208: Quality Assurance and Drug Regulatory Affairs

(Common paper for all specializations)

1. The concepts of quality assurance, GMP, TQM- Principals and objectives, process control, sources and control of quality variation, statistical quality control, in process quality control, dosage forms control, specifications.

2. GMP- A study of Schedule M of Drugs and Cosmetics Act, WHO specifications, US FDA guidelines. The study shall include special emphasis on premises, personnel, sanitation, equipment, manufacturing operations and documentation.

3. Validation: Types of validation, protocol for process validation, cleaning validation, validation of air handling, validation of equipment and facilities in sterile and non-sterile areas. Analytical method validation

4. Ware housing for materials and products; complaints and recalls- evaluation of complaints and recall procedures; finished product release-Quality review-Quality audits- Handling of returned goods, recovered materials and reprocessing.

5. Documentation related to Product Development, standard operating procedures, standard test procedures, cleaning methods, quality control documents, batch release document, distribution records, complaints and recalls records, retention of records.

6. Regulatory Affairs - Drugs and Cosmetic Act, DPCO, Intellectual Property Right and Patent laws.

7. New Drug Development and Approval Process:

Investigational New Drugs (IND), New Drug Applications (NDA), Supplemental New Drug Application (SNDA). ICH requirements for registration of Pharmaceuticals.

**Course No. 3209: Novel Drug Delivery Systems**

1. Introduction to Parenteral Drug Delivery: Basic requirements of Parenteral Controlled release products; release profiles and biofate of intravenously administered systems and intramuscularly administered systems. **4 hours**

2. Targeted Drug Delivery: Concepts of Targeting, Rationale of Drug Targeting, Carriers, Passive Targeting, Inverse Targeting, Active Targeting, First, Second, and Third order Targeting, Ligand Mediated Targeting, Physical Targeting, Dual Targeting, Double Targeting, Combination Targeting and problems associated with Targeted Delivery Systems. **4 hours**
3. Targeting to the Brain, Targeting to the tumour and Targeting to the colon. **4 hours**
4. Sustained release formulations (encapsulated slow release granules, tableted slow release granulations, matrix tablets, drug complexes, ion activated systems, pH independent systems, altered density systems, colonic release systems). **8 hours**
5. Controlled release formulations (osmotic pressure activated systems, hydrodynamic pressure activated systems, hydrodynamically balanced systems, the synchron system, the Penn kinetic system and bio adhesive system); *In vitro* and *in vivo* product evaluation and testing. **10 hours**
6. Design and Evaluation of Novel drug delivery systems: Ocuserts, transdermal drug delivery systems, *In situ* gelling systems, stimuli-sensitive "smart" polymers as drug delivery systems, glucose-responsive insulin delivery, polymer drug conjugates. **10 hours**
7. Novel carriers for controlled targeted drug delivery: Liposomes, Niosomes, Ethosomes, Transferosomes, Virosomes, polymeric nanoparticles, solid lipid nanoparticles, inorganic nanoparticles. **10 hours**

8. Supra molecular systems, micelles/reverse micelles, lipoproteins, liquid crystals, resealed erythrocytes, carbon nanotubes, self-emulsifying drug delivery systems, Aquasomes, DQA somes, nanosuspension, nanocapsules **10 hours**

Books:


1. Targeted and Controlled Drug Delivery, Novel Carrier Systems by S. P. Vyas and R. K. Khar, CBS Publishers and Distributors Pvt. Ltd, First Edition 2012
2. Lachman/Lieberman's The Theory and Practice of Industrial Pharmacy, Fourth Edition, Editors: Roop K Khar, S P Vyas, Farhan J Ahmed, and Gaurav K Jain, CBS Publishers and Distributors Pvt ltd, 2013


**Course No. 3210: Product Formulation and Development**

1. **Pharmaceutical Product Development:** Introduction to product development. Goals of preformulation, preformulation drug characterization in a structured program for different dosage forms. Influence of the parameters like intrinsic solubility, dissociation constant ($pK_a$), salts, solvents, partition coefficient, dissolution, polymorphism, particle size, shape and surface area, bulk density, flowability, hygroscopicity, stability indicating assays, and stability. 10 hr

   **Production, scale up techniques and quality control aspects of large scale manufacture of the following dosage forms**

2. **Oral Liquids: Monophasic Systems, Solutions:** Vehicles, Additives Used in Formulation of Solutions, Oral Solution Products, Equipment, and Compounding, Filling of Liquids.

   **Biphasic Systems: Suspensions:** Formulation and Manufacture of Suspension, Evaluation of Stability.

   **Emulsions:** Microemulsions, Multiple Emulsions, Nanoemulsions Theories of Emulsification, Preparation of Emulsion, Equipment's Used for Emulsification, Stability, evaluation of Emulsions and their applications in drug delivery. 8 hr

3. **Tablets:** Types of Tablets, Components of a Tablets, Excipients, Granulation Methods, Mechanisms and Equipment, Processing Problems of Tablets, working of tablet Machines.

   **Tablet Coating:** Comparison of different coating techniques procedures. Problems involved in each coating and trouble shooting. Equipment used for sugar coating, film coating, aqueous film coating, compression coating, enteric coating.

Novel Drug Delivery. Technologies: Mouth Dissolving Tablets (Orasolv, Durasolv and Zydis Oral Fast Dissolving Dosage Forms), Oral Controlled Release Drug Delivery Systems, Osmotically Controlled release dosage forms, Nanocrystal Technology, IDD Formulations, Self-Repairing Tablets, Effervescent Tablets, Dissocubes. 10 hr

4. **Capsules and Microencapsulation**: Types of gelatin and excipients used in the preparation of soft and hard gelatin capsules. Related advantages of soft and hard gelatin capsules. Methods and equipment involved in the manufacturing of soft and hard gelatin capsules. Powder Filling, Choice of Excipients, Non Powder Filling, Storage, packaging and Stability Considerations of hard gelatin capsules.

   **Microencapsulation:** Methods and Applications of Microencapsulation. 10 hr

5. **Parenteral Products:** Routes of administration, categories of Parenteral Products based on volume, formulation additives, development of Parenteral Products, Important parameters for Parenterals development, manufacturing of Parenterals, Quality Control requirements for Parenterals. 7 hr

6. **Opthalmic Products:** Absorption of drugs in the Eye, product development of ophthalmic products, general safety considerations, conventional ophthalmic dosage forms, Packaging and Storage, approaches for efficient drug delivery.
   Ophthalmic implants and shunts, Inserts, Non erodible ocular inserts, Erodible Ocular inserts, Contact lens, recent development of contact lenses ( bandage lenses, therapeutic contact lenses in drug delivery, Silicone hydrogel based lenses), Collagen Shields and Implants, An anopthalmos and orbital implants, glaucoma shunts, particulate based drug carriers. 6 hr

7. **Topical Products:** Structure of skin, Mechanisms of skin penetration, Percutaneous Absorption, Design of topical drug products (Gels, Liquid-Preparations, powders, Ointments), Novel Drug Delivery Systems for topical Drug Delivery (Micro emulsion, liposome, Transferons, Ethosones,Hydrogels), Evaluation of topical dosage forms.
   Rectal Products: Advantages, Rectal preparations. 6 hr

8. **Pharmaceutical Packaging:** Packaging Materials, Glass, Plastic, Metals, Rubber, Evaluation of Packaging materials. Special problems of container product interactions, pharmacopoeial specifications tests and standards for packaging materials. 6 hr

**Books:**


1. Lachmen/Liberman - Theory and Practice of Industrial Pharmacy, Roop K. Khar, S.P. Vyas, Farhan J. Ahmad, Gaurav K. Jain, 4th Ed.
2. Pharmaceutical Dosage Forms and Drug Delivery Systems, Loyd V. Allen Jr., Nicholas B. Popovich, Howard C. Ansel, 9th Ed.
3. Aulton's Pharmaceutics – The Design and Manufacture of Medicines, Michael E. Aulton, 3rd Ed.
4. Remington – The Science and Practice of Pharmacy, 20th Ed.
5. Encyclopedia of Pharmaceutical Technology, James Swarbrick, 3rd Ed.
6. Pharmaceutical Dosage Forms – Tablets Vol 1 to 3, A. Liberman, Leon Lachman and Joseph B. Schwartz
7. Pharmaceutical Dosage Forms – Disperse Systems Vol 1 to 3, H.A. Liberman, Martin, M.R. and Gilbert S. Banker.
8. Pharmaceutical Dosage Forms – Parenteral Medication Vol 1 & 2, Kenneth E. Avis and H.A. Libermann.


**Course No. 3211: Product Formulation and Development-Practical**

1. Preformulation studies of drugs like aspirin, sulfamethoxazole, nefidipine etc. using different excipients as per ICH guidelines.
2. Preparation and evaluation of matrix controlled drug delivery systems using suitable drugs like theorphylline, diclofenac, aceclofenac.
3. Formulation and evaluation of oral disintegrating tablets using suitable drugs.
4. Formulation and evaluation of transdermal patches
5. Preparation and evaluation of microcapsules using techniques like coacervation-phase separation, ionic gelation method.
6. Formulation of dry syrup and its evaluation.
7. Formulation and evaluation of gastric floating drug delivery system
8. Comparison of different gels using diclofenac/aceclofenac like drugs
9. Formulation of liposomes and their characterization using microscopy.
10. Formulation and evaluation of suspensions containing suitable drugs.
11. Studies on effect of emulsifying agents on the stability of emulsion.