

# **I - M.PHARM**

## **PHARMACEUTICS**

**GOAL:** To produce a competent Industrial Pharmacist.

**OBJECTIVE:** Upon completion of the course, the candidate shall have:

- ❖ An understanding of the concept and design of various pharmaceutical dosage forms
- ❖ The ability to formulate and evaluate various dosage forms
- ❖ The ability to work independently and as a member of the team
- ❖ The ability to plan his / her work for efficient use of time and resources
- ❖ The ability to identify the cause and to solve the problem
- ❖ The ability to think and evaluate scientifically and critically

**Teaching/ Learning Activities:**

1. **Journal Club:** weekly, Journal club meetings to be held to discuss the recent development in the subject published in the national and international journals.
2. **Seminars:** Seminars (5-6 in a year) shall be arranged from experts in the field.
3. **Industrial visits:** Visits to pharmaceutical industries to understand shop floor activities.
4. **Conferences and meetings:** Staff and students are to be encouraged to participate in seminars, workshops and conferences in the area of this subject.

### **TITLE OF PAPERS**

**Paper I: Modern Pharmaceutical Analysis**

**Paper II: Preformulation and Production Management**

**Paper III: Biopharmaceutics and Pharmacokinetics**

**Paper IV: Advances in Drug Delivery Systems**

**Appendix I: List of Required Equipments/Instruments:**

The following common and specialized equipments/instruments, and charts are to be provided by the course conducting department/institution.

**Common Equipments:**

Single pan balances (analytical): 02

Single pan balances (electronic/digital): 02

Hot air oven: 02

Magnetic stirrers: 08

Mechanical stirrers (1,2,5 ltrs): 04

Double pan balances (analytical): 01

Thermostatic digital water baths: 02

Distillation assembly: 5 ltrs. capacity

Hot plates: 04

Refrigerator: 01

TLC Kit and plates

Sieves of different mesh sizes (10, 12, 16, 22, 44, 60, 80, 120): 2 each

**Special Equipments:**

Monsanto & Pfizer hardness testers: 02 each

Disintegration test apparatus: 02

Dissolution test apparatus (single jar): 04

Dissolution test apparatus (6/8 Jars):01

UV-Visible spectrophotometer (Double beam): 01

Tablet compression machine single station: 01

Rotary tablet compression machine (5-10 station): 01

Bath sonicator: 01

Table top centrifuge: 01

Capsule filling machine: 01

Stability chamber: 01

Coating & Polishing pan: 01

Vacuum pump with accessories: 01

Pocket / pen pH meters: 02

Vacuum filtration units: 01

Rotary evaporator: 01

Rotary shaker: 01

Filtration sets: 02

Brookefield Viscometer : 01

### **Desirable**

High performance Liquid Chromatography (HPLC): 01

Computers with UPS and a printer: 04

Freeze dryer: 01

### **Glassware**

Common laboratory glassware for regular experiments: Beakers, measuring cylinders, conical flasks, RB & FB Flasks (1& 2 lt. capacity), filtration unit, distillation unit, thermometers 110 & 360 degree Celsius etc..

### **Chemicals and Reagents**

Common pharma grade pure drug samples, polymers and other adjuvants, solvents etc. for the purpose of formulation required for the regular practicals.

## **PAPER II: PREFORMULATION AND PRODUCTION MANAGEMENT**

**GOAL:** To train the students to be on par with the routine of Industrial activities in R&D, F&D, IPR, RA and Production

**OBJECTIVES:** The candidates shall be able to:

- Confidently handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceutical formulations.
- Assist in Regulatory Audit process.
- To establish safety guidelines, which prevent industrial hazards.

### **COURSE DESCRIPTION**

#### **THEORY**

**50 Hours ( T:2Hours/Week)**

#### **1. PREFORMULATION STUDIES**

**06 Hrs.**

**(Marks allotment : 15 )**

Introduction, Consideration of physico-chemical properties of new drug molecules for different dosage forms. Aqueous solubility, organic solubility, intrinsic solubility, methods of enhancement of solubility-surfactants, pH, co-solvency, solid dispersion, complexation. Techniques for the study of crystal properties and polymorphism - DSC, TGA, PXRD, Optical microscopy, hot stage microscopy. Excipient compatibility studies, Preformulation stability studies.

#### **2. COMPACTION, COMPRESSION, AND CONSOLIDATION**

**05 Hrs.**

**(Marks allotment : 15 )**

Compression, consolidation, decompression, compaction of powders with a particular reference to distribution and measurement of forces within the powder mass undergoing compression. Influence of compression force on the properties of tablets. Effect of particle size, moisture content, lubrication etc. on strength of tablets. A brief study on formulation aspects of tablets such as mouth dissolving tablets, dispersible tablets, chewable tablets and medicated lozenges.

**3. QUALITY BY DESIGN, DESIGN OF EXPERIMENTS, FORMULATION BY DESIGN** **04 Hrs.**

**(Marks allotment : 10 )**

USFDA's view of QbD, Elements of QbD, QbD tools, Design of experiments – Methods and applications Optimization techniques: Concept of optimization, optimization parameters, classical optimization. Statistical design (Simplex and factorial design)

**4. STABILITY TESTING - DRUGS AND DOSAGE FORMS** **04Hrs.**

**(Marks allotment : 10 )**

Solid state drug stability, dosage form stability, accelerated stability testing, shelf life calculations, strategies for prolonging shelf life. Effect of packaging materials on dosage form stability. Basic principles of ICH, stability testing of new drug substance and formulations, photostability testing and oxidative stability, role of containers in stability testing. WHO stability guidelines.

**5. cGMP, ISO 9000 & 14000 SERIES, VALIDATION** **06 Hrs.**

**(Marks allotment : 20 )**

ISO 9000 & 14000 series, guide to Pharmaceutical manufacturing facilities, cGMP considerations with emphasis on documentation practices.

Validation- General concepts, types, approaches to validation and scope of validation. Relationship between calibration, validation & qualification. Validation master plan, qualifications of utilities - HVAC systems, validation of water systems. Validation of manufacturing process for sterile and non-sterile products (briefly protocols and reports), Equipment qualification and cleaning validation.

**6. INVENTORY MANAGEMENT** **03 Hrs.**

**(Marks allotment : 10 )**

Costs in inventory, inventory categories- special considerations, selective inventory control, reorder quantity methods and EOQ, inventory models, safety stock – stock out, lead time – reorder time methods, modern inventory management systems, inventory evaluation.

**7. MATERIAL MANAGEMENT** **06 Hrs.**

**(Marks allotment : 15 )**

Materials—quality and quantity, value analysis, purchasing—centralized and decentralized, vendor development, buying techniques, purchasing cycle and procedures, stores management, salvaging and disposal of scrap and surplus. Selection of material handling systems, maintenance of material handling equipment, unit-load, pelletization and containerization, types of material handling systems.

**8. PILOT PLANT SCALE UP TECHNIQUES** **06 Hrs.**

**(Marks allotment : 15 )**

Scale up of batches for product development, layout of pharmaceutical pilot plant, organization structure, personnel, activities. Pilot plant of tablets, capsules, solutions, dispersions, semisolids, and parenterals. Protocols for technology transfer. Process automation technology (PAT) in Pharmaceutical manufacturing. Introduction to SUPAC guidelines.

**9. IPR AND REGULATORY GUIDELINES** **07 Hrs.**

**(Marks allotment : 15 )**

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filing of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent. Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector, CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA regulatory requirements for contract research organization. Regulations for Biosimilars. Role of GATT, TRIPS, and WIPO.

**10. INDUSTRIAL HAZARDS AND PLANT SAFETY** **03 Hrs.**

**(Marks allotment : 5 )**

Industrial accidents, mechanical hazards, electrical hazards, chemical hazards, gas hazards, dust explosion, fire and explosion hazards, prevention and control of all these hazards, safety management. Industrial pollution and Control measurements.

## PRACTICALS

(T:6Hours/Week)

1. Preformulation study of tablet formulation using various diluents
2. Preformulation study of tablet formulation using various binders.
3. To study the effect of surfactants/Co-solvents on the solubility of drugs.
4. To study the effect of various excipients on the compressibility of tablets.
5. Preparation and evaluation of Diclofenac sodium gel containing different gel bases.
6. Study of the effects of pH on rheological characteristics of carbopol gels using Brookefield viscometer.
7. cGMP considerations for tablets.
8. cGMP considerations for injectables.
9. Preparation and comparative evaluation with marketed product for efficiency of neutralizing property of antacid suspensions.
10. Process validation of tablets.
11. Equipment qualification of an analytical instrument.
12. Equipment qualification of processing equipment.
13. Cleaning validation of an equipment.
14. Designing of plant layouts for tablets and parenterals.
15. Stability studies of dosage form at  $30^{\circ}\text{C}\pm 2$ ,  $65\pm 5\%$  RH and  $40^{\circ}\text{C}\pm 2$ ,  $75\pm 5\%$  RH.

## SCHEME OF EXAMINATION

1. Synopsis - 20 marks
2. Experiment
  - Major - 35 marks
  - Minor - 25 marks
3. Viva-voce - 20 marks
- Total - 100 marks

## REFERENCE BOOKS

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann , Latest edition.
2. Modern Pharmaceutics by Gillbert and S. Banker 4<sup>th</sup> Edition .
3. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2<sup>nd</sup> edition
4. Applied Production and Operation Management By Evans, Anderson and Williams  
GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
5. Pharmaceutical Preformulations by J.J Wells
6. Pharmaceutical Dosage Forms: Tablets vol 1-3 by Leon Lachmann
7. Text book of Remington's Pharmaceutical sciences Vol I and II, 21<sup>st</sup> edition
8. Physical Pharmaceutics by Alfred Martin, 4<sup>th</sup> edition
9. Bentley's textbook of Pharmaceutics-Rawbins
10. ISO 9000-Norms and explanations
11. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker
12. Pharmaceutical powder compaction technology by Goran Alderborn, 1996. Marcel and Dekker
13. D and C act by Vijay Malik, Latest edition, Eastern book company, Lucknow

## JOURNALS

1. Drug Development and Industrial pharmacy
2. Indian Journal of Pharmaceutical sciences
3. Journal of Pharmaceutical Sciences
4. Indian drugs

## URL's

1. [www.cdsc.nic.in](http://www.cdsc.nic.in)
2. [www.journals.elsevier.com](http://www.journals.elsevier.com)
3. [www.fda.gov/](http://www.fda.gov/)
4. [www.mhra.gov.uk](http://www.mhra.gov.uk)
5. [www.anvisa.gov.br/eng/legis/index.htm](http://www.anvisa.gov.br/eng/legis/index.htm)
6. [www.pharmaguideline.com/2010/10/mcc.html](http://www.pharmaguideline.com/2010/10/mcc.html)
7. [www.biosimilarnews.com/european-biosimilars-guidelines.](http://www.biosimilarnews.com/european-biosimilars-guidelines)

## **PAPER III - BIOPHARMACEUTICS AND PHARMACOKINETICS**

**Goal:** To train the students in the area of biopharmaceutics and pharmacokinetics to work efficiently in the R&D Dept of industry, to take part in clinical research (clinical trials)

**Objectives:** Upon completion of the course, the candidate shall have the ability to:

- Calculate Pharmacokinetics parameters from the given data.
- Apply the principle of Pharmacokinetics in new drug development as well as in the design of new formulations.

### **COURSE DESCRIPTION**

#### **THEORY**

**50 Hours ( T:2Hours/Week)**

#### **1. ABSORPTION OF DRUGS**

**(8 Hrs.)**

**(Marks allotment : 20 )**

Structure of cell membrane, Gastro-intestinal absorption of drugs, mechanisms of drug absorption, Factors affecting drug absorption: Biological, Physiological, Physico-chemical and Pharmaceutical. Absorption of drugs from non-per oral routes, Methods of determining absorption: *In-vitro*, *in-situ* and *in-vivo* methods.

#### **2. BIOAVAILABILITY**

**(7 Hrs.)**

**(Marks allotment : 15 )**

Objectives and consideration in bioavailability studies, Concept of equivalence, Measurement of bioavailability, Determination of the rate of absorption, Bioequivalence protocol and its importance, Bioequivalence studies.

#### **3. DISSOLUTION**

**(3 Hrs.)**

**(Marks allotment : 10 )**

BCS Classification, Noyes-Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, *In-vitro* dissolution testing models, *In-vitro* release kinetic models, similarity and dissimilarity factors, bio waivers, *In-vitro- In-vivo* correlation.

#### **4. PHARMACOKINETICS**

**(10 Hrs.)**

**(Marks allotment : 25)**

Basic considerations, Pharmacokinetic models, Compartment modeling: One compartment model - IV bolus, IV infusion, Extravascular; Multi Compartment models; Two compartment model - IV bolus, IV infusion, Extravascular, Three Compartment model in brief, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.

**5. NON-LINEAR PHARMACOKINETICS** (3 Hrs.)  
(Marks allotment : 10 )  
Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of  $K_m$  and  $V_{max}$  with respect to individualization of a drug therapy.

**6. NON-COMPARTMENT PHARMACOKINETICS** (3 Hrs.)  
(Marks allotment : 10 )  
Statistical moment theory, MRT for various compartment models, Physiological pharmacokinetic models.

**7. DRUG DISTRIBUTION** (3 Hrs.)  
(Marks allotment : 10 )  
Factors affecting drug distribution, Volume of distribution, Protein binding- factors affecting, significance and kinetics of protein binding and drug displacement interactions.

**8. BIOTRANSFORMATION** (3 Hrs.)  
(Marks allotment : 5 )  
Phase I (oxidative, reductive and hydrolytic reactions) and Phase II reactions (conjugation), factors affecting biotransformation.

**9. EXCRETION OF DRUGS** (3Hrs.)  
(Marks allotment: 5)  
Renal and non-renal excretion. Concept of clearance- renal clearance, organ clearance and hepatic clearance.

**10. DOSAGE REGIMEN** (7 Hrs.)  
(Marks allotment : 20 )  
Multiple dosing with respect to I.V and oral route, concept of loading dose, maintenance dose, accumulation index, adjustment of dosage in renal and hepatic impairment, individualization of therapy, Therapeutic Drug Monitoring.

**PRACTICALS** (T:6 Hours/Week)

1. Improvement of dissolution characteristics of slightly soluble drugs by Solid Dispersion.
2. Improvement of dissolution characteristics of slightly soluble drugs by Solvent deposition.
3. Improvement of dissolution characteristics of slightly soluble drugs by complexation.
4. Improvement of dissolution characteristics of slightly soluble drugs by solvent evaporation.

5. Comparison of dissolution studies of two different conventional marketed products of same drug. - 2 experiments
6. Influence of polymorphism on solubility.
7. Influence of polymorphism on dissolution.
8. Protein binding studies of a highly protein bound drug.
9. Protein binding studies of a poorly protein bound drug.
10. Permeation study of drug through biological membrane.
11. Calculation of  $K_a$ ,  $K_e$ ,  $t_{1/2}$ ,  $C_{max}$ , and  $T_{max}$  for two sets of data. -2 experiments
12. Calculation of bioavailability from urinary excretion data for two drugs. -2 experiments
13. Calculation of AUC and bioequivalence from the given data for two drugs. -2 experiments

#### **SCHEME OF EXAMINATION**

<b>1. Synopsis</b>	<b>-</b>	<b>20 Marks</b>
<b>2. Experiment</b>	<b>-</b>	<b>40 Marks</b>
<b>3. Calculation</b>	<b>-</b>	<b>20 Marks</b>
<b>4. Viva-voce</b>	<b>-</b>	<b>20 Marks</b>
<b>Total</b>	<b>-</b>	<b>100 Marks</b>

#### **REFERENCE BOOKS**

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4<sup>th</sup> edition, Philadelphia, Lea and Febiger, 1991.
2. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2<sup>nd</sup> edition, Connecticut, Appleton Century Crofts, 1985.
4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Books Pvt Ltd, Bangalore, 2000
5. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 2<sup>nd</sup> 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: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.

8. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
9. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4<sup>th</sup> edition Revised and expanded by Rebert F Notari Marcel Dekker Inc, New York and Basel, 1987.
10. Biopharmaceutics and Relevant Pharmacokinetics by John. G. Wagner and M. Pernarowski, 1<sup>st</sup> edition, Drug Intelligence Publications, Hamilton, Illinois,1971.
11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

## URL's

1. European Journal of Bio pharmaceutics and Pharmacokinetics, Publisher- Elsevier Science, [www.elsevier.com](http://www.elsevier.com).
2. Indian Drugs.
3. Indian Journal of Pharmaceutical Sciences.
4. <http://www.columbia.edu/itc/gsas/g9600/2004/GrazianoReadings/Drugabs.pdf>
5. [http://www.google.co.in/url?sa=t&rct=j&q=absorption%20of%20drugs&source=web&cd=9&sqi=2&ved=0CG4QFjAI&url=http%3A%2F%2Fdaactarbhatti.weebly.com%2Fuploads%2F3%2F5%2F1%2F6%2F3516207%2Fabsorption\\_of\\_drugs\\_by\\_dr.\\_soban.ppt&ei=30AiUI-1N8-srAf1\\_ICwBg&usg=AFQjCNF0Vj-xdwOpxKTzhkKhPHImjs1HKg](http://www.google.co.in/url?sa=t&rct=j&q=absorption%20of%20drugs&source=web&cd=9&sqi=2&ved=0CG4QFjAI&url=http%3A%2F%2Fdaactarbhatti.weebly.com%2Fuploads%2F3%2F5%2F1%2F6%2F3516207%2Fabsorption_of_drugs_by_dr._soban.ppt&ei=30AiUI-1N8-srAf1_ICwBg&usg=AFQjCNF0Vj-xdwOpxKTzhkKhPHImjs1HKg)
6. [http://www.iuphar.org/pdf/hum\\_55.pdf](http://www.iuphar.org/pdf/hum_55.pdf)
7. [http://www.synchronresearch.com/pdf\\_files/ba-be-trials.pdf](http://www.synchronresearch.com/pdf_files/ba-be-trials.pdf)
8. [http://fip.org/files/fip/BPS/Dissolution/FIP\\_AAPS\\_Guidelines%20for%20Dissolution.pdf](http://fip.org/files/fip/BPS/Dissolution/FIP_AAPS_Guidelines%20for%20Dissolution.pdf)
9. [http://www.dissolutiontech.com/DTresour/200702Articles/DT200702\\_A02.pdf](http://www.dissolutiontech.com/DTresour/200702Articles/DT200702_A02.pdf)
10. [http://www.pharmpress.com/files/docs/clinical\\_pharmacokinetics\\_samplechapter.pdf](http://www.pharmpress.com/files/docs/clinical_pharmacokinetics_samplechapter.pdf)
11. [http://rmipharmacokinetics.com/uploads/Public\\_Documents/Introduction%20To%20Pharmacokinetics.pdf](http://rmipharmacokinetics.com/uploads/Public_Documents/Introduction%20To%20Pharmacokinetics.pdf)
12. [http://www.pharmpress.com/files/docs/clinical\\_pharmacokinetics\\_samplechapter.pdf](http://www.pharmpress.com/files/docs/clinical_pharmacokinetics_samplechapter.pdf)
13. <http://archive.ajpe.org/legacy/pdfs/aj650212.pdf>
14. <http://www2.courses.vcu.edu/ptxed/m2/powerpoint/download/Lamb%20Drug%20Distribution.pdf>
15. [http://physiologie.envt.fr/spip/IMG/pdf/Volumes\\_of\\_distribution.pdf](http://physiologie.envt.fr/spip/IMG/pdf/Volumes_of_distribution.pdf)
16. <http://books.mcgraw-hill.com/medical/goodmanandgilman/pdfs/CHAPTER3.pdf>
17. <http://el.trc.gov.om:4000/htmlroot/MEDICAL/tcolon/pharmacology/General/E-Books/Metabolism%20Excretion.pdf>
18. [https://apps.who.int/chd/publications/referral\\_care/referencepdf/15app2.pdf](https://apps.who.int/chd/publications/referral_care/referencepdf/15app2.pdf)

## **PAPER IV- ADVANCES IN DRUG DELIVERY SYSTEMS**

### **GOAL**

To train the students in the area of novel drug delivery systems.

### **OBJECTIVE**

Upon the completion of the course, the student shall have an understanding of the need, concept, design and evaluation of various sustained and controlled release dosage forms.

### **COURSE DESCRIPTION**

#### **THEORY**

**50 Hours ( T:2Hours/Week)**

#### **1. CONCEPTS OF CONTROLLED RELEASE DRUG DELIVERY SYSTEMS**

**(Marks allotment :20) (7 Hrs.)**

Introduction, concept, advantages & disadvantages. Factors to be considered for designing controlled release dosage forms. Dissolution, Diffusion, Combination of dissolution and diffusion controlled drug delivery systems. Evaluation of CRDF.

#### **2. POLYMER SCIENCE ( 3 Hrs.)**

**(Marks allotment : 5 )**

Polymer: Introduction, classification, general synthesis and evaluation techniques. Application of polymers in drug delivery.

#### **3. APPROACHES TO CONTROLLED DRUG DELIVERY SYSTEM (8 Hrs.)**

**(Marks allotment : 20 )**

Classification of rate-controlled drug delivery systems. Rate-programmed release, activation-modulated and feedback regulated drug delivery systems. Effect of system parameters on controlled drug delivery. Hydrodynamically balanced systems, Osmotic pressure controlled, pH controlled, ion exchange controlled systems.

#### **4. MUCO ADHESIVE DRUG DELIVERY SYSTEMS ( 8 Hrs. )**

**(Marks allotment : 15 )**

Concepts, advantages and disadvantages, structure of oral mucosa, transmucosal permeability, theories of muco adhesion and muco adhesive polymers, mucosal membrane models, permeability enhancers. Development and evaluation of buccal, nasal, pulmonary, rectal, vaginal and ocular drug delivery systems and their applications.

## **5. TRANSDERMAL DRUG DELIVERY SYSTEMS**

**(7 Hrs.)**

**(Marks allotment : 15 )**

Rationale behind transdermal drug delivery, Permeation through skin, factors affecting permeation, basic components of TDDS, formulation approaches used in development of TDDS and their evaluation, permeation enhancers. Iontophoresis, sonophoresis and magnetophoresis.

## **6. PARENTERAL CONTROLLED RELEASE DRUG DELIVERY SYSTEMS**

**(Marks allotment: 15 ) ( 5 Hrs. )**

Approaches for injectable controlled release formulations. Development and evaluation of Implantable drug delivery systems, subcutaneous, intramuscular and intrauterine implants.

## **7. NANO DRUG DELIVERY SYSTEMS**

**( 7 Hrs.)**

**(Marks allotment : 25 )**

Formulation, development and evaluation of Nanoparticles- Polymeric nano particles, Nano crystals, Solid Lipid Nanoparticles (SLN), Metal Nanoparticles. Vesicular Systems- Liposomes, Transferosomes, Ethosomes, Niosomes, Virosomes. Carbon Nano Tubes (CNT) and Dendrimers. Safety issues related to nano drug delivery systems.

## **8. TARGETED DRUG DELIVERY**

**(5 Hrs.)**

**(Marks allotment : 15 )**

Concept, advantages and disadvantages, types of targeting and applications. Monoclonal antibodies- hybridoma cell production, diagnostic and therapeutic applications – cancer and autoimmune diseases. Problems related to monoclonal antibodies.

## PRACTICALS

(T:6Hours/Week)

1. Comparative evaluation of marketed sustained release tablets and data treatment.
2. Preparation and evaluation of matrix tablets using natural polymers.
3. Preparation and evaluation of matrix tablets using synthetic polymers.
4. Preparation and evaluation of microspheres by solvent evaporation.
5. Preparation and evaluation of muco- adhesive microspheres by ionic gelation method.
6. Preparation and evaluation of microspheres by temperature change method.
7. Preparation and evaluation of microcapsules by wax embedded method.
8. Preparation and evaluation of buccal patches.
9. Preparation and evaluation of buccal tablets.
10. Preparation and evaluation of transdermal films.
11. Evaluation of the effect of various permeation enhancers on transdermal drug delivery.
12. Preparation and evaluation of hydrodynamically balanced tablets.
13. Preparation and evaluation of ocular *insitu* gel.

## SCHEME OF EXAMINATION

- |                |                  |
|----------------|------------------|
| 1. Synopsis    | - 20 marks       |
| 2. Experiment  |                  |
| a) Formulation | - 35 marks       |
| b) Evaluation  | - 25 marks       |
| 3. Viva-voce   | - 20 marks       |
| <b>Total:</b>  | <b>100 marks</b> |

## REFERENCES

1. Chien YW., Novel drug delivery systems, 2nd edition, revised and expanded, Marcel Decker, Inc., New York, 1992.
2. Robinson JR., Lee VHL. Controlled drug delivery systems, Marcel Decker, Inc., New York, 1992.
3. John Wiley and sons, Inc, Encyclopedia of controlled delivery, Editor-Edith Mathiowitz, Published by Wiley Interscience Publication, New York/Chichester/Weinheim
4. Jain NK., Controlled and novel drug delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001)
5. Vyas SP., Khar RK., Controlled drug delivery-concepts and advances, Vallabh Prakashan, New Delhi, first edition 2002.
6. Indian Pharmacopoeia 2010. Volume-I, II & III, Indian Pharmacopoeia Commission. New Delhi.
7. United States Pharmacopoeia, US Publications, US
8. British pharmacopoeia
9. Howard C. Ansel, Nicholas G., Popovid loyd, Allen junior BI. Pharmaceutical dosage forms & drug delivery systems. Waverly pvt, Ltd, New Delhi, Sixth edition
10. Leon Lachman, Lieberman, Kanig JL., Theory and Practice of Industrial Pharmacy, Varghese Publishing House, Bombay, 3<sup>rd</sup> Edition, 1987.
11. Banker and Rhodes, Modern Pharmaceutics, Marcel Decker Inc., New York, 2<sup>nd</sup> Edition, 1990.
12. Ansel HC., Introduction to Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincott Williams and Wilkins, New York, 7<sup>th</sup> Edition, 2000.
13. Remington, the Science and Practice of Pharmacy, Lippincott Williams, 21<sup>st</sup> Edition, 2000.
14. Patrick J. Sinko. Lippincott Williams and Wilkins. Martin's physical pharmacy and pharmaceutical sciences. Fifth edition.
15. Wilium Alfred Martin P, Bustamante AH., Chun. Physical Pharmacy, B. I. Waverly Pvt Ltd, new Delhi, 4<sup>th</sup> edition 1995
16. S.Bharath. Pharmaceutical Technology-Concepts and Applications, Pearson Education in South Asia, First edition, 2013.

## JOURNALS

1. Indian Journal of Pharmaceutical Sciences (IPA)
2. Indian drugs (IDMA)
3. Journal of Pharmaceutical Education and Research
4. Dissolution Technologies
5. Journal of Controlled Release (Elsevier Sciences), desirable
6. Drug Development and Industrial Pharmacy (Francis and Taylor) desirable
7. European journal of Pharmaceutical sciences

8. European Journal of Biopharmaceutics
9. International Journal of Pharmaceutics
10. Journal of Pharmaceutical Sciences
11. DARU: Journal of Pharmaceutical Sciences
12. Asian Journal of Pharmaceutical Sciences
13. AAPS Pharma Sci Tech
14. Advances in Drug Delivery Reviews
15. Rajiv Gandhi Journal of Pharmaceutical sciences

### **URL's**

<http://www.pharmtech.com/>

<http://www.pharmacytimes.com/>

<http://pharmacie-globale.info/>

<http://www.pharmacy.org/>

<http://www.dissolutiontech.com/>

<http://onlinelibrary.wiley.com>

<http://www.uspharmacist.com>

<http://www.pharmpress.com/>

<http://www.elsevier.com/>