EAST POINT COLLEGE OF PHARMACY
East Point Campus, Jnana Prabha, Virgo Nagar Post,
Bengaluru – 560049, Karnataka

QUESTION BANK

M Pharmacy

PHARMACEUTICS

Semester-I

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Modern Pharmaceutical Analytical Techniques

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LONG ESSAYS 7.5 MARKS

UNIT-I UV, IR, Flourimetry

1. Describe and derive the equation for Beer‘s – Lambert’s law. Add a note on deviations and limitations of beers law.
2. Explain the principle, instrumentation and applications of UV-Visible spectroscopy.
3. Draw a neat labelled diagram of double beam UV-Visible spectrophotometer and explain the working principle of monochromators and any two detectors.
4. Explain the working of double beam UV-Visible spectrophotometer with the help of neat labelled diagram.
5. Discuss the principle, theory of IR spectroscopy and give its applications.
6. Draw a neat labelled instrumentation layout of IR spectrophotometer and explain the sample handling techniques in IR.
7. Discuss the different sources of radiations & detectors used in IR spectroscopy.
8. Describe the detectors of an IR spectrometer.

UNIT-II NMR spectroscopy

9. Explain in detail the theory and instrumentation of NMR spectroscopy.
10. Explain in detail the principle of NMR spectrometer and explain chemical shift and factors affecting chemical shift.
11. Outline the salient features of NMR spectroscopy which are used in structural elucidation.
12. Discuss chemical shift and its utilization in NMR spectroscopy.

UNIT-III Mass spectroscopy

13. Fragmentation rules used in mass spectroscopy.
14. Explain in detail the theory and instrumentation of Mass spectroscopy.
15. Explain the theory of mass spectroscopy and add a note on matrix assisted laser desorption ionization mass spectroscopy.

UNIT-IV Chromatography

16. Define and classify chromatography with suitable examples.
17. Explain the principle and practical steps involved in TLC for separation of components.
18. Explain the PRINCIPLE and different types of paper chromatography for separation of components
19. Explain the factors affecting efficiency of column in chromatography. Explain the packing method of adsorbent in column chromatography with their merits and demerits.
20. Draw a neat schematic diagram of GC. Explain about columns used in GC
21. Explain the instrumentation of HPLC with block diagram. Explain about the various detectors used in HPLC
22. Describe in brief the principle, instrumentation and applications of gas chromatography.
23. Enlist the Detectors and sample injection techniques used in Gas Chromatography & explain in detail each of two.
24. Explain the instrumentation of HPLC with neat diagram with more emphasis on pumps and detectors used.

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Drug Delivery Systems

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LONG ESSAY 7.5 MARKS

UNIT I: Sustained Release (SR) and Controlled Release (CR) formulations

1. Write note on various Physiochemical and Biological factors approaches for SR or controlled release formulations.
2. Write note on importance of Bioelectronics medicines.
3. Write note on importance of 3D printing in pharmaceuticals.
4. Explain various methods used to Formulation of diffusion controlled delivery system
5. Write a note on personalized medicine.
6. Write the classification of polymers with their properties and applications.
7. What do you understand by Telepharmacy?
8. Explain the general synthesis and applications of polymers in drug delivery systems.
9. Write notes of choice of polymers used for controlled and sustained release drug delivery system. Add a note on hydro-gels.
10. Explain customized drug delivery.
11. Discuss the concept and rationale for controlled drug delivery.
12. Discuss the applications of synthetic polymers in controlled drug delivery.
13. Discuss about biodegradable and natural polymers.
14. Classification of CDDS.
15. Write in detail on biodegradable and non-biodegradable polymer with examples and their applications.

UNIT II: Rate Controlled Drug Delivery Systems

1. Explain the various approaches used to Formulation of Feedback regulated drug delivery system.
2. Describe the mechanically activated controlled drug delivery system.
3. Write note on pH activated drug delivery systems.
4. Explain Osmotic controlled drug delivery systems.
5. Explain ion exchange controlled drug delivery systems.
6. Explain in detail about various rate controlled drug delivery systems.
7. Explain hydro dynamically balanced drug delivery systems.
8. Briefly discuss enzyme activated drug delivery systems.
9. Explain bio-respective feedback regulated controlled drug delivery system with example.
10. Concept and design of elementary osmotic pump. Enlist the osmogens.

UNIT III: Gastro-Retentive Drug Delivery Systems

1. Write the principle involved in Formulation of Buccal drug delivery system.
2. Concept of Gastro retentive drug delivery system with a note on polymers used GRDDS.
3. Explain the concepts of Gastro retentive drug delivery system. Give the advantages and disadvantages.
4. Briefly explain the principle of mucoadhesion.
5. Write the merits and limitations of mucoadhesive delivery systems.
6. Explain the various theories of muco adhesion.
7. Give a note on development and evaluation of buccal drug delivery systems with its applications.
8. Write a note on Buccal absorption.
9. Describe the advantages and limitations of Gastro-retentive drug delivery.
10. Describe mucoadhesive polymers.
11. Describe the in vivo methods for buccal absorption.
12. Write about the Factors influencing permeation.
13. Explain about Mucoadhesive prepartions.

UNIT IV: Occular Drug Delivery Systems:

1. Explain the methods of Formulation and Evaluation of Occular drug delivery system.
2. Advantages and disadvantages of ocular drug delivery system
3. Explain the methods to overcome the barriers for drug permeation by ocular route.
4. Discuss the design and development of occuserts.
5. State briefly on ophthalmic inserts.
6. Explain any two methods to overcome the corneal barrier.
7. Write a note on bioerodible ocular inserts.

UNIT V: Transdermal Drug Delivery Systems

1. Explain various approaches used to Formulations of Trandermal drug delivery systems.
2. Permeation enhancers used in transdermal drug delivery system
3. State on transmucosal permeability and their limitations.
4. Give different components of transdermal drug delivery systems.
5. Explain the concept of permeation of drugs through skin .
6. Explain the evaluation methods of transdermal drug delivery systems
7. Discuss iontophoretic transdermal drug delivery with examples.
8. Discuss the factors affecting skin permeation of drugs.

UNIT VI: Protein and Peptide Delivery:

1. Write note on Drug delivery systems of proteins and other macromolecules.
2. Explain about the Protein drug delivery through parental route.
3. Explain the barriers for protein drug delivery and strategies to overcome these barriers.
4. Stabilizers used in the preparation of Protein Drug Delivery System.
5. Briefly discuss the evaluation of protein delivery systems.
6. Discuss the protein binding in SRDDS.
7. Write the mechanism of protein and peptide?

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UNIT VII: Vaccine delivery systems:

1. Write notes on single shot vaccines?
2. Describe the importance of uptake of Antigens and Transdermal vaccines.
3. Explain transdermal delivery of vaccines.
4. Explain the techniques for transdermal delivery of vaccines.
5. Write a note on uptake of antigens?
6. Write the formulations of vaccines?

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Modern Pharmaceutics

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LONG ESSAY 7.5 MARKS

Unit I-Preformation Concepts

1. Explain the different methods to study drug excipient interactions
2. Explain the preformulation studies to new drug formulated in to semi-solid dosage form.
3. Explain the formulation of self emulsifying drug deliverysystem.
4. Explain theories of emulsification.
5. Explain stability of emulsions.
6. Explain formulation of small volume of parenterals
7. Explain the formulation of sterile suspension. How do you maintain their stability?
8. Write the preformulation studies for new drug molecule.
9. Discuss in detail manufacture and evaluation of small volume parenterals.
10. Write about photostability testing of new drug substance. Mention importance of kinetics of stability.

Unit II-Optimization Techniques in Pharmaceutical Formulation

1. Explain in detail the concept & parameters of optimizationin formulation
2. Discuss applications of optimization in formulation
3. Explain 2^2factorial designs
4. Define optimization. Classify & explain factorial design
5. Explain the statistical design of optimization techniques
6. Discuss in detail about the importance of optimization and enlist the various parameters considered in optimization technique.
7. Explain the concept of optimization and discuss the various methods of optimization.
8. Explain in detail factorial designs of optimization.
9. Define Optimization. Discuss optimization techniques used in pharmaceutical formulation.
10. Explain response surface methodology. Discuss contour designs.

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Unit III-Validation

1. Define validation. Explain process validation andoperational Validation.
2. Explain Validation of Master Plan
3. Define Validation. Classify, write important characteristicsof Validation as per ICH guideline.
4. Explain the steps involved in product validation
5. Explain retrospective validation & revalidation
6. Write a note on validation of the sterile dosage form?
7. Explain validation of non-sterile specific dosage form(tablet)?
8. Define and classify of validation. Write detail protocol of autoclave validation.
9. Explain prospective and concurrent validation.
10. Explain in detail process validation procedure as per as ICH Guidelines.

Unit IV-cGMP & Industrial Management

1. Define cGMP. Explain the fundamental principles of cGMP .
2. What are the cGMP consideration for parentral dosage forms?
3. Define inventory management. Explain in detail.
4. Write the different inventory control techniques in pharma industries
5. Explain the term EOQ and ROQ in purchasing a raw materials.
6. Explain phases in production planning.
7. Explain the concept of TQM
8. Explain essential components of TQM
9. Write the important principles of TQM
10. Write a note on sales forecasting
11. Explain the term EOQ and ROQ in purchasing of raw materials.
12. Mention objective of production planning. Explain elements of production control.
13. Explain the principle of budget and cost control in pharma industry.

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Unit V-Compression and compaction

1. Explain the physics of tablet compression
2. Explain compaction profile of tablet?
3. Explain factors such as particle size and moisture content on compression tablet.
4. Different methods to improvement of compaction behavior of powder bed.
5. What is compression and compaction? Explain process of compression in detail.
6. Explain the term consolidation, compression and compaction. What is the effect of friction on compression?
7. Quantification of compressibility and compatibility of powder.
8. Describe in detail various factors affecting compressions of tablets.
9. Explain the merits of ICH and WHO guidelines for tablet compression machine.
10. Discuss in detail the steps involved in the compression of the material explaining the forces of distribution..

Unit VI-Study of consolidation parameters

1. Explain the solubility analysis of new drug molecule.
2. Enlist the solubility enhancement techniques.Explain any one technique?
3 Define solid dispersion.classify and explain any two methods of preparation?
4. Define standard deviation and its significance.
5. explain the similarity factors , write its significance ?
6. write briefly about heckle's plot ?
7. write briefly about higuchi's equation & peppas plot ?
8. Discuss about difference factor (F1) and similarity factor (F2). What is its importance?
9. Explain significance of student T-test. Explain criteria to apply ANOVA.
10. List out various model dependent methods for drug release. Describe Higuchi and Peppas models in detail.

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PHARMACEUTICAL REGULATORY AFFAIRS

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LONG ESSAY 7.5 MARKS

UNIT I Documentation of Pharmaceutical Industry

1. Explain in detail on DMF system in India
2. Explain the approval process and timeline for investigational new drug.
3. Define common technical document (CTD) and electronic common technical document (eCTD). Explain different modules in CTD and eCTD.
4. Explain the stages in development of new drug
5. What is CTD and eCTD. Explain the different modules of CTD in detail
6. Discuss the application and approval process for ANDA
7. Explain the stages in drug development process
8. Explain the regulatory approval process for New Drug Application.
9. Discuss briefly open part and closed part of DMF.
10. What is innovator and generic products?

UNIT II: Regulatory requirement for product approval

1. Explain stage in development of generic formulations
2. Define CTD and discuss the process involved in its submission
3. Explain the organization and functions of regulatory bodies of EU and Australia
4. Explain the regulatory approval process for ANDA
5. Explain different stages of drug discovery
6. Explain the application and approval process of IND
7. Explain different stages involved in development of new drugs
8. Explain the organization and functions of Australia and US drug regulatory bodies
9. Explain the application and regulatory approval process for IND
10. Discuss the process of DMF system

UNIT III: CMC

1. Explain the different modules of CTD in detail
2. Explain the different modules of ACTD
3. Discuss the various stages involved in generic product development
4. Discuss approval process of NDA
5. Explain the organization and functions of regulatory bodies of EU and Japan

6. Discuss different stages of pre-clinical studies
7. Discuss the application and approval process of ANDA
8. Discuss the procedure for the export of the pharmaceutical products
9. Explain stages in drug development process
10. Explain different modules of ACTD.

UNIT IV: Non clinical drug development

1. Explain the organization and functions of regulatory bodies of EU and Japan Explain code for federal regulation with respect to Part 21
2. What is CTD and eCTD? Differentiate them.
3. Explain inclusion and exclusion in clinical trials
4. Explain changes made to approved NDA
5. Explain salient features of orange book
6. Discuss the criteria for selection of human volunteers in clinical trials
7. Explain the development of clinical trial protocols.
8. Explain different stages in non-clinical studies.
9. Explain the application and approval process for IND
10. Explain the organization structure and functions of Japan drug regulatory body

UNIT V: Clinical Trials

1. Explain the stages of drug discovery process
2. Discuss the importance of orange book in development of generic product
3. Explain the application and approval of ANDA
4. Write briefly on clinical trial protocol
5. Explain the salient features of pharmacovigilance
6. Explain the differences between brand and generic products
7. Explain organization structure and functions of Europe drug regulatory authority
8. Write an overview on ACTD
9. Explain the non -eCTD electronic submission form (NeeS).
10. Explain the organization and functions of CDSCO.

Vision and Mission of the Institution

Vision

The East Point College of Pharmacy aspires to be a globally acclaimed institution, **recognized** for **excellence in** pharmaceutical education, research and nurturing students for **holistic development.**

Mission

M1 Create pharmacy graduates through **quality education**

M2 Promote innovation, **creativity**, and excellence **in teaching**, learning, and **research**

M3 **Inspire** integrity, teamwork, critical thinking**, personal** development, and ethics in **students** and lay **the** foundation for lifelong learning

M4 **Serve** the **healthcare, technological, scientific**, and **economic** needs of then **society**.