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Total No. of Pages : 01

Total No. of Questions : 06

M.Pharmacy (Pharmaceutics) (Sem.-1)

REGULATORY AFFAIRS

Subject Code : MPH-104T

M.Code : 74660

Date of Examination: 18-12-2024

Time : 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.

1.
 - a) What is a CRO? Highlight the essential requirements for a CRO.
 - b) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records.
2.
 - a) What are combination products? Give examples. Highlight the regulatory requirements to be fulfilled for them.
 - b) Briefly discuss Master Formula Record and its importance.
3.
 - a) What is the constitution of Institutional Ethics Committee? Highlight the functions of Ethics Committee.
 - b) What is meant by HIPPA? Highlight its key features aimed at protecting sensitive patient data.
4. Write short notes on:
 - a) Pharmacovigilance
 - b) e CTD
5.
 - a) How are bioequivalence studies conducted? Mention the ICH requirements for products to be declared bioequivalent.
 - b) Clarify the role of CROs in bioequivalence testing.
6.
 - a) What is post marketing surveillance? Highlight its purpose and briefly discuss the methods to conduct PMS.
 - b) Write a note on ICH requirements pertaining to drug distribution records.

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M.Pharmacy (Pharmaceutics) (Sem.-1)

MODERN PHARMACEUTICS

Subject Code : MPH-103T

M.Code : 74659

Date of Examination: 20-12-2024

Time : 3 Hrs.

Max. Marks: 75

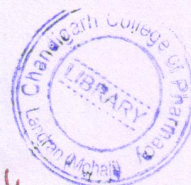
INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
2. Each question carries FIFTEEN marks.
1. a) What are the different zones with respect to stability testing of pharmaceuticals? Discuss the stability testing conditions for each zone.
- b) Discuss the basic concept of optimization in product development. Highlight the application of contour designs for this purpose.
2. a) Discuss the critical process and formulation variables for tablet formulation.
- b) Explain the application of optimization technique for a Box Behnken design.
3. a) What is validation and revalidation? Enumerate their advantages. Outline the general process of retrospective validation for a dosage form.
- b) Discuss the validation of an enteric coated tablet dosage form.
4. a) Write a note on inventory management.
- b) Briefly, discuss the cGMP norms for services in a pharmaceutical dosage form manufacturing unit.
5. a) Highlight the influence of frictional forces on ease of tablet formation, how are these forces overcome?
- b) Explain disintegration "between the grain" and "across the grain". How does particle size and material characteristics influence them?
6. a) Give a brief account of the pharmacokinetic parameters indicative of rate and extent of drug absorption.
- b) Explain similarity and dissimilarity in dissolution data.

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M.Pharmacy (Pharmaceutics) (Sem.-1)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code : MPH-101T

M.Code : 74657

Date of Examination: 16-12-2024

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. Attempt any FIVE questions out of SIX questions.
 2. Each question carries FIFTEEN marks.
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1. a) Discuss the role of solvents in influencing UV-VIS spectra of drugs.
b) Differentiate between IR and FTIR techniques. Highlight the advantages of FTIR.
 2. a) Discuss the theory behind spectrofluorimetry and mention the advantages.
b) Discuss the factors influencing chemical shift in NMR spectroscopy.
 3. a) Discuss the applications of mass spectroscopy.
b) What is affinity chromatography? Explain the technique and mention the advantages.
 4. a) Write briefly about gel electrophoresis and its applications.
b) Explain the X-ray crystallographic technique.
 5. a) Write a note on RIA.
b) What is meant by moving boundary electrophoresis? Giving examples, mention the applications of this method.
 6. Write short notes on:
 - a) Blue shift.
 - b) Quenchers.
 - c) Bragg's law.

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