Roll No. | | | | | | | | | | | |

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.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

Roll No. | | | | | | | | | | | |

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (Sem–1)

DRUG DELIVERY SYSTEM

Subject Code : MPH-102T

M.Code : 74658

Date of Examination : 23-12-2024

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) Discuss the mechanisms of drug permeation through the oral route.

   b) Give a brief account of the polymers commonly used to control the rate of drug release from solid dosage forms.

2. a) What are osmotic activated drug release dosage forms? Give an account of these formulations and mention the function of each excipient used in them.

   b) Enumerate the approaches employed for modulating the gastric transit time of dosage forms. Give a brief account of floating tablet formulations.

3. a) Discuss the challenges for ocular drug delivery.

   b) Distinguish between a reservoir and matrix type of TDDS. Give a brief account of in-vitro and in-vivo evaluation of TDDS.

4. a) Enumerate the approaches employed for oral protein delivery. Discuss any one in detail.

   b) Write briefly about mucosal delivery of vaccines and the formulation ingredients used in such vaccines.

5. a) Give examples of muco adhesive polymers. Give a brief account of evaluation of muco adhesive films.

   b) Explain 3D printing process and mention its applications.

6. **Write short notes on :**

   a) Pharmacogenetics.

   b) Telepharmacy.

   c) Uptake of antigens.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

(S31)-2018

DEC-2024

Roll No. | | | | | | | | | | |

Total No. of Pages : 01

Total No. of Questions : 06

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.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

(S31)-1823

Dec-2024

Roll No. | | | | | | | | | | |

Total No. of Pages : 01

Total No. of Questions : 06

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.

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 advanatages.

   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.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.

(S31)-1431

DEC-2024