

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 : 15-12-2023

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) Write a note on detailed account on master formula record. (7.5)
b) What are Generic drugs and how are they different from Proprietary medicines? Write briefly about the development of generic versions of a drug. (7.5)
2. a) What is eCTD? What are the advantages of filing e CTD? (7.5)
b) Briefly explain the non-clinical investigations carried out for supporting approval process. (7.5)
3. a) What is meant by "informed consent"? What is the role of informed consent in drug approval? (7.5)
b) Explain IMPDI dossier. (7.5)
4. **Write short notes on :** (7.5 × 2 = 15)
a) HIPAA
b) Hatch-Waxman Act
5. a) What are the elements of a clinical trial? Describe systematically the protocol of a clinical trial. (7.5)
b) Mention the composition and functions of Institutional Review Board. (7.5)
6. a) What is a CRO? Highlight the essential requirements for a CRO. (7.5)
b) What is the purpose of maintaining drug distribution records? Write a note on ICH requirements pertaining to drug distribution records. (7.5)

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.



DEC-2023

[illegible]

Total No. of Questions : 06

MODERN PHARMACEUTICS

Subject Code : MPH-103T

M.Code : 74659

Date of Examination : 13-12-2023

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. What is optimization with respect to dosage form design? Enumerate different optimization designs and explain the Contour design taking a hypothetical example. Mention the limitations of employing optimization design.
2.
 - a) What is prospective, retrospective and concurrent validation? Highlight the situations when they are employed for pharmaceutical dosage forms.
 - b) Discuss the validation of an autoclave.
3.
 - a) What is meant by materials management? Highlight issues related to materials management in a tablet production unit.
 - b) Explain the effect of friction during tablet compression and its remedies.
4.
 - a) Define IQ, OQ and PQ and mention their utility on pharmaceuticals.
 - b) What are SMEDDS? Mention their formulation ingredients and advantages of preparing them.
5. **Write short notes on (any three) :**
 - a) Drug excipient interactions
 - b) Volume changes during compaction
 - c) Stability testing
 - d) Fish - bone diagrams.
6.
 - a) Comment on diffusion parameters and their significance.
 - b) Explain the "paired" and "unpaired" t-test.

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.

1 | M-74659

(S31)-1788



DEC-2023

Roll No.

Total No. of Pages : 02

Total No. of Questions : 06

M.Pharmacy (Pharmaceutics) (Sem.-1)
DRUG DELIVERY SYSTEM
Subject Code : MPH-102T
M.Code : 74658

Date of Examination : 11-12-2023

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) Explain the mechanisms of drug release from controlled release dosage forms. Enumerate the different types of oral controlled release formulations.
b) What is pharmacogenetics? Discuss the concept of pharmacogenetics and its rationale giving suitable examples.
2. a) What are feedback regulated drug delivery systems? Give two examples of such system and discuss the mechanism of drug release from them.
b) Discuss the mechanisms of mucoadhesion and give examples of polymers used in such dosage forms.
3. a) Discuss the barriers for successful ocular drug delivery and the approaches used for overcoming them.
b) Distinguish between matrix and reservoir TDDS. Enumerate the barriers for successful transdermal drug delivery.
4. a) Give an account of vaccine delivery systems.
b) Explain 3D printing process and mention its advantages.
5. a) Discuss the reasons for failure of oral protein delivery. Enumerate the approaches employed for oral protein delivery.
b) Explain the mechanism for uptake of antigens.

1 | M-74658

(S31)-1558



6. Write short notes on :

- a) Hydrodynamically balanced drug delivery systems
- b) Single shot vaccines
- c) Evaluation of mucoadhesive systems.

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.

2 | M-74658

(S31)-1558

Total No. of Questions : 06

Total No. of Pages : 01

M.Pharmacy (Pharmaceutics) (Sem.-1)
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
Subject Code : MPH 1017

Subject Code : MPH-101T

M.Code : 74657

Date of Examination : 08-12-2023

Time : 3 Hrs.

Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

- QUESTIONS TO CANDIDATES :**
1. Attempt any **FIVE** questions out of **SIX** questions.
 2. Each question carries **EQUAL** marks.
-
1. a) Enumerate various factors affecting vibrational frequency in a molecule. Explain with at least two examples for each factor.
b) How does a spectrofluorimeter differ from a UV spectrophotometer?
 2. a) Define coupling constant. How spin-spin coupling occurs? Predict the multiplicities of signals in H-NMR spectrum of aspirin.
b) How relaxation rate affects signal sharpness in NMR spectra?
 3. What is the principle of mass spectrometry? Explain various modes of ionization used in it. Give merits, limitations and specific applications of each mode.
 4. Classify chromatographic techniques on the basis of mechanism of separation. Write a detailed account on instrumentation and applications of gas chromatography.
 5. Write a detailed account of immunological assays.
 6. a) Discuss the principle, instrumentation and applications of iso-electric focusing based electrophoresis.
b) What are the different techniques based on use of secondary x-rays? Give a brief account of any one.

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.



DEC-2023