Roll No.

Total No. of Pages: 01

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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: $(7.5 \times 2 = 15)$
 - 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)

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

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.
- Each question carries FIFTEEN marks.
- What is optimization with respect to dosage form design? Enumerate different optimization designs and explain the Contour design taking a hypothetical example. 1. Mention the limitations of employing optimization design.
- a) What is prospective, retrospective and concurrent validation? Highlight the situations 2. when they are employed for pharmaceutical dosage forms.
 - b) Discuss the validation of an autoclave.
- a) What is meant by materials management? Highlight issues related to materials 3. management in a tablet production unit.
 - b) Explain the effect of friction during tablet compression and its remedies.
- a) Define IQ, OQ and PQ and mention their utility on pharmaceuticals. 4.
 - b) What are SMEDDS? Mention their formulation ingredients and advantages of preparing them.
- Write short notes on (any three): 5.
 - a) Drug excipient interactions
 - b) Volume changes during compaction
 - c) Stability testing
 - d) Fish bone diagrams.
- a) Comment on diffusion parameters and their significance. 6.
 - b) Explain the "paired" and "unpaired" t-test.

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Roll No.

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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

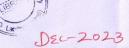
Time: 3 Hrs.

Max. Marks: 75

- INSTRUCTIONS TO CANDIDATES:

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

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- Write short notes on :
 - a) Hydrodynamically balanced drug delivery systems
 - b) Single shot vaccines
 - c) Evaluation of mucoadhesive systems.

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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: 08-12-2023

Time: 3 Hrs.

Max. Marks: 75

INSTRUCTIONS TO CANDIDATES:

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

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