

Enrollment No.....

Master of Pharmacy (Pharmaceutics)
First Semester Examination, Dec-2020
Drug Delivery System (MPH-102T)

Time: 3:00 Hrs

Max Marks 75

Note : Attempt any five questions. All questions carry equal marks.

- Q.1** Give detailed account of various formulation mechanisms in gastric retentive drug delivery system?
- Q.2** Explain the transport of drugs across mucosal membrane and give various types and mechanism of action of penetration enhancer.
- Q.3** Explain design and mechanism of occuserts.
- Q.4** Discuss the challenges in the delivery of protein and peptide based drugs.
- Q.5** Explain the different permeation enhancer used for skin permeation with examples?
- Q.6** Write notes on:-
(i) Nanoparticles.
(ii) Resealed erythrocytes.
- Q.7** Write short note on single shot vaccines.
- Q.8** Discuss the preparation methods and application of nano – particles.

Master of Pharmacy (Pharmaceutics)
First Semester Main Examination, Dec-2020
Modern Pharmaceutics (MPH 103T)

Time: 3:00 Hrs

Max Marks 75

Note : Attempt any five questions. All questions carry equal marks.

- Q.1** (a) Explain in detail the physicochemical and biological factors affecting stability of drug.
(b) Describe in brief ICH guidelines for stability studies.
- Q.2** (a) Differentiate consolidation and compression with definition. Write a detailed note on distribution and measurement of forces and physics of tablet.
(b) Define validation. Write its importance and its type.
- Q.3** (a) Explain the various approaches for injectable controlled release formulation.
(b) Explain the role of the PH and tonicity adjustment in parenteral explain with suitable examples
- Q.4** (a) Describe production area design of high – purity water unit in pharma – industry
(b) Give detail of preparation and application of high purity water for parenteral dosage form.
- Q.5** (a) Write in detail about production management and GMP consideration for the pharmaceutical industry.
(b) Explain in brief about safety measures in pharmaceutical industry.
- Q.6** (a) Explain the experimental design approach used in the optimization of formulation.
(b) Write a short note on statistical design.
- Q.7** (a) Explain in detail factorial design approach.
(b) Describe the use of ‘t’ test and standard deviation in evaluation of data.
- Q.8** (a) Write a short note on application of linear regression of standard curve in drug analysis.
(b) Give comparison between one way and two way ANOVA.

Master of Pharmacy (Pharmaceutics)
First Semester Main Examination, Dec-2020
Regulatory Affairs (MPH 104T)

Time: 3:00 Hrs

Max Marks 75

Note: Attempt any five questions. All questions carry equal marks.

- Q.1 (a) NDA approval process.
(b) Post marketing surveillance.
- Q.2 (a) Write the ICH guidelines for stability testing of pharmaceutical.
(b) Write investigation medicinal product dossier.
- Q.3 (a) Describe Pharmacovigilance safety monitoring in clinical trials.
(b) Write note on clinical trial protocols.
- Q.4 (a) Write constitution and composition of state pharmacy councils.
(b) Explain the trade mark filling procedure.
- Q.5 (a) Write salient features of Indian Patent Act.
(b) Post approval regulatory affairs.
- Q.6 (a) Enlists various documents of clinical trial protocol.
(b) Write short note on IND and orphan drugs.
- Q.7 (a) Write the concept of innovator and generic drug.
(b) Write note on CFR.
- Q.8 Write short note on –
(a) Drug Master File
(b) ISO