2/1/20

Paper Code : MPH101T A (SVSU:2019-20/R)

Enrollment No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

MPH-101T/ MPL-101T

(1st YEAR , Ist SEM.) EXAMINATION

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

[Max. Marks : 75]

TIME 3.00 Hrs

Attempt all questions

Q.1. Answer any *five* of the following: **(3×5 = 15)**

i. Discuss electronic transitions
ii. Discuss bending vibration
iii. Write about Lamberts law
iv. Detector in infrared spectroscopy
v. Discuss chemical shift
vi. Discuss stretching vibration
vii. Define Beers law

Q.2. Answer any *five* of the following: **(3×5 = 15)**

i. Write a note on Thin Layer chromatography.
ii. Discuss H.P.L.C
iii. Applications of mass spectroscopy.
iv. Discuss chromatography
v. Discuss Flourimetry
vi. Write a note on paper chromatography
vii. Discuss different types of spectroscopy

Q. 3. Answer any *two* of the following: **(7.5×2 = 15)**

i. Discuss E.L.I.S.A
ii. Discuss vibration in I.R spectroscopy
iii. Discuss applications of U.V visible spectroscopy.

Q. 4. Answer any *two* of the following: **(7.5×2 = 15)**

i. Discuss instrumentation of mass spectroscopy
ii. Discuss electrophoresis in detail
iii. Discuss sample handling in I.R spectroscopy

Q. 5. Answer any *one* of the following: **(15×1 = 15)**

i. Give a note on gas chromatography in detail.

ii. Discuss principle and instrumentation of U.V visible spectroscopy

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4/7/20

Paper Code : MPH102T B (SVSU:2019-20/R)

Enrollment No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

MASTER OF PHARMACY- (MPH)

(1st YEAR , Ist SEM.) EXAMINATION

DRUG DELIVERY SYSTEM

[Max. Marks : 75]

Time- 3 Hours

Attempt all questions. Each question carries equal marks.

Q1.Attempt any five questions- **(3X5=15)**

a) Evaluation of TDDS'

b) Short note on 'OROS'

c) Define Pharmacogenetics.

d) Pharmaceutical applications of polymers.

e) 3-D printing of pharmaceuticals.

f) Explain Bioelectronic medicines.

Q2. Attempt any five questions- **(3X5=15)**

a) Explain the factors affecting drug permeation through skin.

b) Write a note on telepharmacy.

c) Advantages and disadvantages of FDDS

d) Single shot vaccines.

e) Principle of bioadhesion

f) Mechanism of drug delivery from controlled release products.

Q3. Attempt any two questions- **(7.5X2=15)**

a. Explain customized drug delivery systems.
b. Application of Pharmacogenetics.
c. Describe formulation of FDDS.

Q4. Attempt any two questions- **(7.5X2=15)**

a) Describe various formulation approaches of TDDS.

b) Write a note on factors affecting SR/CR formulations.

c) Define polymers. Classify them and write the properties of polymers.

Q5. Attempt any one question- **(15X1=15)**

a) Explain in detail about ocular drug delivery systems.

b) Write a note on oral controlled drug delivery systems.

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7/1/2020

Paper Code : MPH103T A (SVSU:2019-20/R)

Enrollment No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

MASTER OF PHARMACY- (MPH)

(1st YEAR , Ist SEM.) EXAMINATION

MODERN PHARMACEUTICS

[Max. Marks : 75]

Time:3hr

Q1. (Attempt any five questions) **3X5 = 15**

a. Mention various applications of SMEDDS.
b. Enlist various excipients used parenteral solutions.
c. Application of equipment qualification.
d. Mention various types of validation.
e. Application of factorial design in pharmacy.
f. Write a note on material control.

Q2. (Attempt any five questions) **3X5 = 15**

a. VED Analysis.
b. Mention various suspending agents used in the formulation of suspension.
c. Discuss layout of building of pharmaceutical production unit.
d. Discuss objectives of cGMP.
e. Explain linearity concept of significance.
f. Explain the effects of frictional forces encountered during tablet compression.

Q.3 (Attempt any two questions) **7.5X2 = 15**

a. Describe various regulations imposed by government in validation process.
b. Explain similarity factor (f_2) analysis and its significance.
c. Give the layout of parenteral section and draw flowchart of material movement in parenteral section.

Q.4 (Attempt any Two questions) **7.5X2 = 15**

a. Give a detail account on various degradative pathways of drugs products.
b. Explain Validation and discuss validation of solid dosage forms.
c. Give the ICH guidelines for calibration and validation of equipments.

Q.5 (Attempt any One questions) **15X1 = 15**

a. Discuss about various optimization techniques for pharmaceutical formulations.
b. Give a detailed account on various pharmacokinetic parameters for dissolution studies.

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9/1/2020

Paper Code : MPH104T C (SVSU:2019-20/R)

Enrollment No. ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

MASTER OF PHARMACY- (MPH)

(1st YEAR , Ist SEM.) EXAMINATION

REGULATORY AFFAIR

[Max. Marks : 75]

TIME 3 Hr

Attempt all questions. Each question carries equal marks.

Q1. Attempt any five questions **(3X5=15)**

a) Define the term CRO.

b) Phase –IV clinical trial define.

c)Write about CTD format

d)What is DMF?

e) Informed Consent process and procedure

f) Regulation of combination product

g) Role of ANDA.

Q2. Attempt any five questions **(3X5=15)**

a) Role of FDA

b) Formulation and working procedures in clinical trials

c) Bioequivalence and drug product assessment in vivo

d) Global submission of IND

e) Independent ethical committee

f) Investigator brochure

g) Master formula record.

Q3.. Attempt any two questions **(7.5X2=15)**

a) Describe the ways and means of US registration of foreign drugs.

b) Describe code of federal regulation(CFR).

c) Explain regulatory requirement of product approval for novel drug formulations.

Q4. Attempt any two questions **(7.5X2=15)**

a) Describe Scale-up process approval changes (SUPAC)

b) Explain regulatory requirements of TGA countries.

c) Write short note on post marketing surveillance

Q5. Attempt any one question **(15X1=15)**

a) Health Insurance Portability and Accountability Act (HIPPA)

b) Explain in detail about Hatch-Waxman act ant its amendments.

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