24/03/21

Printing Page(s) : 1

Paper Code : MPH- 102T

(A) (SVSU:2020-21/R)

Enrolment No.

M.PHARM

I[st] YEAR, Ist SEMESTER EXAMINATION

SUB-Drug Delivery Systems-

Time : 3 Hours]

NOTE: Attempt all the questions as per instructions.

[Max. Marks : 75

1. Attempt any five questions
   a) Explain Telepharmacy and write its application
   b) Short note on oral osmotic pump 'OROS'
   c) Barriers for drug penetration through eyes.
   d) Classify polymers with examples.
   e) Classify cosmetics for eyes.
   f) Explain pH activated DDS.

[3×5=15]

2 Attempt any five questions
   a) Explain structure of skin.
   b) Explain customized DDS.
   c) Differentiate between sustained release and controlled release dosage form.
   d) Write a note on permeation enhancers.
   e) Short note on single shot vaccines.
   f) Explain barriers for protein delivery.

[3×5=15]

3 Attempt any two questions
   a) Explain in detail about ocular drug delivery systems.
   b) Explain various modulated drug delivery systems.
   c) Classify various gastro-retentive DDS. Describe formulation and evaluation of FDDS.

[7.5×2=15]

4 Attempt any two questions
   a) Describe various formulation approaches of TDDS. Explain their evaluation.
   b) Write a note on pharmacogenetics.
   c) Explain mucosal and transdermal delivery of vaccines.

[7.5×2=15]

5 (Attempt any one question)
   a) Describe release kinetics, advantages, disadvantages and approaches of controlled drug delivery systems.
   b) Explain various parenteral controlled drug delivery systems in detail.

[15 x 1 =15]

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26/03/21

Printing Page(s) : 1 Paper Code : MPH- 103T (B) (SVSU:2020-21/R)

Enrolment No.

M.PHARM

I[st] YEAR, Ist SEMESTER EXAMINATION

MODERN PHARMACEUTICS

Time : 3 Hours] [Max. Marks : 75

NOTE: Attempt all the questions as per instructions.

I Attempt any five questions [3×5=15]

1. What are the objectives of Preformulation studies?
2. Mention the need of formulation optimization.
3. Define validation.
4. What do you mean by concurrent validation?
5. What is the need of user specific requirements during instruments validation?
6. What is the importance of sales forecasting in production management?

II Attempt any five questions [3×5=15]

1. What is the effect of friction on tablet compression?
2. Define level of significance.
3. Give the formula for calculation of standard deviation.
4. Define cGMP.
5. Mention various parameters of dissolution study.
6. Write a note on budget control..

III Attempt any Two questions [7.5×2=15]

1. Describe various regulations imposed by government in validation process.
2. Explain Heckel plots and their significance.
3. Describe various theories of emulsification.

IV. Attempt any Two questions [7.5×2=15]

1. Write a note on manufacturing and evaluation of large volume parenteral.
2. What is factorial design? Explain with suitable example
3. Describe chi-square test with suitable example.

V. Attempt any One question [15×1=15]

1. Discuss in detail about various techniques to detect drug-excipients interactions.
2. What is production management? Discuss Pharmaceutical production management in detail.

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31/03/21

Printing Page(s) : 2

Paper Code : MPH-104T
(A) (SVSU:2020-21/R)

Enrollment No. | | | | | | | | | | | | |

M.Pharmacy
I^st Year, I^st Semester
Regulatory Affair

[Time -3 hr.] **[MM-75 marks]**

Attempt all questions. Each question carries equal marks.

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

a) Write short note on master formula record.
b) Give a note on Phase –III clinical trial.
c) What is importance of labeling of drugs .
d) Drug product performance
e) Write function of USFDA
f) Write about Chemistry, Manufacturing, and Controls (CMC) in brief.
g) Generic drug.

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

a) Write short note on Drug-master file
b) Common technical document (CTD) Format
c) Pharmacovigilance safety monitoring in clinical trials.
d) What do you understand by distribution record.
e) Outsourcing BA and BE studies to contract research organization

f) Medicines & Healthcare products Regulatory Agency.
g)Define bioequivalence.

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

a) Write a note on Code of federal regulation
b) What is Investigator Brochure (IB) ?
c) Write various ICH guidelines for stability testing of pharmaceuticals.

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

a) Explain generic drug product information in detail.
b) Institutional ethical committee.
c) Health Insurance Portability and Accountability Act (HIPPA)

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

a) Describe 'The Drug Price Competition and Patent Term Restoration Act' (Waxman Act)
b) Describe in detail about ICH 'Q' Guidelines.

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