Registration No: | 2 | 1 | 0 | 8 | 2 | 5 | 1 | 0 | 1 | 1 |

Total Number of Pages: 01

M. Pharm
MPH104T

**1st Semester Regular / Back Examination: 2021-22**
**REGULATORY AFFAIR**
**BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS**
**Time: 3 Hour**
**Max Marks: 75**
**Q. Code: OF728**

**Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.**
**The figures in the right hand margin indicate marks.**

## Part-I

**Q1** **Answer the following questions:** (2×10)

a) Enlist the importance of documentation in pharmaceutical industry?
b) How is innovator drug different from generic?
c) What is NDA in drug development?
d) Write down the objectives of ICH.
e) What is global submission of IND?
f) How do the regulatory requirements in ROW countries harmonise?
g) What do you mean by IMPD dossier?
h) Write down the role of Data and Safety Monitoring Board in clinical trial.
i) What is the role of HIPPA in clinical trial?
j) What is triage in pharmacovigilance?

## Part-II

**Q2** **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Give details note on NDA.
b) Write a note on ANDA. Explain PARA I to IV filling in ANDA.
c) Explain in details Master Formula Record. (MFR).
d) Explain guidelines of ICH-Q.
e) How to develop clinical trials protocol at institute level?
f) Give details note on MHRA.
g) Define CTD and eCTD. Explain in detail.
h) Give in details of Pharmacovigilence safety monitoring in Clinical Trials.
i) Define orange book. Explain investigator brochure (IB).

## Part-III

**Long Answer Type Questions (Answer Any Two)**

**Q3** Give important of CRO. What about out sourcing of BA & BE studies to CRO? **(10)**

**Q4** Explain the various components of FDA. **(10)**

**Q5** What is dossier? Explain regulatory requirements of dossier for ROW countries. **(10)**

**Q6** What is Post Marketing Surveillance (PMS)? Give it's important in clinical trials. **(10)**

Registration No : | 2 | L | 0 | 8 | 2 | 5 | L | 0 | L | L |

Total Number of Pages : 01

M.Pharm
MPH102T

1st Semester Regular / Back Examination: 2021-22
DRUG DELIVERY SYSTEM
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS
Time : 3 Hour
Max Marks : 75
Q.Code : OF629

**Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.**
**The figures in the right hand margin indicate marks.**

**Part-I**

Q1 **Answer the following questions :** (2×10)

a) What are toxoids?
b) Why permeation enhancers are used for TDDS?
c) What is pharmacogenetics?
d) What is the importance of adhesive rims for TDDS?
e) Differentiate proteins and peptides.
f) Classify pH-sensitive drug delivery systems.
g) Mention the importance of swelling index?
h) What is wicking agent? Give an example.
i) Define rate limiting step of a dosage form.
j) What do you mean by Fickian diffusion?

**Part-II**

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Personalized medicine
b) Various approaches for SR/CR formulations.
c) Polymer application in pharmacy
d) Osmotic activated Drug Delivery Systems
e) 3-D printing
f) Single shot vaccines
g) Telepharmacy
h) Approaches to extend GI transit.
i) Barriers for protein delivery.

**Part-III**

**Long Answer Type Questions (Answer Any Two)**

Q3 Name various skin barriers for penetration of drug. Discuss in detail the technologies involved in TDDS. (10)

Q4 Differentiate between CR and SR; Discuss various mechanisms of Drug Delivery from SR/CR formulations in detail. (10)

Q5 Write the Principle of muco-adhesion, discuss in detail about formulation and evaluation of buccal drug delivery systems (10)

Q6 Mention the drawbacks for ocular permeation. Discuss various drug delivery systems for eye. (10)

Registration No : 2 1 0 8 2 5 1 0 1 1

Total Number of Pages : 01

M.Pharm
MPH103T

1st Semester Regular / Back Examination: 2021-22
MODERN PHARMACEUTICS
BRANCH(S): PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS
Time : 3 Hour
Max Marks : 75
Q.Code : OF679

Answer Question No.1 (Part-1) which is compulsory, any seven from Part-II and any two from Part-III.
The figures in the right hand margin indicate marks.

## Part-I

Q1 Answer the following questions : (2×10)

a) What are the objectives of preformulation studies?
b) Why is Real-Time stability testing performed?
c) What is SMEDDS?
d) State the scope of validation.
e) What do you mean by Quality by Design?
f) What is a Contour Plot?
g) Define multiple emulsion and microemulsion.
h) What are the main objectives of cGMP?
i) How does decompression affect the quality of tablets?
j) What is Chi square test?

## Part-II

Q2 Focused-Short Answer Type Questions- (Answer Any Seven) (5×7)

a) Write about the theories of dispersion.
b) Write a short note on accelerated stability testing.
c) How is pyrogen testing of parenterals performed?
d) Wnat are the different types of process validation?
e) Write about the ICH guidelines for calibration of equipments.
f) Give a brief note on master formula record.
g) Write about the principles of GMP.
h) Explain product recall system.
i) Give a brief note on ANOVA test.

## Part-III

Long Answer Type Questions (Answer Any Two)

Q3 Describe briefly about the compression force-time profiles of tablets. (10)

Q4 Illustrate the different concepts of Total Quality Management. (10)

Q5 Discuss about the optimization techniques in pharmaceutical formulations. (10)

Q6 Describe briefly about the URS, DQ, IQ, OQ, and PQ processes of facilities. (10)

Registration No : | 2 | 1 | 0 | 8 | 2 | 5 | L | 0 | 1 | 1 |

Total Number of Pages : 02

M.Pharm
MPA101T/ MPC101T/ / MPG101T/
MPH101T/ MPL101T/ MQA101T

1st Semester Regular / Back Examination: 2021-22
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES
BRANCH(S): ANALYSIS & QUALITY ASSURANCE,
PHARMACEUTICAL ANALYSIS/ CHEMISTRY/ PHARMACOGNOSY/
PHARMACEUTICAL TECHNOLOGY, PHARMACEUTICS/ PHARMACOLOGY/ PQA
Time : 3 Hour
Max Marks : 75
Q.Code : OF587

**Answer Question No.1 (Part-1) which is compulsory, any eight from Part-II and any two from Part-III.**
**The figures in the right hand margin indicate marks.**

## Part-I

Q1 **Answer the following questions :** (2×10)

a) What are chromophores and Auxochromes. Give examples?
b) At wave number 1710 to 1740 cm–1 what are the functional groups that may appear for an organic compound in IR spectrum.
c) What is quenching? Give two examples of quencher.
d) Define chemical shift. Write the significance TMS.
e) What is the difference between the base peak and the molecular ion peak?
f) What is HPLC and UHPLC. Write the advantages of UHPLC over HPLC.
g) What is theoretical plate. Write its significance.
h) Write the sources of X-Rays. Write the importance of X-Ray crystallography in structure elucidation.
i) Why is nitrogen gas used in TGA analysis?
j) When and why, for a pharmaceutical preparation, one can proceed for DTA or DSC analysis.

## Part-II

Q2 **Focused-Short Answer Type Questions- (Answer Any Seven)** (5×7)

a) Briefly discuss the electronic transition in UV spectroscopy.
b) Explain the principle and application of capillary electrophoresis.
c) Explain about spin-spin coupling and its importance in NMR.
d) Explain Bragg's equation.
e) What is shielding and de-shielding write the importance of J constant.
f) Write the criteria for fluorescence and its pharmaceutical application.
g) Write the principle instrumentation and application of flame photometry.
h) Explain the principle involved in Gas-chromatography.
i) Explain the functional group region of IR spectrum. How will you proceed for an IR spectrum. Interpretation

## Part-III

**Long Answer Type Questions (Answer Any Two)**

**Q3** Discuss instrumentation and principle of mass spectroscopy with a diagram **(10)**

**Q4** Write a note on any two. **(10)**

a) Paper electrophoresis.
b) Ion exchange chromatography
c) MALDI
d) HPTLC

**Q5** Explain solvents and selection criteria for UV spectroscopy. Discuss various sample preparation techniques for IR spectroscopy. **(10)**

**Q6** What are the electrodes used in potentiometry. Write the principle of DSC and application of TGA. **(10)**