MPC/MPH/MQA/MPG/MPV/MIP/MPA/MPL-101T

Roll No. | | | | | | | | | | |

Odd Semester Examination, 2019-20

M.Pharma (Semester-1)- Pharmaceutical Chemistry

(Modern Pharmaceutical Analytical Techniques)

Time: 3:00 hrs. **Max. Marks: 75**

Total no. of printed pages: 1

All questions are compulsory:

Section-A

Q 1. Answer all questions. **[10x2=20]**

a) Discuss spin-spin coupling

b) Explain principle and detector of IR spectroscopy

c) Define flame emission spectroscopy

d) What is ring rule and Braggs equation.

e) McLafferty rearrangement

f) What is X-ray powder diffraction method.

g) Define Electrophoresis

h) Principle of paper chromatography

i) Define quenching methods in spectrofluorometric analysis

j) Write short note on thin layer chromatography

Section-B

Q2. Long Answer type (Attempt any Two): **[2x10=20]**

a) Explain beer's - Lambert law and write about instrumentation associated with UV.

b) Explain principle instrumentation and application of NMR.

c) Draw well labeled diagram of HPLC and explain principle, detector and application of HPLC.

Section-C

Q3. Short Answer Type (Attempt any seven): **[7x5=35]**

a) Write basic principle and application of potentiometric titration

b) Explain in detail about instrumentation of X-ray crystallography.

c) Discuss nitrogen rule and its applications in mass spectrometry.

d) Write note on coupling constant and chemical shift.

e) Explain principle and application of Gas chromatography

f) Write general rules for predicting prominent peaks in mass spectroscopy.

g) Explain ion exchangers. Discuss about factor affecting ion exchanging separations

h) Explain the principal and application of column chromatography

i) Explain shielding -de shielding effect with one example of each.

j) Explain principle and application of atomic absorption spectrophotometer.

MPH-102T

Roll No. | | | | | | | | | | | |

Odd Semester Examination, 2019-20
M.PHARMA. (SEMESTER-I)-PHARMACEUTICS
DRUG DELIVERY SYSTEM (MPH-102T)

Time : 3:00 hr **Max. Marks : 75**

Total no. of printed pages: 2

Note: Attempt all questions as mentioned:

1. Attempt All The Questions. Each Question Carry Equal Marks **10x2=20**

a) What is the need to develop controlled drug delivery system?

b) What is the need to make gastroretentive drug delivery system?

c) Differentiate between controlled and sustained drug delivery system

d) Define personalized drug delivery system

e) Define erosion mechanism

f) Drug is not a suitable candidate if it is of-

a) Limited solubility b) Limited permeability

c) None of them d) Both of them

g) Rate of dissolution depends on-

a) Solubility b) Surface area

c) Hydrophilicity d) All of them

h) Dye test may fail in the case of-

a) Use of non-ionic emulsifiers b) Use of ionic emulsifiers

c) Water in oil emulsion d) oil in water emulsion

i) Example of suspending agent

a) Sodium sulfate b) Sodium chloride

c) Gelatin d) Sodium tartrate

j) Water attack test is used specially in the case of

a) Borosilicate glass b) Soda lime glass

c) Plastics d) Treated soda lime glass

k) Gastro transit time depends upon

a) Nature of food intake b) Patho-physiological condition

c) circadian rhythm d) all of the

P.T.O

2. **Long Answer Questions (answer any two questions)** **2x10=20**

a) Discuss various factors affecting the selection of suitable drug candidate while designing the controlled drug delivery system

b) Discuss the various types and method of preparation of transdermal drug delivery system

c) Discuss the method of formulation and evaluation delivery system for protein and other macromolecules

3. **Short answer type (attempt any seven question out of nine questions)** **7x5=35**

a) Write in brief about bioelectric medicines

b) Explain term protein and peptide delivery. What are barriers for protein and peptide delivery

c) Discuss the evaluation of transdermal drug delivery system

d) What are the various approaches for gastroretentive drug delivery system?

e) Discus about single shot vaccine

f) Give a neat labeled diagram of skin and also discuss the mechanism of drug penetration through skin

g) Discuss the mechanically activated drug delivery system

h) Discus in brief about the drug release mechanism form sustained release drug delivery system

i) Discuss telepharmacy with their advantage and probable disadvantages.

Roll No. | | | | | | | | | | | |

Odd Semester Examination, 2019-20
M.PHARM (SEMESTER 1)
MODERN PHARMACEUTICS (MPH103T)

Time : 3:00 hr | Max. Marks : 75

Total no. of printed pages: 1

Note : Attempt all sections as mentioned :

SECTION A

ATTEMPT ALL QUESTIONS **(10 X2 = 20 MARKS)**

Q1. Define optimization.
Q2. Give full form of IQ, DQ, OQ and PQ.
Q3. Name various methods of Drug-Excipients interaction studies.
Q4. Mention the objectives of cGMP.
Q5. Differentiate between validation and calibration.
Q6. Define Heckel Plot.
Q7. What if the role of friction during tablet punching.
Q8. Define ANOVA Test.
Q9. What does SMEDDS stand for? What is its purpose?
Q10. Define response surface method.

SECTION B

ATTEMPT ANY TWO QUESTIONS **(2 X 10 = 20 MARKS)**

Q1. Elaborate on cGMP requirements for equipment's, returned and salvaged drug products, batch processing records and Master formula records.
Q2. Enumerate dissolution variables and the parameters of dissolution. Explain F1 AND F2 tests and their significance.
Q3. Outline the principle areas of Preformulation research. Explain any five

SECTION C

ATTEMPT ANY SEVEN QUESTIONS **(7 X5 = 35 MARKS)**

Q1. Describe the process of Procurement of materials.
Q2. Write in detail about material management and its importance in pharmaceutical industry.
Q3. Give a brief account of preformulation of Emulsions.
Q4. Write briefly about sales forecasting in pharmaceutical Industry.
Q5. Explain ICH Guidelines for calibration of pharmaceutical equipments.
Q6. Write a brief note on Total Quality management.
Q7. Explain evaluation parameters of suspensions.
Q8. Describe the concept and parameters of Optimization.
Q9. Write in detail about various types of validation.

MPH-104T

Roll No. | | | | | | | | | | | |

Odd Semester Examination, 2019-20
M.PHARM (PHARMACEUTICS) 1ST YEAR (1ST SEMESTER)
REGULATORY AFFAIRS (MPH- 104 T)

Time : 3:00 hr **Max. Marks : 75**

Total no. of printed pages: 1

Note : Attempt all sections as mentioned :

Section – A

Very Short Answer type of questions (answer all question) **10x 2= 20**

Q.1 What is drug master file
Q.2 Write full form of NDA and ANDA
Q.3 What is post marketing surveillance
Q.4 What is the purpose of TGA guidelines
Q.5 What is code of federal regulation
Q.6 What is the purpose of institutional review board
Q.7 Define pharmacovigilance
Q.8 What is the purpose of ICH guidelines
Q.9 What are the steps in drug registration process
Q.10 Regulation of medical devices

Section – B

Long answers type of questions (answer 2 out of 3 questions) **2x10= 20**

Q1. Describe in details the drug approval and registration process.
Q2. Explain in details ICH - guidelines of ICH-Q, S E, M
Q3. Discuss the development of clinical trial protocols and the role of institutional. Review board/ independent ethics committee.

Section – C

Short answers type of questions (answer 7 out of 9 questions) **7x 5= 35**

Q1. Write a note on MHRA
Q2. Write a brief note on dossier development.
Q3. Regulation for combination products and medical devices
Q4. Write down the general parameters bioequivalence study design.
Q.5. Write a note on post approval process.
Q6. Write a note on industry and FDA liaison
Q7. What are the requirements of clinical study process,
Q8. Discuss the pharmacovigilance safety monitoring in clinical trials.
Q9. Discuss Hatch-Waxman Act.

Lib.

MRM 301T

ROLL NO.

ODD SEMESTER EXAMINATION
M.PHARM 3RD SEMESTER
RESEARCH METHODOLOGY

Time: 3.00 hrs **Max Marks: 75**

Attempt any five question each question carry equal marks 5×15=75

1. **a.** Give general introduction about bias in research. Discuss in details about reducing biases in research.

b. Describe in details about cross-over study design.

2. Describe in detail about general principle of declaration of Helsinki.

3. **a.** describe as per CPCSEA guideline transportation of laboratory animals.

b. discuss essential animal husbandary practices in laboratory animal facility.

4. **a.** Define research, types of research. Difference between Descriptive and fundamental research

b. Give description about different types of hypothesis.

5. Write a note on any three

a. Benificence **b.** Non- Maleficence

c. Autonomy **d.** Medical Futility

6. Setup ANOVA for the following per hectare yield for three varieties of wheat each grown on four plots:

X1	X2	X3
6	5	5
7	5	4
3	3	3
8	7	4