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**Odd Semester Examination, 2019-20**  
**M.Pharm (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]**

- Discuss spin-spin coupling
- Explain principle and detector of IR spectroscopy
- Define flame emission spectroscopy
- What is ring rule and Bragg's equation.
- McLafferty rearrangement
- What is X-ray powder diffraction method.
- Define Electrophoresis
- Principle of paper chromatography
- Define quenching methods in spectrofluorometric analysis
- Write short note on thin layer chromatography

**Section-B**

**Q2. Long Answer type (Attempt any Two):**

**[2x10=20]**

- Explain Beer's - Lambert law and write about instrumentation associated with UV.
- Explain principle instrumentation and application of NMR.
- 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]**

- Write basic principle and application of potentiometric titration
- Explain in detail about instrumentation of X-ray crystallography.
- Discuss nitrogen rule and its applications in mass spectrometry.
- Write note on coupling constant and chemical shift.
- Explain principle and application of Gas chromatography
- Write general rules for predicting prominent peaks in mass spectroscopy.
- Explain ion exchangers. Discuss about factors affecting ion exchanging separations
- Explain the principle and application of column chromatography
- Explain shielding -de shielding effect with one example of each.
- Explain principle and application of atomic absorption spectrophotometer.

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**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)**

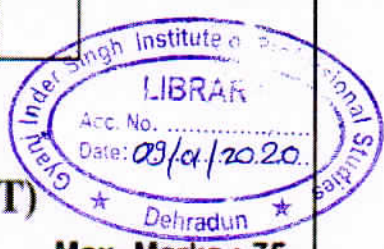
**2x10=20**

- 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) Discuss 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) Discuss in brief about the drug release mechanism from sustained release drug delivery system
- i) Discuss telepharmacy with their advantage and probable disadvantages.

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<b>Odd Semester Examination, 2019-20</b> <b>M.PHARM (SEMESTER 1)</b> <b>MODERN PHARMACEUTICS (MPH103T)</b>											
Time : 3:00 hr											
 <b>Max. Marks : 75</b>											

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 is 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)**

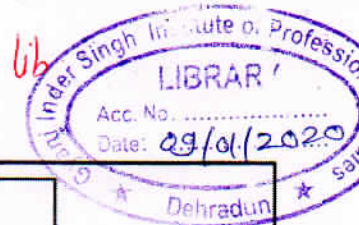
- Q1. Elaborate on cGMP requirements for equipment's, returned and salvaged drug products, batch processing records and Master formula records.
- Q2. Enumerate dissolution variables and the parameters of dissolution. Explain F1 AND F2 tests and their significance.
- Q3. Outline the principle areas of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



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**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.
- Q5. 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.

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**Max Marks: 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