Odd Semester Examination, 2017-18

M.PHARMA. (SEMESTER-I)

REGULATORY AFFAIRS

Time: 03:00 Hours **Max Marks : 75**

Note : Attempt **any five** questions, each question carry equal marks.

1. (a) What is NDA? What are the general requirements for filling an NDA? Write about the Review time frame for it. (8)

   (b) What is Hatch Waxman Act? What do you understand by 180 days exclusivity period? (7)

2. From the last few years, the generic drugs are replacing the brand name drugs in the market and they have been considered as a boon to the public'. Justify the statement with the suitable assertions. (15)

3. Write note on **any two** : (7.5x2)

   (a) General structure of an IMPD including substantial amendment.

   (b) Difference between submission of NDA and ANDA

   (c) Content and resources of IND.

4. In-Vivo and In-Vitro comparison assessments are key parameters in evaluating or enhancing a drug product performance.' Give the logical explanation in support of the above statement. (15)

5. Write short notes on the following : (7.5X2)

   (a) Post approval regulatory affairs.

   (b) Trigger period and Suspension of approval of an abbreviated new drug application:

6. (a) Define CFR? Give the highlighted points regarding CFR and what is the importance of maintaining such records? (7.5)

(b) What is the significance of CMC requirements for any clinical trial or marketing application? (7.5)

7. (a) Discuss about composition, functions and procedure of IRB. (7.5)

(b) Write a note on major sections of Investigator Brochure. (7.5)

8. (a) Explain standard operating procedure for informed consent procedure. (7.5)

(b) Discuss common practice for safety monitoring in clinical trials. (7.5)

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Odd Semester Examination 2017-18

M.PHARMA. (SEMESTER-I)

MODERN PHARMACEUTICS

Time: 03:00 Hours **Max Marks : 75**

Note: Attempt **any five** questions.All carry equal marks.

1. (a) Give the importance of drug- excipient interaction in prefomulation studies. How can you detect interactions between drug and excipient by DSC. [7.5]

   (b) What is the purpose of stability testing. Explain the terms accelerated, intermediate , long term stability studies and give the storage conditions and testing frequency. [7.5]

2. (a) Explain DLVO theory and give its application in suspensions. [6]

   (b) Give the importance of buffers and protectants in parenterals.How are lyophilized powders for parenterals prepared. [4+5]

3. Throw light on optimization techniques in pharmaceutical formulations.Enlist the various factors and responses during optimization of tablets, capsules and liquids. [10+5]

4. Explain the terms compression and consolidation. Discuss the events that occur during process of compression. [3+12]

5. Define the terms URS,DQ, IQ,OQ,PQ. Differentiate between validation and calibration . Write a note on Validation Master Plan. [8+2+5]

6. Give the importance and functions of inventory control in material management .Discuss the techniques of inventory control. [5+10]

7. Discuss dissolution profile comparison by using similarity factor. Explain Higuchi and Peppas model on drug release. [6+9]

Or

From the following table check whether two attributes x and y are associated with each other or not.(χ^2 at 1% level of significance is 3.84) [15]

	x	y
x	230	148
y	151	471

8. (a) Write short notes on **any two** :

(i) SMEDDS

(ii) Types of process validation

(iii) Sales forecasting [7.5x2]

Or

(b) Three samples have been obtained from normal population of equal variances .Test the hypothesis at 5% level that the population means are equal .Given that $F_{0.05}$ = 3.88 for d.f.2 and 12. [15]

X_1	X_2	X_3
8	7	12
10	5	9
7	10	13
14	9	1
11	9	14

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Odd Semester Examination, 2017-18

M.PHARM. (SEMESTER-I)

DRUG DELIVERY SYSTEM

Time: 03:00 Hours **Max Marks: 75**

Notes: (1) All questions carry **equal** marks.

(2) Attempt **any five** questions.

1. Classify vaccines and define all types of vaccines. Explain factors affecting delivery of vaccines by mucosal route. [5+10]

2. Classify smart polymers. Discuss role of smart polymers in pH regulated and enzyme regulated drug delivery systems. [3+6+6]

3. What is the rationale for developing gastroretentive drug delivery systems? Explain muoadhesion and effervescent approaches for gastric retention of drugs. [5+10]

4. Enumerate various barriers for oral delivery of peptides and proteins. Discuss at least four formulation approaches to overcome these barriers. [3+12]

5. With the help of suitable diagrams, illustrate various physiological barriers of permeation in ocular drug delivery. Discuss any two approaches for delivery of drug to the posterior segment of eye. [5+10]

6. Classify different oral sustained release drug delivery systems. Describe oral sustained release drug delivery systems giving emphasis on their formulation, factors affecting, drug release rate equations and schematic diagrams. [15]

7. Enumerate different in vitro and in vivo evaluation tests for transdermal patches. Discuss in vitro drug release testing of transdermal patches using compendial and non-compendial apparatuses. [15]

8. Write short notes on **any three**: [5+5+5]

   (a) 3D Printing

   (b) Formulations of proteins and peptides

   (c) Mechanical activated drug delivery

   (d) Single shot vaccine

   (e) Evaluation of mucoadhesion property of polymers

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M.Pharm (Pharmaceutics)

New Syllabus

Odd Semester Examination 2017-18

M.PHARMA. (PHARMACEUTICS) (SEMESTER-I)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Time: 03:00 Hours **Max. Marks : 75**

Note: Attempt **any five** questions. All questions carry equal marks.

1.	(a)	Describe the theory and principle of UV-Visible spectroscopy.	(7.5)
	(b)	Write the applications of UV- Visible spectroscopy in organic compounds.	(7.5)
2.	(a)	Describe in detail the principle and instrumentation of IR spectroscopy.	(7.5)
	(b)	Describe in detail the factors affecting Infrared spectroscopy.	(7.5)
3.	(a)	Write in detail the principle of NMR spectroscopy.	(7.5)
	(b)	Explain in detail the factors influencing chemical shift.	(7.5)
4.	(a)	Describe in detail the principle and instrumentation of Mass spectroscopy.	(7.5)
	(b)	Explain the general fragmentation patterns for the interpretation of organic compounds in Mass Spectroscopy.	(7.5)
5.	(a)	Explain the principle and application of flame emission spectrophotometer.	(7.5)
	(b)	Describe the factors affecting Fluorescence intensity.	(7.5)
6.	(a)	Draw a schematic diagram of Gas Chromatograph set up and briefly explain the instrumentation.	(7.5)
	(b)	Compare and contrast Normal Phase Chromatography and Reverse Phase Chromatography.	(7.5)
7.	Write notes on: (**any three**)		(5×3=15)
	(a)	Gel electrophoresis	
	(b)	Affinity Chromatography	
	(c)	Ion exchange chromatography	
	(d)	Column Chromatography	
8.	(a)	State Bragg's law. Explain the X-ray powder diffraction method.	(7.5)
	(b)	Explain the principle and methods involved in Radio Immunoassay.	(7.5)

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