Odd Semester Examination, 2017-18

M.PHARMA. (SEMESTER-I)

ADVANCED ANALYTICAL TECHNIQUES

Time: 03:00 Hours **Max Marks: 70**

Note: (1) Attempt **any five** questions.

(2) All questions carry **equal** marks.

1. (a) Write theory and principle of UV spectroscopy. [7]

(b) Differentiate between the following: [3.5×2]

i. Hypsochromic shift and Bathochromic shift

ii. Fluorescence and Phosphorescence

2. (a) Describe in detail the factors affecting Infrared spectroscopy. [7]

(b) Explain the sampling handling techniques in Infrared spectroscopy. [7]

3. (a) Write in detail principle of ^{1}HNMR spectroscopy. [7]

(b) Write short note on: [3.5×2]

i. Chemical shift

ii. Spin-spin coupling

4. (a) Describe the principle and instrumentation of Gas chromatography. [7]

(b) Differentiate between the following: [3.5×2]

i. Reverse phase and Normal Phase Chromatography

ii. HPLC and GC

5. Write short note on: [3.5×4]

(a) Instrumentation of Raman spectroscopy

(b) Factors interfering with Fluorescence intensity

(c) Principle of Atomic absorption spectroscopy

(d) Interferences in Atomic emission spectroscopy

6. (a) Describe in detail the principle and instrumentation of Mass spectroscopy. [7]

(b) Explain the following: [3.5×2]

i. McLafferty rearrangement

ii. General rules of fragmentation

7. Explain the following in detail: (**any two**) [7×2]

(a) High performance capillary electrophoresis

(b) HPTLC

(c) X-ray diffraction

(d) Differential Scanning Calorimetry

8. (a) Explain the applications of UV spectroscopy. [7]

(b) Explain in detail the applications of Mass spectroscopy [7]

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Odd Semester (Back Paper) Examination, 2017-18

M.PHARMA. (SEMESTER-I)

PHARMACEUTICAL STATISTICS AND COMPUTER APPLICATION

Time: 03:00 Hours **Max Marks: 70**

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

1. Write short note on **any two**: [2x7=14]

   (a) Graphical representation of data

   (b) Random and Systematic sampling

   (c) Regression

2. Calculate Mean, Mode & Median for given data [14]

Class Interval	0-5	5-10	10-15	15-20	20-25	25-30	30-35
Frequency	3	5	2	10	4	5	1

3. (a) Define probability and its various definitions. [2x7=14]

   (b) It is given that 3% of the electric bulbs manufactured by a company are defective. Find The probability that a sample of 100 bulbs will contain no defective bulb. (Given that $e^{-3}=0.05$)

4. (a) Find the coefficient of rank correlation for the following data : [2x7=14]

X	8	36	98	25	75	82	92	62	65	35
Y	84	51	91	60	68	62	86	58	35	49

   (b) From the data given below estimate the most likely height of a father whose son's height is 70". The coefficient of correlation between the height of father and son is 0.8. Father's mean height is 67" & standard deviation 3.5" and son's mean height is 65" & Standard deviation 2.5".

5. The following table gives the classification of 200 fishes according to the sex and the infection. Test whether infection is independent of the sex of fish. [14]

Sex	Infected	Uninfected
Male	65	45
Female	35	55

(Given that the value of chi-square at 0.05 level of significance is 3.84)

6. Three samples below have been obtained from normal population of equal variances. Test the hypothesis at 5% level of significance. [Given $F_{0.05}(2,12)=3.88$]. [14]

X_1	X_2	X3
8	7	12
10	5	9
7	10	13
14	9	12
11	9	14

7. Write short note on **any two**: [2x7=14]

   (a) Binomial Distribution

   (b) Correlation and its types

   (c) Factorial Design

8. Discuss the roll of computer in pharmaceutical sciences in detail. [14]

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Odd Semester (Back Paper) Examination 2017-18

M.PHARMA. (SEMESTER-I)

DRUG REGULATORY AFFAIRS AND INTELLECTUAL PROPERTY RIGHTS

Time: 03:00 Hours **Max Marks : 70**

Note : Answer **any five** of the following questions :

1.	(a)	What do you mean by drug regulatory affairs? Briefly discuss on primary, secondary and tertiary literature by giving suitable example.	[7]
	(b)	Write a note on Schedule 'Y' of Drugs and cosmetic act 1940.	[7]
2.	(a)	Briefly discuss on registration procedure of Pharmaceutical products for International marketing.	[7]
	(b)	Write a note on SMF.	[7]
3.	(a)	Write a note on Orange guide	[7]
	(b)	Write a detail note on ICH guidelines.	[7]
4.	(a)	Write an overview on GLP and its requirements in pharmaceutical industries	[7]
	(b)	Write a note on GWP.	[7]
5.	(a)	Discuss on Intellectual property rights	[7}
	(b)	Write a short note on Patents act	[7]
6.	(a)	Briefly discuss on Trademark act	[7]
	(b)	Discuss on Copyright Act	[7]
7.	(a)	Briefly discuss on Schedule 'M' of Drugs and cosmetic act 1940.	[7]
	(b)	Write a note on dossiers preparation.	[7]
8.	(a)	Briefly discuss 210 and 211 parts of 21 CFR.	[7]
	(b)	What do you mean by Validation? Discuss process validation in brief.	[7]

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Odd Semester (Back Paper) Examination, 2017-18

M.PHARMA. (SEMESTER-I)

PRODUCT DEVELOPMENT-I

Time: 03:00 Hours **Max Marks : 70**

Note : Attempt **any 5** questions. All carry equal marks.

1. Throw light on pre and post independence scenario of Indian Pharmaceutical Industry. Explain the term "SWOT ANALYSIS". Give SWOT analysis of Indian pharmaceutical industry . (7+2+5)

2. Why is it necessary to carry out preformulation studies. Throw light on the the importance of dissolution study in preformulation studies. Discuss the various types of dissolution studies . (2+4+8)

3. Describe the various steps involved in product development with aid of flow chart. (14)

4. Define stability indicating assay methods. Discuss various steps involved in the development of SIAMs. (2+12)

5. Discuss the various formulation additives in solid dosage form . What do you understand by the term " bolting of lubricants". (12+2)

6. (a) Give classification by age of pediatric and geriatric population . (6+8)

   (b) Give reasons for the following :

   (i) Why enteric coated tablets are not preferred for elderly patients.

   (ii) Why sugar containing excipients are avoided in geriatric dosage forms.

   (iii) Why is it difficult to accurately predict absorption rates for sublingual and buccal formulation in elderly population

   (iv) Why the tatrazine and lactose should be avoided in pediatric formulations

7. Discuss photo stability testing in detail. (14)

8. Write short notes on **any two** : (7+7)

(i) Stress testing

(ii) Polymorphism and its effect on bioavailability, chemical and physical stability.

(iii) Shelf life determination

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Odd Semester Examination, 2017-18

M.PHARMA. (SEMESTER-I)

QUALITY ASSURANCE-I

Time: 03:00 Hours **Max Marks : 70**

Note : Attempt **any five** questions. Each question carries equal marks.

1. Discuss the concept of Quality Management in Pharmaceutical Industry.

2. Explain the procedure and Penalties in Consumer Protection Act.

3. Write a short note on **any two** :

   (a) Schedule M2

   (b) Schedule Y

   (c) Schedule M1

4. Give the silent features of environmental Protection Act -1986.

5. Discuss the Various amendments with reference to Drug and Cosmetics Act 1940.

6. Discuss briefly about the features of loan License and compulsory Licensing.

7. Write a short note on **any one** :

   (a) Drug Prices Control Act.

   (b) Pollution Control Act.

   (c) O.Q.

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MPHR-125 2074

Even Semester Examination 2017-18

M.PHARMA. (Pharmaceutics) (SEMESTER-II)

BIOPHARMACEUTICS & PHARMACOKINETICS

Time: 03:00 Hours **Max Marks : 70**

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

Q.1 Discuss various factors that influence the process of drug absorption in body. (14)

Q.2 a. Discuss Phase I drug metabolism process. (7)

b. Explain the correlation between volume of distribution, plasma half life and clearance. (7)

Q.3 a. Explain in detail about biopharmaceutics classification system. (7)

b. Explain pharmacokinetic interactions observed during drug absorption and drug excretion. (7)

Q.4 Derive various pharmacokinetic parameters for a drug when it follows one compartment open model intravenous bolus administration. (14)

Q.5 a. Explain various dissolution apparatus used for evaluation of solid dosage form. (7)

b. Explain the reason for nonlinearity of drug pharmacokinetics. (7)

Q.6 a. Discuss pharmacokinetic variables that influence biopharmaceutical performance of a drug. (7)

b. Explain the concept of individualization of of drug dosage regimen. (7)

Q.7 a. Explain various routes of non-renal excretion of drugs. (7)

b. Explain crossover design. (7)

Q.8 Give short notes on (any two) : (7×2)

a. Partition coefficient and drug absorption

b. Therapeutic drug monitoring

c. Tissue protein binding

d. Dose adjustments in renal and hepatic failure

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Even Semester Examination 2017-18

M. PHARMA. (I year)(SEMESTER-II)

ADVANCES IN DRUG DELIVERY SYSTEM

Time: 03:00 Hours **Max Marks: 70**

Note: Attempt **only five** questions, one question in each Unit. Each question carries equal marks.

1. Write the: **(any one)**

   (a) Definition, classification, characterization, properties and application of biodegradable polymers.

   (b) Definition, classification, characterization, properties and application of non-biodegradable polymers.

2. Explain **(any one)** of the following:

   (a) Concept, systems of design, and classification for controlled drug delivery system.

   (b) Rate preprogrammed activation modulated drug delivery system.

3. Write in detail: **(any one)**

   (a) Formulation and evaluation of controlled release systems– oral.

   (b) Formulation and evaluation of controlled release systems– parenteral.

4. Discuss in detail: **(any one)**

   (a) Factors influencing delivery, formulation and evaluation of – Transmucosal.

   (b) Factors influencing delivery, formulation and evaluation of – colonic drug delivery system.

5. Give the role of prodrugs in Target oriented drug delivery systems. Write classification and advantages of prodrugs.

6. Discuss the various factors influencing transdermal delivery. Write about formulation and evaluation lonophoresis.

7. Write in detail about nano particles OR Liposomes -Target oriented drug delivery systems.

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