

Your Roll No.....

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School of Pharmaceutical Education and Research
M. Pharm. I Semester Examination (2023-24)

Subject: Advanced Pharmaceutical Analysis
Paper Code: MPA 102T Date: 11-03-2024

Maximum Marks: 75
Time: Three hours

(Write your Roll No. on the top immediately on receipt of this question paper)

Note: This paper has two Sections; A and B. Attempt both the sections.

Section A: Answer all the questions.

Section B: Answer any 4 out of 6 questions

Abbreviations Used:

CO-Course Outcome, PO- Program Outcome, BTL- Bloom Taxonomy Level: BT level 1- Remember; BT level 2- Understand; BT level 3- Apply; BT level 4- Analyze; BT level 5- Evaluate; BT level 6- Create.

C A

SECTION-A

Answer the following in brief (Attempt all questions)

5x3= 15 Marks

Q. No 1	Question	BTL	CO	PO
(a)	Define impurities. Write the classification of impurities in drug substance or API as per ICH guidelines.	4	3	1, 4
(b)	What is the control threshold limit and its importance in elemental impurities determination?	4	3	1, 4
(c)	Explain briefly about PCR studies for gene regulation.	3	4	1, 3, 10
(d)	Write briefly about HPTLC fingerprinting.	2	5	1, 3, 4, 10
(e)	Write the differences between fluorescence immunoassays and luminescence immunoassays.	3	4	1, 3, 10

SECTION B

Long type Questions (Attempt any 4 out of 6)

4x15= 60 Marks

	Question	BTL	CO	PO
Q. No 2	Write a full account of impurities in residual solvents including their classification, limits and reporting levels.	4	3	1, 4
Q. No 3	Write detailed notes on (i) Quantification and applications of immunoassays. (ii) Quantification of impurities as per ICH guidelines.	3, 4	3, 4	1, 3, 4, 10
Q. No 4	Write the principle and method for the assays of Heparin sodium and Adsorbed Diphtheria vaccine.	3	4	1, 3, 10
Q. No 5	Write a full account of WHO and ICH stability testing guidelines with regard to impurity profiling and degradant characterization.	4	3	1, 4
Q. No 6	Discuss different analytical methods used for the identification of potential elemental impurities.	4	3	1, 4
Q. No 7	Write a full account of stability testing protocols.	4	3	1, 4