Your Roll No.....

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M. Pharm. I Semester Examination (2023-24)

Subject: **Pharmaceutical Validation** Maximum Marks: **75**
Paper Code: **MPA 103T** Date: **13-03-2024** 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 all the two 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.

SECTION-A

Answer the following in brief (Attempt all questions) **5x3= 15 Marks**

Q. No 1	Question	BTL	CO	PO
(a)	What is a Validation Master Plan (VMP) and why is it considered an essential document in the validation process?	2	2	1, 2-4, 6
(b)	What are the acceptance criteria for measuring cylinders and beakers during the qualification process, and how do they contribute to ensuring precise volumetric measurements?	2	2	1, 2-4, 6
(c)	What are the critical parameters that need to be evaluated during the qualification of a Pharmaceutical Water System and pure steam generation system?	4	4	1,5,9
(d)	Define Digital signature, Electronic record and Electronic signature as per CFR 21 part 11	2,3	3	1,6
(e)	What are the criteria for the invention to be patented?	1	2	1, 2-4, 6

SECTION B

Long type Questions (Attempt any 4 out of 6) **4x15= 60 Marks**

	Question	BTL	CO	PO
Q. No 2	a. How would you streamline the qualification and validation process to ensure efficiency without compromising quality?	2	2	1,2,4,6
	b. What are the specific challenges associated with qualifying manufacturing equipment compared to analytical instruments and laboratory equipment?	3	4	1,5,9
Q. No 3	a. When qualifying electronic balances, what are the critical parameters to consider, and how do they differ from the qualification process for other analytical instruments like pH meters or spectrophotometers?	3	4	1,5,9
	b. Outline the specific qualification procedures for any one of the following instruments: UV-Visible spectrophotometer and HPLC?	2,3	3	1,6
Q. No 4	a. Discuss the validation process for HVAC systems in pharmaceutical facilities, including the key parameters evaluated and the acceptance criteria?	2	3	1,6
	b. Discuss the importance of cleaning equipment and facilities in pharmaceutical manufacturing, particularly in terms of product quality and patient safety?	2,3	3,4	1,5,9

Q. No 5	a. What are the key steps involved in validating an analytical method according to the ICH guidelines and USP standards? b. How do the validation requirements differ for different types of analytical methods, such as chromatographic methods, spectroscopic methods, and titration methods?	3 2,3	4 2,3,4	1,5,9 1,2,5,9
Q. No 6	a. Define the following terms: (i) Patent agent (ii) PCT (iii) Patent squatting (iv) Process Patent (v) Compulsory licensing. Write the process of filing a patent application, including the required forms, guidelines, and steps involved in preparing and submitting a patent application? b. How do you define patent infringement, and what factors determine the scope of infringement in intellectual property law?	4	4	1,5,9
Q. No 7	a. What are the key components of a computerized system validation process? Explain the procedure of validation of computer systems giving example of HPLC system validation. b. What are the different types of patent applications, such as provisional and non-provisional, PCT (Patent Cooperation Treaty), and convention patent applications, and how do they differ in terms of scope and international protection?	3,4	4	1,5,9