Your Roll No.....

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School of Pharmaceutical Education and Research
M.Pharm. I Semester Examination (2023-2024)

Subject: **Regulatory Affairs** Maximum Marks: 75
Paper Code: MPH 104T Date: **15-03-24** Time: **Three hours**

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

Note: *This paper has **2 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)	Analyze the importance of CMC.	1,2	1,2	1
(b)	Discuss about ANDA approval process	1	1	2
(c)	What do you understand by Post Marketing Surveillance?	1.3	4	1
(d)	How do you identify CROs for outsourcing BA and BE studies?	4	1	2
(e)	What are the regulatory requirements for the approval of medical devices?	1,4,5	1,2, 5	2

SECTION B

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

Q. No	Question	BTL	CO	PO
Q. No 2	Analysis to be discussed for the SUPAC guidelines with respect to component or composition and manufacturing process or equipment.	4	2,4	3
Q. No 3	Discuss in detail about ICH M guidelines.	5	1, 2	1
Q. No 4	Describe the global submission of Investigational New Drug Process in India.	2	2	2
Q. No 5	What are the drug approval process in European countries?	5	6	2
Q. No 6	Explain the following a. Master formula record b. Informed consent Form c. Pharmacovigilance	2,3	1	3
Q. No 7	What are implications of HIPAA? Discuss the detail requirement to clinical safety process	1,4,5	4,5,6	3