M 166/015

Enrolment Number										

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Monsoon, 2023

M.Pharm (Pharmaceutics) Semester Examinations

REGULATORY AFFAIR

Course Code: MPH104T

Full Marks – 75 **Time – Three hours**

The figure in the margin indicates full marks for the questions.

I. Answer *all* the questions *(Within 50 words)* **(10 x 2 = 20)**

1. Explain the significance of 21CFR part 314?
2. What are the key distinctions between IND, NDA, and ANDA applications?
3. How does the Orange Book contribute to the pharmaceutical industry?
4. Identify the regulatory bodies responsible for drug regulation in India and the USA.
5. Define the term "dossier" in the context of Drug Regulatory Affairs.
6. In what ways do distribution records play a role in supporting regulatory affairs?
7. What is the purpose of an Investigator Brochure in clinical research?
8. Elaborate on the importance of Pharmacovigilance safety monitoring in clinical studies.
9. Why is Drug Regulatory Affairs considered important in the pharmaceutical field?
10. Differentiate between a Generic drug product and an Innovator drug product?

II. Answer any *seven* questions *(Within 500 words)* **(7 x 5 = 35)**

1. Explain the *In-vitro* drug product performance.
2. Can you provide a detailed explanation of the responsibilities of institutional review boards/independent ethics committees in clinical trials?
3. Elaborate on the key components of an investigator brochure used in clinical research.
4. Describe the pharmaceutical distribution system in India and its intricacies.
5. How does HIPAA contribute to the effectiveness of clinical trials, and what is its relevance?
6. Provide examples to illustrate various activities performed by CROs in the pharmaceutical industry.
7. Explain the process of handling post-approval changes in approved ANDAs.
8. What does MFR stand for, and what are the contents of a Master File in the pharmaceutical context?
9. Discuss the utility of the Hatch-Waxman Act and its impact on the pharmaceutical landscape.

III. Answer any *two* questions *(Within 1000 words)* **(2 x 10 = 20)**

1. Describe the regulatory requirements for ICH guidelines with special reference to ICH-Q, S, E, M
2. Give a detailed account of documentation in pharmaceutical industries with suitable examples.
3. Write in detail about developing clinical trial protocols and other working procedures for conducting clinical trials.