Library
Pharmaceutical Technology
Brainware University

BRAINWARE UNIVERSITY

Term End Examination 2024-2025
Programme – M.Pharm(Pharmaceutics)-2024
Course Name – Regulatory Affair
Course Code - MPH104T
(Semester I)

Full Marks : 75 **Time : 3:0 Hours**

[The figure in the margin indicates full marks. Candidates are required to give their answers in their own words as far as practicable.]

Group-A
(Short Answer Type Questions) 5 x 5=25

1. Define the objectives of post marketing surveillance. (5)
2. Explain about the non-clinical regulatory guidelines. (5)
3. Explain the review process in ANDA. (5)
4. Analyze the WHO guidelines for distribution records. (5)
5. Explain a short note on Institutional Review Board. (5)

OR

Explain about the selection and qualification of the monitors in clinical trial. (5)

Group-B
(Long Answer Type Questions) 10 x 5=50

6. Describe briefly about the regulatory requirements of different countries. (10)
7. Explain in detail about drug Price Competition and Patent Term Restoration Act. (10)
8. Describe Scale up process and its significance. (10)
9. Illustrate the medical care facilities required for the study participants during CT. (10)

OR

Explain the study design and management during clinical trial. (10)

10. Explain about the Manufacturing, Packaging, Labeling and Coding of investigational Products as per the ICH guidelines in case of clinical trial. (10)

OR

Explain briefly about the composition and documentation process of an Institutional Review Board & Independent Ethics Committee. (10)

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