BRAINWARE UNIVERSITY

Term End Examination 2023-2024
Programme – M.Pharm(Pharmaceutics)-2023
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 safety guidelines under ICH. (5)
3. Explain the different protocol of clinical trial asper the ICH Good Clinical Practice guidelines. (5)
4. Describe a short note on stability study guidelines under ICH. (5)
5. Explain about the functions of Independent Ethics Committee in clinical trial. (5)

OR

Explain the process of record keeping during clinical trial. (5)

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

6. Illustrate briefly about the protocols for the development of Clinical trial as per the ICH-GCP guidelines. (10)
7. Explain about the record and informed consent maintain system during clinical trial. (10)
8. Illustrate briefly about the quality guidelines of ICH. (10)
9. Describe briefly about the regulatory requirements of different countries. (10)

OR

Enumerate briefly about the rules and responsibilities of European union and TGA as regulatory authorities. (10)

10. Explain the outsourcing protocol for the bioavailability and bioequivalence studies to contract research organization. (10)

OR

Explain in detail the various stages involved in FDA's new drug approval process. (10)

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