Seat No.: _____ **Enrolment No. _____**

PARUL UNIVERSITY
FACULY OF PHARMACY
M.Pharm. Winter 2022 - 23 Examination

Semester: 1 **Date: 20/03/2023**
Subject Code: MPH104T **Time: 10:00am to 1:00pm**
Subject Name: Regulatory Affair **Total Marks: 75**

Instructions:
1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) **(30)**

1. a) Explain in detail – Drug Master File.

   b) Write a detailed note on ANDA for generic drugs.

2. a) Discuss about Non clinical drug development process and write a note on IMPD.

   b) Discuss composition and functions of Institutional Review Board.

3. Discuss ICH Guidelines for Pharmaceutical Drug Development.

Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) **(25)**

1. Explain Hatch-Waxman act and its amendments.
2. Write a short note on Regulatory Requirements for Product Approval.
3. Explain in details CTD and E CTD formats.
4. Write a Short note on an Investigator Brochure (IB).
5. Write a short note on a HIPPA.
6. Write Detailed note on CFR (Code of Federal regulation).

Q.3 Short Answers. (2 Marks Each) **(20)**

1. List out the types of documents in Pharmaceutical industry.
2. Why ANDA is called as Abbreviated New Drug Application?
3. Give full form of BA, BE and CRO.
4. List out the Applications of Bioavailability and Bioequivalence studies.
5. Write a brief note on Indian Medical Device Regulatory Act (IMRDA).
6. Explain Combination products in Pharmaceuitcals.
7. Brief on Non Clinical drug development in CTD Modules.
8. Write a brief note on Types of INDs.
9. Define Clinical Trials and list out its phases.
10. Define Informed Consent.