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

PARUL UNIVERSITY

FACULY OF PHARMACY

M.Pharm. Winter 2017 - 18 Examination

Semester: 1 **Date: 16/01/2018**
Subject Code: MPH104T **Time: 10:00 am to 1:00 pm**
Subject Name: Regulatory Affairs **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. Discuss the regulatory aspects of Drug Approval Process with special emphasis on preclinical and clinical trial.
2. Enlist different sections of New Drug Application. Describe the CMC section of NDA.
3. Discuss content and format of Investigational New Drug Applications (INDA).

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

1. Discuss generic formulation development of drug with suitable example.
2. Write a note on “Hatch Waksman Act and Generic Drug Exclusivity period”.
3. Describe the ICH guideline for stability studies of drug substances and products.
4. Discuss constitution and responsibilities of USFDA.
5. Write in detail about different types of Drug Master File (DMF).
6. Write review process of NDA.

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

1. Comment on the statement “If a work in Pharmaceutical Industry is not documented it means it is not done”
2. Define Investigational Brochure (IB) and give its content.
3. Enlist different steps of “Post marketing surveillance”.
4. Write a note on constitution of ICH.
5. Enlist different guidelines that comes under ICH Q and S.
6. Write a note on Clinical Trial Protocol.
7. Write the importance of scale up studies in pharmaceutical industry.
8. Write in brief about HIPAA and its significance.
9. Give the importance of Pharmacovigilance in Clinical Trial.
10. Write in brief about CFR.