Seat No: _____ Enrollment No: _____

PARUL UNIVERSITY
FACULTY OF PHARMACY
B.Pharm Winter 2018-19 Examinations

Semester: 7 **Date: 04/12/2018**
Subject Code: 08101404 **Time: 10:00 am to 01:00 pm**
Subject Name: Industrial Pharmacy **Total Marks: 75**

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

Q.1 Essay type Questions. (Any 2 out of 3) (10 marks each) **(20)**

1. What is validation? Describe detail method validation of granulation process in Tablet Manufacturing.
2. What is cGMP? Describe in detail requirements of Building, Equipment, Personnel, Components, Documentation, Containers and Labeling as per cGMP.
3. Describe in detail about Analytical Method Validation As per ICH.

Q.2 Short Essay type Questions. (Any 7 out of 9) (5 marks each) **(35)**

1. What is patent? Describe detail steps of Indian patent filing as per Indian Patent Act 1970.
2. Write down the requirements and Interpretation of ISO 9000.
3. Discuss the basic issues and quadrants of GLP.
4. What are QA and QC? Write down its functions and importance of QA and QC.
5. Describe Batch Manufacturing Record and Batch Packaging Record in detail.
6. What is Intellectual Property Right? Discuss briefly about Copyright and Trademark.
7. Discuss the Quality Management System.
8. What is ICH? Discuss ICH Quality and Safety guidelines.
9. Describe IPR governing bodies.

Q.3 Answer in short. (2 marks each) **(20)**

1. Differentiate QA and QC.
2. Explain Line clearance.
3. Discuss briefly about validation protocol.
4. Define Operation qualification (OQ) and Performance qualification (PQ).
5. Discuss briefly about type of Patent application as per Indian Patent act 1970.
6. What is SOP?
7. Write down Recovery & Reprocessing requirements as per cGMP.
8. Write down the minimum qualification of Analyst as per Good Laboratory Practice (GLP).
9. What is Patent Infringement? Give one example of patent infringement.
10. Write down five clauses of standard as per ISO 9000.