

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**B.Pharm. Winter 2019-20 Examination**

**Semester: 7****Subject Code: 08101404****Subject Name: Industrial Pharmacy****Date: 25/11/2019****Time: 10:00 am to 01:00 pm****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. Explain the manufacturing requirements according to Schedule M. What are the important factors considered while selecting and purchasing equipments for manufacturing?
2. Explain the procedure for patent filing in India. Explain the functions of WIPO.
3. Define Validation. Explain different types of validation. Explain validation parameters as per ICH guideline.

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

1. Define quality control. Describe the responsibilities and activities of quality control laboratory.
2. Enumerate various records to be maintained for finished product release, distribution of drug product, and waste disposal.
3. Explain Validation parameters for granulation process.
4. Write a note on copyright.
5. Describe in detail "Validation Master Plan"
6. What is WTO? What are its functions?
7. What is importance of line clearance and describe how it is practiced during Production and packing process?
8. Write a note on fundamentals of GLP.
9. What are standard operating procedures? What are the factors that must be considered while writing a SOP?

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

1. Differentiate between BMR and BPR.
2. What is ISO? What are its amendments?
3. What is GATT?
4. How the sample is selected for quality control testing?
5. Differentiate between QA and QC.
6. What is Doha declaration on TRIPS agreement?
7. According to Patent act, what cannot be patented?
8. What is the need of ISO certification in pharmaceuticals?
9. Define and classify IPR?
10. Define trademark. Give different types of it.