

PARUL UNIVERSITY
FACULTY OF PHARMACY
B.Pharm Summer 2018-19 Examination

Semester: 7
Subject Code: 08101404
Subject Name: Industrial Pharmacy

Date: 25/04/2019
Time: 02:00pm to 05:00pm
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. Discuss the function and responsibilities of Quality control and Quality assurance.
2. What is validation? Describe the detail validation method for granulation process in tablet manufacturing.
3. What is patent? Explain in detail the steps for filling of patent in India.

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

1. Define cGMP. Explain cGMP requirements for Packaging and Labeling.
2. What is ICH guideline? Discuss in detail.
3. Discuss about Analytical method validation as per ICH guideline.
4. What is GLP? Discuss the basic issues and quadrants of GLP.
5. Discuss the ISO 9000 series.
6. Describe the IPR governing bodies.
7. Define SOP. Enlist the objectives of SOP and explain the format of SOP.
8. What is Process validation? Discuss different types of process validation.
9. What do you mean by QC and QA? Differentiate between QC and QA.

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

1. Differentiate between intellectual property and intellectual property rights.
2. Give the importance of laboratory calibration and testing.
3. Write the functions of quality management system.
4. Define: Copyright and Geographical indication
5. What do you mean by Line clearance?
6. Explain the format of BMR.
7. Explain the Operational qualification and Performance Qualification.
8. Brief on Schedule M.
9. Give the importance of Documentation.
10. What is the meaning of precision and accuracy?