

Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

B.Pharm/ 4th year/ 7th Sem/ Time 3 hrs/ FM 75/ 2024-25

Course: Industrial Pharmacy-II

Code: BP702T

Q1. Answer the following questions (Question 1 is Compulsory) 10x2M=20 Marks

- a. What are the areas of changes in change control?
- b. What is the full form of QbD and define it?
- c. When and who developed the concept of Six Sigma?
- d. Define quality of design and quality of conformance.
- e. What is the full form of QMS? What are the four components of QMS?
- f. Define IQ and acceptance criteria.
- g. Explain SUPAC.
- h. Define QRM.
- i. Give the full form of APCTD, NRDC, TIFAC, BCIL.
- j. Define platform technology.

Long Answer Questions 2 x 10Marks = 20Marks

(Answer 2 out of 3)

Q2. Discuss methods of DMAIC and DMADV for Six Sigma implementation. 5+5

Q3. What are the purpose and benefits of Quality management system? Define the certification process for QMS. Write down the benefits of QMS certification. 4+2+4

Q4. Discuss the WHO guidelines for Analytical Method transfer. 10

Short Answer Question

7 x 5Marks = 35Marks

(Answer 7 out of 9)

Q5. Describe the function of CDSCO.

Q6. Describe the structure of CDSCO.

Q7. Describe the ISO 9000 series and its utility.

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Q8.What is CoPP? How is CoPP implemented?

Q9. Enlist the Approved Regulatory Bodies for TT.

Q10. Mention all the information of API which is to be transferred from SU to RU.

Q11. Define transfer of technology. Give the components of TT protocol.

Q12. Write a note on platform technology.

Q13. Give the importance of QRM.