

Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

B.Pharm/ 4th year/ 7th Sem/Time 3 hrs/ FM 75/ 2023-24

Course: Industrial Pharmacy-II

Code: BP702T

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

- a. What is the full form of CDSCO and QbD.
- b. How OOS can be defined in regulatory affairs?
- c. Explain the role of NABL.
- d. Who introduced the Six sigma concept for quality improvement ?
- e. Define QMS.
- f. Define pilot batch and scale up in pharmaceutical industry.
- g. Define QRM.
- h. Give full form of APCTD, NRDC, TIFAC & SIDBI.
- i. The SU & RU stands for ----- in scale up technology.
- j. Define DMF & DQ.

Long Answer Questions 2 x 10Marks = 20Marks

(Answer 2 out of 3)

Q2. Discuss different elements and different principles of the quality management system. What are the benefits of QMS certification? 7+3

Q3. Write the functions of CDSCO. Discuss the organizational structure of CDSCO. How does State Drug Control organization function? 2+6+2

Q4. Write about pilot plant scale up considerations for solid dosage form. 10

Short Answer Question

7 x 5Marks = 35Marks

(Answer 7 out of 9)

Q5. Describe in short 'Process for Approval of New Drug'

Q6. Give a historical overview of Regulatory affairs.

Q7. Write the name of different regulatory bodies in different countries.

Q8. Write in short about the process of preclinical drug development.

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Q9. Discuss ISO9000 series and shed light on the different levels of Six sigma concept. 2.5+2.5

Q10. Discuss in short the SUPAC guidelines.

Q11. Give importance of pilot plant & scale up technology.

Q12. Write about two TT agencies in India.

Q13. Give a note on QRM.