Jadavpur University
Department of Pharmaceutical Technology
Kolkata-700032.

B.Pharm/ 4thyear/ 7th Sem (Supplementary)/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.

b. How Dbd can be defined in regulatory affairs?

c. Explain the role of NABL.

d. What is Six sigma concept for quality improvement ?

e. Define TQM.

f. Define transfer of technology.

g. Enlist the Approved Regulatory Bodies for TT.

h. Give the components of TT protocol.

i. Define pilot plant.

j. Define SUPAC guidelines.

Long Answer Questions2 x 10Marks = 20Marks

(Answer 2 out of 3)

Q2. What is the full form of QMS?Why QMS certification is needed?Discuss different elements and different principles of the QMS.
2+2+6

Q3. How does CDSCO function?Give details about the structural organization of CDSCO.
4+6

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

[Turn over

Short Answer Question **7 x 5Marks = 35Marks**

(Answer 7 out of 9)

Q5. Discuss the historical overview of regulatory works.

Q6. Describe the process for approval of new drug..

Q7. In different countries, different regulatory body works. Name those regulatory bodies.

Q8. Describe the six Sigma concept in detail.

Q9. Discuss the ISO9000 series and the function of different series. 2.5+2.5

Q10. Give the full form of APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI

Q11. Define the following terms- DMF, DQ, IQ, acceptance criteria, SOP, SU and RU.

Q12. Give a brief note on QRM.

Q13. Discuss the importance of pilot plant and scale up technology.