

(3 Hours)

[Total Marks: 80]

- N.B.: 1) Q.No. 1 is compulsory.  
2) Attempt any 3 questions from Q.No. 2 to 6.  
3) All questions carry equal marks

- Q1. Answer the following (any four):-  
(i) Write a note on WHO guidelines for GLP  
(ii) Write a note on FDA and BSTI Laws and Action  
(iii) Explain the various approaches for cleaning and disinfection in Pharmaceutical and food industries.  
(iv) Explain the steps involved in the risk assessment of biological hazards  
(v) What are chemical hazards? Explain the various routes of exposure of individuals to toxic substances 20
- Q2. (a) Explain the importance of Quality assurance and Quality management in industries 10  
(b) Write a note on laws imposed by the Government on trade standards 10
- Q3. (a) Explain the cGMP guidelines for designing a hygienic food plant 10  
(b) Write a note on the types of validation in pharmaceutical industry 10
- Q4. (a) What do you mean by Quality Attributes? Explain their importance in food industry 10  
(b) Write a note on the role of Critical Control Points in quality control in food industries 10
- Q5. (a) Write a note on the laboratory associated infections and hazards 10  
(b) Write a note on the different types of Biosafety cabinets 10
- Q6. Write a note on (any two):- 20  
(a) Housekeeping instrumentation for safe operation  
(b) Personal protective equipment for toxic substances  
(c) GMO