



- 13) Contamination may be caused by
  - a) Poor hygiene practices
  - b) Inadequate cleaning
  - c) Residual cleaning agent
  - d) All of these
- 14) Which of the following is non parenteral type of glass?
  - a) I
  - b) II
  - c) III
  - d) IV
- 15) Water attack test is used to identify the alkalinity in
  - a) Type-I glass
  - b) Type-II glass
  - c) Type-III glass
  - d) Umber coloured glass
- 16) OOS stands for
  - a) Out of scope
  - b) Out of site
  - c) Out of specification
  - d) None of these
- 17) PQR is
  - a) Product Query Report
  - b) Process Query Report
  - c) Product Quality Review
  - d) Product Quality Report
- 18) The guidelines that describes the Analytical Method Validation-Text & Methodology are?
  - a) ICH Q2
  - b) ICH Q1
  - c) ICHQ8
  - d) ICH Q9
- 19) Equipment Validation must be always done by
  - a) User
  - b) Vendor
  - c) Manufacturer
  - d) Dealer
- 20) Regulatory basis of process validation is available in:
  - a) FDA
  - b) USP
  - c) BP
  - d) IP

2. Long answer questions (solve **any two**) **2x10 =20**
- 1) Explain in detailed about classification of Areas in Pharmaceutical Company and its requirement.
  - 2) Explain in detailed about Total Quality management.
  - 3) Discuss in detail the concept of Quality Control, quality assurance, GMP.

3. Short answer question (Solve **any seven**) **7x5= 35**
- 1) Write short note on Process of Harmonization.
  - 2) Write short note on warehouse and material management.
  - 3) Write short note on ICH and objective of ICH.
  - 4) Write a note on Good warehousing practice
  - 5) Write a note on master formula record
  - 6) General principle of analytical method validation.
  - 7) Discuss the concept of quality by design
  - 8) Write note on ISO9000 and 14000
  - 9) Write note on quality audit.

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