

TIME: 3HRS

MAX MARKS: 75

Q. 1 Attempt all multiple-choice questions (MCQ)

20M

Sr No	Questions	Options
1	According to USP General Chapters <1251> Weighing on an Analytical Balance all the following tests are performed except	<ul style="list-style-type: none"> a Eccentricity b Repeatability c Linearity d Robustness
2	Following are the reasons to perform process revalidation, except_____.	<ul style="list-style-type: none"> a Change in equipment b Change in raw material c Change in packaging material d Change in personnel
3	Validation carried out during routine production of products intended for sale is known as_____.	<ul style="list-style-type: none"> a Concurrent validation b Retrospective validation c Prospective validation d Analytical validation
4	Factory acceptance test is performed_____.	<ul style="list-style-type: none"> a After IQ b Before SAT c After DQ d Before DQ
5	Locking is the response measured in the qualification of _____.	<ul style="list-style-type: none"> a Capsule filling machine b FTIR c Laminar air flow d Autoclaves
6	Holmium perchlorate solution is used to check _____in qualification of UV spectrophotometer	<ul style="list-style-type: none"> a Wavenumber accuracy b Wavelength accuracy c Photometric accuracy d Photometric linearity
7	The biological indicator used in the qualification of Autoclave is _____.	<ul style="list-style-type: none"> a <i>Bacillus pumilus</i> spores b <i>Pseudomonas aeruginosa</i> c <i>Proteus vulgaris</i> d <i>Clostridium sporogenes</i>
8	Which of the following tests is used to validate HVAC system?	<ul style="list-style-type: none"> a ELISA b RIA c HEPA filter integrity test d Bioluminescence
9	Number of oscillation per min test is performed for which apparatus?	<ul style="list-style-type: none"> a Dissolution apparatus b Friability tester c Disintegration apparatus d Rotating cylinder

- 10 Which paper is used for detecting the presence of moisture and oil content in nitrogen gas?
- a Whatmann Paper
 - b Blotting Paper
 - c Gloss coated Paper
 - d Tissue Paper
- 11 The quantitation limit (QL) may be expressed as.....
- a $QL = 10 \sigma/S$
 - b $QL = 3.3 \sigma/S$
 - c $QL = 10 S/\sigma$
 - d $QL = 3.3 S/\sigma$
- 12 Process validation involves a series of activities taking place over the entire lifecycle of the product and process. How many stages of activities have been identified in the FDA lifecycle approach to process validation?
- a One
 - b Five
 - c Three
 - d Six
- 13 Following are the reasons to perform process revalidation, except_____.
- a Change in personnel
 - b Change in raw material
 - c Change in packaging material
 - d Change in equipment
- 14 In Cleaning validation, the maximum time allowed between end of cleaning and further usage is called as _____
- a Dirty equipment cleaning Time
 - b Sterile Equipment Hold Time
 - c Clean equipment Drying Time
 - d Clean equipment Hold Time
- 15 The ability to assess unequivocally the analyte in the presence of components which may be expected to be present; such as, impurities, degradants, matrix, etc. is called as _____
- a Selectivity
 - b Precision
 - c Accuracy
 - d Specificity
- 16 As per ISO in HVAC what should be the air changes per hour for class 6 _____
- a 150-240
 - b 5-60
 - c 240-600
 - d 60-150

- 17 How long do patents usually last for? a 20 months
b 18 months
c 20 years
d 60 years
- 18 If a research and development team of a pharmaceutical formulation R and D develops a new technology that improves performance of its main product, what type of intellectual property can they use to stop others from copying their invention? a Trade secrets
b Copyright
c Trademarks
d Patents
- 19 Copyright Act is enforced from ----- a 1970
b 1977
c 1957
d 1999
- 20 Which is of the following is not a trademark? a invention
b Way of writing
Product/company name
c logo
d symbol

Q 2. Attempt any TWO questions.

- I.** What is Validation and Calibration? Explain types of Validation. Add a short notes on- “Validation master Plan” and “validation protocol”. (10)
- II** What is patent? Explain different types of patent application? Discuss how to file a patent in India? Give Rights and responsibilities of a patentee. (10)
- III** Discuss in detail validation of analytical method as per ICH guidelines and USP. (10)

Q 3. Attempt any SEVEN questions.

- I** Explain in detail- “Cleaning Validation” (05)
- II** Enlist parameters evaluated in performance qualification of UV-Visible spectrophotometer. How to perform qualification of HPLC. (05)
- III** Discuss qualification of dissolution test apparatus (05)

- IV** What is process Validation? Explain process Validation of Capsules formulation. **(05)**
- V** Discuss validation of utility systems in pharmaceutical industry: “Pharmaceutical water system” and “HVAC system”. **(05)**
- VI** Compare - **(05)**
1. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT)
 2. Performance qualification and operational qualification
- VII** What is Intellectual Property (IP)? Discuss role of IP in pharmaceutical industry? **(05)**
- VIII** What is patent infringement? Discuss- “Trademarks” and “Copyrights” in detail. **(05)**
- IX** Explain qualification of Tablet manufacturing equipment- “Tablet Compression Machine”. **(05)**
