

TIME: 3HRS

MAX MARKS: 75

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

20M

Sr. No	Questions	Options
1	According to V model of validation, operational qualification is associated with _____.	a User requirement specification b Functional requirement specification c Technical requirement specification d Raw material and finished product specification
2	Analytical methods are ----- as per ICH Q2R1 guidelines.	a developed b calibrated c validated d qualified
3	Procedures and acceptance criteria of various parameters of analytical method validation are mentioned in -----	a Validation master plan b Validation protocol c Validation report d Validation policy
4	User requirement specifications is part of _____	a Method validation b Calibration c Design Qualification d Performance Qualification
5	----- is performed if any change in method is done.	a Retrospective Validation b Performance Qualification c Revalidation d Concurrent Validation
6	Action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results is referred as	a Calibration b QbD c Qualification d Validation
7	PPQ stands for -----	a Process Performance Qualification b Product Profile Quality c Primary Packaging Quality d Product Process Qualification
8	Instrument qualification of UV spectrophotometer is done with the help of all of these parameters except-----	a Photometric accuracy b Wavelength accuracy c Wavenumber accuracy d Photometric linearity

- 9 Dose uniformity is the monitoring parameter in qualification of -----
- a HEPA
 - b Tablet compression machine
 - c Dry powder mixer
 - d Capsule filling machine
- 10 Select the biological indicator used in the qualification of autoclave.
- a *Bacillus pumilus* spores
 - b *Clostridium sporogenes*
 - c *Proteus vulgaris*
 - d *Pseudomonas aeruginosa*
- 11 In cleaning validation, ----- can introduce fibres into the system.
- a Swab sampling
 - b Product sampling
 - c Placebo sampling
 - d Product sampling
- 12 The time required at a certain temperature for a 90% reduction in microbial population is referred as
- a D-value
 - b P-value
 - c Z-value
 - d X-value
- 13 Validation carried out during routine production of products intended for sale is known as _____.
- a Retrospective validation
 - b Revalidation
 - c Prospective validation
 - d Concurrent validation
- 14 Holmium perchlorate solution is used in qualification of -----
- a HPLC
 - b FTIR
 - c Uv-visible spectrophotometer
 - d pH meter
- 15 In HVAC, hygrometer is used to check which validation test?
- a Pressure difference
 - b Temperature and humidity uniformity
 - c Air flow pattern
 - d None of these
- 16 ----- checks the accuracy of an instrument and determines the traceability of the measurement.
- a Revalidation
 - b Operational Qualification
 - c Prospective validation
 - d Calibration

- 17 Pharmaceutical research invention can be protected by -----
- a Registered design
 - b copyright
 - c Trademarks
 - d Patents
- 18 Any new and unique composition made by music artist, can be protected by -----
- a Geographical indication
 - b Trademarks
 - c Patents
 - d Copyright
- 19 ----- is validity period for copyright in India?
- a 20 years after the creator's death.
 - b 10 years after the creator's death.
 - c 60 years after the creator's death.
 - d 5 years after the creator's death.
- 20 A grant given by the Government to an inventor for having made an invention, which possesses the property of novelty, non-obvious and industrial utility is referred as -----
- a Industrial Design
 - b Copyright
 - c Patent
 - d Trademark

Q 2. Attempt any two questions

- I. Discuss calibration and validation with respect to definition, Scope, frequency, importance and advantages. (10)
- II. What are Intellectual Property Rights (IPR)? Give factors affecting choice of Intellectual Property (IP) protection. What is role of Intellectual Property (IP) in pharmaceutical industry? (10)
- III. Explain concept, process and documentation of process validation with examples of process validation of coated tablet and capsule formulation. (10)

Q 3. Attempt any SEVEN questions

- I** What is qualification? Discuss FAT and SAT with respect to qualification. **(05)**
- II** Explain qualification of UV-Visible spectrophotometer. **(05)**
- III** Discuss qualification of laboratory equipments with suitable example. **(05)**
- IV** Discuss various parameters of analytical method validation as per ICH guidelines and USP. **(05)**
- V** Give definition, legal rights obtained by applicants and validity period for each of following IPRs. **(05)**
1. Patents
 2. copyrights
- VI** Write short notes on- **(05)**
1. User Requirement Specification
 2. Performance Qualification
- VII** Discuss filing of a patent application in India. **(05)**
- VIII** Explain the concept of cleaning Validation. **(05)**
- IX** Give an overview of- **(05)**
1. Patent infringement
 2. Trademarks
