

TIME: 3HRS

MAX MARKS:75

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

20M

Sr No	Questions	Options
1	_____ is one of the key advantages of validation.	<p>a Decreased customer satisfaction</p> <p>b Increased regulatory scrutiny</p> <p>c Reduced risk of non-compliance</p> <p>d Higher production costs</p>
2	What is the recommended hydrocarbon content for a compressed air system?	<p>a 3 ppm</p> <p>b 9ppm</p> <p>c 1 ppm</p> <p>d 5 ppm</p>
3	Validation carried out during routine production of products intended for sale is known as_____.	<p>a Concurrent validation</p> <p>b Retrospective validation</p> <p>c Prospective validation</p> <p>d Analytical validation</p>
4	A Site Acceptance Test (SAT) is typically conducted by _____.	<p>a End-users or stakeholders</p> <p>b Equipment suppliers</p> <p>c Regulatory authorities</p> <p>d Quality control personnel</p>
5	Locking is the response measured in the qualification of	<p>a Capsule filling machine</p> <p>b FTIR</p> <p>c Laminar air flow</p> <p>d Autoclaves</p>
6	In PCT process, the timeline for an international patent application PCT I to enter in national phase is ----- months from first filing/priority date.	<p>a 09</p> <p>b 12</p> <p>c 20</p> <p>d 30</p>
7	The biological indicator used in the qualification of Autoclave is	<p>a <i>Bacillus pumilus</i> spores</p> <p>b <i>Pseudomonas aeruginosa</i></p> <p>c <i>Proteus vulgaris</i></p> <p>d <i>Clostridium sporogenes</i></p>
8	Which of the following tests is used to validate HVAC system?	<p>a ELISA</p> <p>b RIA</p> <p>c HEPA filter integrity test</p> <p>d Bioluminescence</p>
9	Potential failure modes should to be verified during _____.	<p>a DQ</p> <p>b IQ</p> <p>c OQ</p> <p>d PQ</p>

- 10 The purpose of a Factory Acceptance Test is to _____
- a evaluate the performance of equipment at the manufacturing site
 - b assess the design and functionality of equipment at the supplier's facility
 - c document employee training records
 - d test the cleanliness of manufacturing facilities
- 11 Number of oscillation per min test is performed for which apparatus?
- a Dissolution apparatus
 - b Friability tester
 - c Disintegration apparatus
 - d Rotating cylinder
- 12 In order to satisfy patentability criteria, an innovation must be evaluated for all of the given options EXCEPT-
- a Usefulness
 - b Non-obviousness
 - c Cost effectiveness
 - d Novelty and Inventiveness
- 13 Process revalidation is not recommended, in case of change in _____ of product manufacturing process.
- a personnel
 - b raw material
 - c packaging material
 - d equipment
- 14 URS is important for -----
- a Process validation
 - b Calibration
 - c Design Qualification
 - d Technology transfer
- 15 In analytical method validation, ----- ensures identity of analyte in the presence of other components such as, impurities, degradants, matrix, etc.
- a Precision
 - b LOD
 - c Specificity
 - d Accuracy
- 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 USP - type I dissolution apparatus is
- a Flow through cell
 - b Paddle over disk
 - c Paddle
 - d Basket

- 18 Which of the following is not an intellectual property? **a** Trade secretes
b Innovations
c Copyright
d Trademarks
- 19 Qualification of FTIR spectrometer deal with checking ----- of instrument measurement. Accuracy and precision of absorbance maxima
Baseline flatness
Wavenumber accuracy
Transmittance linearity

Match "column A" with "Column B"

Column A: IP		Column B:IPP	
v	Jingles	o	Industrial design
w	Pharmaceutical research invention	p	Geographical indication
x	Label on product container/ pack	q	Trademarks
y	Product name	r	Patent
z	Leaves of Medicinal plants in himalayala	s	copyright

20

a v-s, w-r, x-o, y-s, z-p
b v-s, w-r, x-q, y-q, z-r
c v-s, w-r, x-q, y-q, z-p
d v-q, w-o, x-s, y-q, z-p

Q 2. Attempt any TWO questions.

- I.** Explain the terms – **(10)**
 a. Qualification,
 b. Calibration,
 c. Validation Protocol
 d. Validation master Plan,
 e. URS.
- II** Discuss factors affecting choice of IPR. Explain PCT in details. **(10)**
- III** What is validation? Discuss in detail validation of analytical method as per ICH guidelines and USP. **(10)**

Q 3. Attempt any SEVEN questions.

- I** Write short notes on- (05)
1. Cleaning Validation
2. GAMP
- II** Discuss in brief qualification of FTIR and HPLC (05)
- III** Explain in detail- “Qualification of dissolution test apparatus” (05)
- IV** What is process Validation? Brief on a life cycle approach of USFDA guidelines on process validation. (05)
- V** Explain validation of – (05)
a. Pharmaceutical water system
b. HVAC system
- VI** Compare - (05)
1. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT)
2. Performance qualification and operational qualification
- VII** What is copyright? Discuss role of Intellectual Property (IP) in pharmaceutical industry? (05)
- VIII** What is IPP? Explain the terms- (05)
a. Patent infringement
b. Trademarks
- IX** Explain qualification of “capsule filling Machine”. (05)
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