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.	**a**	Decreased customer satisfaction
		b	Increased regulatory scrutiny
		c	Reduced risk of non-compliance
		d	Higher production costs
2	What is the recommended hydrocarbon content for a compressed air system?	**a**	3 ppm
		b	9ppm
		c	1 ppm
		d	5 ppm
3	Validation carried out during routine production of products intended for sale is known as_____.	**a**	Concurrent validation
		b	Retrospective validation
		c	Prospective validation
		d	Analytical validation
4	A Site Acceptance Test (SAT) is typically conducted by _____.	**a**	End-users or stakeholders
		b	Equipment suppliers
		c	Regulatory authorities
		d	Quality control personnel
5	Locking is the response measured in the qualification of	**a**	Capsule filling machine
		b	FTIR
		c	Laminar air flow
		d	Autoclaves
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.	**a**	09
		b	12
		c	20
		d	30
7	The biological indicator used in the qualification of Autoclave is	**a**	*Bacillus pumilus* spores
		b	*Pseudomonas aeruginosa*
		c	*Proteus vulgaris*
		d	*Clostridium sporogenes*
8	Which of the following tests is used to validate HVAC system?	**a**	ELISA
		b	RIA
		c	HEPA filter integrity test
		d	Bioluminescence
9	Potential failure modes should to be verified during _____.	**a**	DQ
		b	IQ
		c	OQ
		d	PQ

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

20 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

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- 1. Cleaning Validation 2. GAMP	**(05)**
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 – a. Pharmaceutical water system b. HVAC system	**(05)**
VI	Compare - 1. Factory Acceptance Test (FAT) and Site Acceptance Test (SAT) 2. Performance qualification and operational qualification	**(05)**
VII	What is copyright? Discuss role of Intellectual Property (IP) in pharmaceutical industry?	**(05)**
VIII	What is IPP? Explain the terms- a. Patent infringement b. Trademarks	**(05)**
IX	Explain qualification of "capsule filling Machine".	**(05)**