

TIME: 3HRS

MAX MARKS: 75

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

20M

Sr. No	Questions	Options	
1	Select the appropriate name for following activity: “The collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products.”	a	IPQC
		b	QbD
		c	Process Validation
		d	Design Qualification
2	ICH Q2R1 guidelines give recommendations for -----	a	Analytical method development
		b	bioanalytical method validation
		c	Impurity profiling and forced degradation studies for stability indicating method development
		d	Analytical method validation
3	Select the document that gives procedures and acceptance criteria of various parameters of analytical method validation.	a	Validation report
		b	Validation policy
		c	Validation master plan
		d	Validation protocol
4	URS is part of _____	a	Process validation
		b	Instrument Calibration
		c	Design Qualification
		d	Vendor Qualification
5	Select the activity to be performed if any change in method is done.	a	Calibration
		b	Performance Qualification
		c	Revalidation
		d	Concurrent Validation
6	What is action of proving and documenting that any process, procedure or method actually and consistently leads to the expected results?	a	Accuracy
		b	Qualification
		c	QbD
		d	Validation
7	In pharmaceutical quality assurance and validation PPQ is common abbreviation of _____	a	Process Performance Qualification
		b	Product Profile Quality
		c	Primary Packaging Quality
		d	Product Process Qualification
8	Which one of the given options is inappropriate for qualification of UV spectrophotometer?	a	Photometric accuracy
		b	Wavelength accuracy
		c	Wavenumber accuracy
		d	Photometric linearity

9	In which of the following dose uniformity is primarily monitored?	a	Qualification of FBD
		b	Qualification of tablet compression machine
		c	Qualification of dry powder mixer
		d	Qualification of capsule filling machine
10	----- is used as biological indicator in the qualification of autoclave.	a	<i>Proteus vulgaris</i>
		b	<i>Clostridium sporogenes</i>
		c	<i>Bacillus pumilus</i> spores
		d	<i>Pseudomonas aeruginosa</i>
11	Which activity of cleaning validation can introduce fibres into the system?	a	Placebo sampling
		b	Product sampling
		c	Product sampling
		d	Swab sampling
12	Select the right option - “The time required at a certain temperature for a 90% reduction in microbial population”.	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	In instrument qualification experiments, holmium perchlorate solution is used for which of the following instruments?	a	UPLC
		b	Colorimeter
		c	Uv-visible spectrophotometer
		d	pH meter
15	In HVAC, which of the following device is used to report the humidity level as a percentage (relative humidity or RH)?	a	AHU
		b	Laminar Air flow meters
		c	Hygrometers
		d	Thermometers
16	Which of the following activity deals with checking the accuracy of an instrument, determining the traceability of the measurement and ensuring performance accuracy of instrument.	a	Revalidation
		b	Operational Qualification
		c	Prospective validation
		d	Calibration

17	ALL are entitled to apply for Indian patent for an invention; EXCEPT-	a	A person claiming to be first inventor of the invention
		b	A Legal representative of the first inventor of the invention (If inventor is deceased)
		c	Any person who is aware of the invention done by the inventor
		d	Any person who is the assignee of the first inventor of the invention
18	When a design is registered, the registered proprietor of the design shall, subject to the provisions of this Act, have copyright in the design for the duration of how many years from the date of registration?	a	20 years
		b	15 years
		c	10 years
		d	12 years
19	Copyright in India can be obtained for all EXCEPT-----	a	Anonymous work
		b	Pseudonymous work
		c	Reproduced work
		d	Jointly owned work
20	In India, Trademark registration fees is ----- -----	a	4,000 INR for small enterprises 7,500 INR for large entity
		b	4,500 INR for small enterprises 9,000 INR for large entity
		c	5000 INR for small enterprises 8,000 INR for large entity
		d	5,000 INR for small enterprises 10,000 INR for large entity

Q 2. Attempt any two questions

- I.** Compare calibration and validation covering all aspects -need, importance Scope, benefits, frequency and documentation. **(10)**
- II** Give importance of Intellectual Property (IP) in pharmaceutical industry? **(10)**
Define and classify Intellectual Property Rights (IPR)? Discuss types of patent application and process of a patent application in India.
- III** Define and give importance of process validation? Discuss in detail a process validation of coated tablet and capsule formulation. **(10)**

Q 3. Attempt any SEVEN questions

- I** What is design qualification? Explain FAT and SAT in detail. **(05)**
- II** Discuss how to carryout qualification of UV-Visible spectrophotometer. **(05)**
- III** What is scope of laboratory equipment qualification? Give an overview of qualification of laboratory equipment with suitable example. **(05)**
- IV** What is analytical method validation? Give experimental procedures and recommendations of ICH to establish linearity, precision and robustness of analytical method. **(05)**
- V** Define, give validity period and legal rights obtained by applicants for each of following IPRs. **(05)**
1. Patents
2. Trademarks
- VI** Give details and importance of following documents- **(05)**
1. Validation master plan
2. URS
- VII** What is industrial design? Give factors affecting choice of Intellectual Property (IP) protection. **(05)**
- VIII** Give an overview of cleaning validation with respect to pharmaceutical manufacturing industry. **(05)**
- IX** Write short notes on- **(05)**
1. Patent infringement
2. Copyright
