

The most commonly used wavelength (UV) for microbial reduction in pharmaceutical water treatment systems is _____	a	254 nm
	b	245 nm
	c	280 nm
	d	220 nm
Carbon beds remove organic chlorine compounds and _____ dissolved in feed water.	a	low molecular weight carbon compounds
	b	high molecular weight carbon compounds
	c	intermediate molecular weight carbon compounds
	d	all kinds of carbon compounds

**Q.2 Attempt ANY TWO question out of the following.**

**20M**

- i. Elaborate on the auditing of water systems. Discuss the design considerations of a water system
- ii. Define audit evidence? List the factors affecting internal audit evidence. Explain the steps of an audit process
- iii. Explain in detail the points considered in auditing the HVAC system in relation with the environmental aspects of the plant

**Q.3 Attempt ANY SEVEN questions out of the following**

**35M**

- i. Explain the "evaluation activities" of quality system?
- ii. What is vendor audit? Discuss the important parameters taken into consideration while auditing vendors for pharmaceuticals.
- iii. Write a note on auditing of granulation operation in dry production area.
- iv. Discuss schematically the workflow in conducting the audit of a packaging area of a pharmaceutical company
- v. Discuss in brief "laboratory layout and equipments" elements for audit of microbiology laboratory
- vi. Discuss important consideration related to raw materials and water as an essential element for microbiology laboratory audit
- vii. What is CAPA? Explain the functions of quality assurance.
- viii. Illustrate "Equipment and Raw Materials" as a component of cGMP Regulations.
- ix. Describe how you will audit the qualification and training requirements of personnel working in a microbiological laboratory.

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Time: 3 Hours

Marks: 75

Q.1 Attempt All Multiple-Choice Questions (MCQs)

(20M)

Questions	Options
Which of the following statements defines an internal audit?	a Process that improves the effectiveness of risk management, control, and governance processes
	b Process that develops knowledge and confidence in Partnership Agreements
	c Processes for fulfilling compliance
	d Processes for certification or registration by authorities
A 'First-party' audit refers to _____	a A regulatory body conducting an audit for registration
	b A self-audit by people belonging to the same organization
	c A customer conducting an audit on a supplier or a contractor
	d An independent body conducting an audit for certification
Audits of a contract manufacturer not conducted may be a source of a	a Minor Defect
	b Major Defect
	c Critical Defect
	d Internal Control Defect
The obligation on part of the Auditor to report truthfully and accurately is based on the principle of	a Integrity
	b Fair Presentation
	c Confidentiality
	d Diligence
Which of the following is an element of quality system?	a Management responsibilities
	b Licensing
	c Sales and distribution
	d Price control regulation
_____ is a component of quality risk management.	a Resources
	b Manpower
	c Risk communication
	d Manufacturing operations
_____ include actions taken in response to quality data to address the cause of potential nonconformities to prevent their occurrence.	a corrective actions
	b risk management
	c preventive actions
	d Sanitation and hygiene
_____ activities are those processes and activities conducted to assure that a product or service consistently satisfies its requirements and is fit for its intended use.	a Quality control
	b Quality assurance
	c Manufacturing
	d Packaging