

(3 Hours)

Total Marks: 75

Q. 1 Attempt all multiple-choice questions

20M

Sr.No	Questions	Options	
1	----- guidelines provide stability testing of pharmaceuticals	a	ICH Q1
		b	ICH Q2
		c	ICH Q3
		d	ICH Q6
2 is process to identify and correct the defects in finished products	a	Quality control
		b	Quality management
		c	Quality procedure
		d	Quality approach
3regulates drug products defined in FDA.	a	CBRD
		b	CSER
		c	CDER
		d	CRBD
4	The guidelines that describes the residual solvent Impurities is	a	ICH Q3A
		b	ICH Q3 B
		c	ICH Q3 C
		d	ICH Q3 D
5	GLP is a formal regulation created by USFDA as these regulations were proposed in 1976 and designated as a new part of chapter 21 of CFR as ----- in 1979	a	21 CFR part 58
		b	21 CFR part 11
		c	21 CFR part 210
		d	21 CFR part 56
6	What is the first step of QA	a	Identification of customer needs
		b	Development of standards
		c	Servicing
		d	Material control
7	Following are the responsibilities of warehouse management except	a	Transportation consolidation.
		b	Formulation development
		c	Docking
		d	Good supply chain

8	Packaging and labeling control is a part of?	a	GMP
		b	GLP
		c	GCP
		d	GDP
9	Which of the following parameters is covered in GMP?	a	Personnel responsibilities
		b	Marketing
		c	Sanitation and Hygiene
		d	Training
10	Which of the following type of packaging material is taken into consideration when performing stability evaluation of formulations	a	Primary packaging
		b	Secondary packaging
		c	Tertiary packaging
		d	Inserts
11	As perbulk drug substances and finished product specifications important for worldwide product license application		ICH Q6
			ICH Q7
			ICH Q8
			ICH Q3
12	Which of the following holds true for Quality Control	a	It is a proactive measure
		b	It is a verification activity
		c	Aims to Identify defect
		d	Aims to Prevent defect
13	Which of the following test is applicable for testing quality of creams	a	Hardness
		b	Friability
		c	Viscosity
		d	Disintegration time
14	In-depth examination of the particular product / service is carried out in	a	Regulatory audit
		b	Control audit
		c	External audit
		d	Self audit
15		a	used as a reference for BMR
	All of the statements are applicable to Master Formula Record except	b	prepared by R&D team
		c	maintained for each batch of product
		d	includes information on manufacturing process
16	----- is a task-oriented document	a	Manual
		b	Procedure
		c	Records
		d	Work instructions

17	Storage, Retention and retrieval of documents is responsibility of ?	a	QC department
		b	QA department
		c	R&D department
		d	Marketing department
18	Good indoor air quality is maintained by	a	HVAC
		b	Air conditioning
		c	Fans
		d	Humidifiers
19	Quality Assurance is a ----- tool	a	Testing
		b	Managerial
		c	Processing
		d	Marketing
20	Air borne contamination are controlled through effective	a	Line clearance
		b	Production in segregated areas
		c	Trained people
		d	HVAC system

Q 2. Attempt any two question

- i. Elaborate the protocol for the conduct of non-clinical testing 10M
- ii. Write a note on IPQC and FPQC of creams. 10M
- iii. Discuss the need for Documentation in Pharmaceutical industry and write a note on Master Formula Record 10M

Q 3. Attempt any seven questions

- i. Explain the scope, advantages and disadvantages of GLP. 5M
- ii. Give an goal and five Quality guidelines of ICH 5M
- iii. Discuss the role and responsibilities of quality assurance unit 5M
- iv. Give an account on ICH Q3 guidelines. 5M
- v. Discuss the building and manufacturing facilities for pharmaceuticals 5M
- vi. Write a note on mix ups and cross contamination in manufacturing operations 5M
- vii. Elaborate on the elements of Quality Audit 5M
- viii. Explain the processing of Intermediate and Bulk products 5M
- ix. Discuss the sanitation of Manufacturing premises 5M