Question Paper

Exam Date & Time: 25-May-2024 (10:00 AM - 01:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal College of Pharmaceutical Sciences
Manipal Academy of Higher Education, Manipal
B Pharm VI Semester - End Semester Examination, May 2024
Sub title: Pharmaceutical Quality Assurance
Sub code: PQA - BP606T

Pharmaceutical Quality Assurance (Theory) [PQA-BP606T -S1]

Marks: 75 **Duration: 180 mins.**

I Multiple Choice Questions (MCQs)

Answer all the questions. Section Duration: 30 mins

1) Product complaint report shall be approved by (1)

- QA head
- QC chemist
- Operator
- Supervisor

2) Recall of the banned products can be called as (1)

- Statutory recall
- Voluntary recall
- Patient recall
- Regulatory recall

3) The ability to measure unequivocally the desired analyte in the presence of components such as excipients and impurities that may also be expected to be present. (1)

- Range
- Accuracy
- Precision
- Specificity

4) AMV stands for (1)

- Analyst Method Verification
- Analytical Method Verification
- Analytical Method Validation
- Analyst Method Validation

5) The lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value. (1)

- Limit of detection
- Accuracy
- Limit of Quantitation

Specificity

6) Always rinse the pH electrodes with (1)

WFI
De-ionized water
Mineral water
Portable water

7) SAT stands for equipment qualification (1)

Standard Accreditation Test
Site Acceptance Test
Site Accreditation Test
Standard Acceptance Test

8) Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes is termed as (1)

Calibration
Validation
Qualification
Verification

9) The responsibility of QA person in validation is to (1)

Perform testing contracts validation testing
Deals with product design
Ensure compliance and that documentation and procedures are in place. Approves protocols and reports.
Storage of the samples

10) Which of the following code of federal regulations describes cGMP requirements? (1)

21CFR Part 11
21CFR Part 820
21CFR Part 811
21CFR Part 211

11) Quality Risk Management" is covered under which of the following quality guideline of ICH? (1)

ICH Q4
ICH Q6
ICH Q9
ICH Q10

12) Medical labs seeking NABL accreditation should comply with which of the following ISO standards? (1)

ISO/IEC17025
ISO/IEC15189
ISO/IEC170243
ISO/IEC17034

13) Accelerated stability study conditions for Drug substance intended for storage in a refrigerator is _____ (1)

35°C ± 2°C/60% ±

5%
25°C ± 2°C/65% ± 5%
45°C ± 2°C/60% ± 5%
25°C ± 2°C/60% ± 5%

14) The main objective of ISO 9000 is _____ (1)

Profit making
Customer Satisfaction
Skill enhancement
To avoid Environmental issues

15) Expand the acronym HVAC (1)

Heating ventilation and air conditioning
Heating ventilation and air cooling
Heating ventilation and air controlling
Heating ventilation and air circulation

16) Type III glass is (1)

Neutral glass
Borosilicate glass
Sodalime glass
Treated sodalime glass

17) The acceptance score for metal particles in collapsible metal tubes for ophthalmic ointment is (1)

< 100
< 200
< 500
< 1000

18) The test system for "Intracutaneous test" for plastic containers for parenteral preparations is (1)

Mice
Rat
Rabbit
Monkey

19) Provisions of GLP are applicable to (1)

Laboratories conducting animal studies
Laboratories for clinical diagnosis
Laboratories performing calibration study
Laboratories performing chemical analysis

20) Documentation records, raw data and specimens pertaining to non-clinical study supporting a marketing approval shall be retained for: (1)

6 months
1 Year
2 Years
5 Years

II Long Answers

Answer all the questions.

1)	How to maintain eating facilities in the pharmaceutical industry?	(5)
a)		
b)	Provide a comprehensive overview of the training requirements for new employees in the Pharmaceutical industry, outlining the key areas such as regulatory compliance, Good Manufacturing Practices (GMP), safety protocols, and any specialized skills essential for their roles.	(5)
2)	Discuss the steps in implementing Quality management Systems (QMS) for an organization as per ISO9001.	(10)

III Short Answers

Answer all the questions.

1)	Discuss in detail Good Documentation Practices in the Pharmaceutical industries with a pyramid chart	(5)
2)	Discuss about Pharmaceutical distribution records	(5)
3)	Explain the performance Qualification parameters for UV Visible Spectrometer	(5)
4)	Explain the commonly used calibration methods for Pharmaceutical instruments	(5)
5)	What key factors should be taken into consideration when selecting equipment for use in the Pharmaceutical industry?	(5)
6)	Write the procedure and acceptance criteria for "Hydrolytic resistance tests" for evaluation of glass containers and explain how type I and type II glasses can be differentiated?	(5)
7)	Write the GLP guidance on "Testing facility management".	(5)

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