MQA203
F.Y. M. Pharm
11/8/2025

Time: (3 Hours) **Max. Marks: - 75**

Q1 Multiple choice questions **20 M**

1. An exercise in information gathering is
a) To perform thorough document review
b) to test something that is usually done at the facility as part of the routine
c) checking all the records that are produced in the process
d) simplest way to check how a process works is to observe it in action

2. Which of the following is an element of quality system?
a) Product Price Determination
b) Distribution
c) Manufacturing operations
d) Licensing

3. 'Following a specific development from the beginning until the end' in information gathering process is called
a) Interview
b) Reviewing Documents
c) Vertical tracking
d) Observation

4. Which of the following is Evaluation Activity of Quality System?
a) Examine Inputs Materials
b) Create an organizational structure
c) Conduct internal audits
d) Design and develop product and Processes

5. In transitioning to quality systems 'arrange with other organizations that have successfully made the transition' is called as
a) Consider benchmarking
b) Conduct a gap analysis
c) Consult with experts
d) Sell the system

6. In which of the manufacturing operations product being manufactured should be defined
a) Design and develop product and Processes
b) Examine Inputs Materials
c) Perform and monitor operations
d) Address nonconformities

7. _____is responsible for identifying resource requirements and providing resources accordingly
a) Manufacturing Department
b) Quality Unit only
c) Management
d) Store department

8. Corrective and Preventive Actions is part of
a) Management responsibilities
b) Resources
c) Manufacturing operations
d) Evaluation activities

9. Acids, bases and reagents used in Quality control lab are
a) Active Pharmaceutical Ingredients
b) Excepients
c) Registered intermediates
d) Non-critical raw materials

10. KPIs stands for
a) Key Practice Indicator
b) Key Performance indicator
c) Key Procedure indices
d) Key Purity indication

11. Packaging Component – Critical (PCC) is
a) non-printed packaging component
b) secondary (non contact)
c) Printed carton of cough syrup bottle
d) any printed packaging component, primary(product contact) component or device

12. During the audit of personnel of a tablet manufacturing area, the recommended number of personnel records to be checked is
a) Three
b) Five
c) Two
d) Seven

13. Minimum acceptable quality of water as excipient in formulation of Nasal/Ear Preparations is
a) Water for injection
b) Purified Water
c) Potable water
d) Not specified any Criteria

14. For Injectables facilities Preferred class of cleanroom is
a) Class 100,000
b) Class 10000
c) Class 1000
d) Class 100

15. Which of the following is part of Preliminary treatment process in Effluent Treatment Plant (ETP)
a) Trickling filter
b) Grit Chamber
c) Neutralization tank
d) Ion Exchange

16. Acceptable limits for pH of effluent is
a) Between 6.5 to 9
b) Less than 5
c) More than 10
d) Any pH is acceptable

17. Label of prepared solution in microbiology lab should with
a) Prepared by, date of preparation, Expiration date
b) Prepared by, Procedure of preparation, expiry date
c) Procedure of preparation and composition of solution
d) Prepared by and composition only

18. During Audit _____is considered as documentary evidence for equipment usage
a) Maintenance records
b) Log book
c) SOP revision date
d) Validation records

19. During audit of microbiology lab results of LAL test are examined for
a) Past three Months
b) Past six months
c) Past one month
d) Past two months

20. Which of the following area can be expected to have more stringent microbial controls?
a) Oral solutions
b) Tablets
c) Ophthalmic preparations
d) Topical creams

QII Answer the following **(any two)** **20 M**

1. Write in detailed about various methods of information gathering in Audit.

2. Explain in detailed management responsibilities & Quality Assurance functions in quality system.

3. Write a note on a) Auditing of sterile production area b) Auditing of granulation department.

Q III Answer the following **(any seven)** **35 M**

1. Write short note on management of audit
2. Give account of transitioning to quality approach
3. Give process of vendor selection and short listing
4. Write short note on evaluation activities in quality system
5. Write a note on Auditing of Capsule Production area
6. Which information to be collected in the pre- audit phase and during field visit for auditing of microbiology lab?
7. Give essential consideration in relation to raw materials and water as an elements of microbiology laboratory audit
8. Write short note on stages of effluent treatment process and highlight points to be considered during audit
9. Enlist important points to be considered during audit of HVAC system