Sem-I. M. Pharm 2023 Quality Assurance

Paper / Subject Code: 90721 / Quality Control and Quality Assurance (R-2019)
MQA 103 T

Time : 3 Hours Marks : 75

NB:
1. Figures to the right indicate full marks
2. All questions are compulsory

I. Multiple choice questions **20**

1. Quality control is a _____ tool
a. Preventive
b. Corrective
c. Managerial
d. Distribution

2. _____ regulations must be followed by drug manufacturing company
a. Current Good manufacturing Practices
b. General manufacturing practices
c. General manufacturing process
d. Good management Practices

3. _____ controls quality of biotechnological products
a. ICH Q5 C
b. ICH Q3
c. ICH Q 11
d. ICH Q 6

4. Type III Drug Master file is related to?
a. Manufacturing site and Facilities
b. Drug Substance, Intermediate and Bulk Products
c. FDA Accepted Reference Material
d. Packaging Material

5. _____is performed during the manufacture of either the drug substance or drug product, rather than as part of the formal battery of tests which are conducted prior to release

a. In-process test

b. After process test

c. Finished product test

d. Confirmatory test

6. _____ is a set of principles intended to assure the quality and integrity of non-clinical laboratory studies

a. GMP

b. GCP

c. GDP

d. GLP

7. _____ regulates drug products defined in FDA.

a. CDER

b. CSER

c. CEFB

d. NCRT

8. Evaluation of Impurities in New Drug Substance is covered under

a. ICH Q3A

b. ICH Q6

c. ICH Q1

d. ICH Q7

9. In the CTD/ eCTD Module 2 is related to .....

a. Clinical study reports

b. Non-clinical study reports

c. Quality overall summary

d. Region specific

10. The procedure that ensures that changes are implemented in a controlled manner is defined as?

a. OOT

b. Deviation

c. Change control

d. OOS

11. Subpart D of GLP refers to:

a. Facilities

b. Equipment

c. Test and control articles

d. Organization and Personnel

12. _____ is a part of quality system controlling manufacturing, testing of raw material and finished products.

a. GWP

b. GMP

c. GLP

d. GHP

13. _____discusses about scientific and technical aspects of drug registration

a. International council for harmonization

b. International council for human resources

c. International council for humanities

d. International bureau for harmonization

14. Storage, Retention and retrieval of documents is responsibility of?

a. R & D Department

b. QC Department

c. QA Department

d. Marketing Department

15. Air-borne contamination are controlled through effective _____

a. HVAC system

b. Trained people

c. Line clearance

d. Production in segregated areas

16. Packaging and labeling control is a part of?

a. GMP

b. GLP

c. GCP

d. GDP

17. _____ ensures consistency in daily operations.

a. Standard operating procedures

b. Quality assurance

c. Quality control measures

d. Material analysis

18. _____is a commercial document and possesses requirement specifications indicating types, quantities, and agreed prices for products or services.

a. Purchase order

b. Process order

c. Bill

d. Payment order

19. _____ is a standardized procedure in manufacturing for ensuring equipment and work areas are free of products, documents, and materials from a previous process.

a. Line clearance

b. Product clearance

c. Custom clearance

d. Line approval

20. An idealized system where the government or other organizations oversee the market, control the forces of supply and demand, and to some extent regulate the market actions _____

a. Regulated market

b. Non-regulated market

c. Semi regulated market

d. Free market

II. Answer the following (Any two out of three) **20**

1. a. Write a note on CPCSEA guidelines

   b. Differentiate between CTD and eCTD

2. a. Define Quality Control and Quality Assurance. Give 3 points of difference between Quality Control and Quality Assurance

   b. Write a note on good warehousing practices

3. a. Write a note on IPQC and FPQC of tablets/suppositories.

   b. Write a note on mix-ups and cross contamination. How can it be avoided for manufacturing a quality product?

III. Answer the following (Any seven out of nine) **35**

1. Discuss in detail plant layout, design and construction for solid dosage forms.

2. Enlist the principles of GLP. Write a detailed note on any two principles

3. Discuss batch formula record and batch formula record

4. Explain the term GMP. Write a detailed note on 'Building and Facilities'

5. Write a note on change control and process deviation

6. What is a CTD? What are its benefits? Describe with a suitable diagram different module of CTD

7. Write a note on 'Three tier documentation'

8. Give a brief account of aseptic process control of sterile products manufacturing

9. Discuss ICH guidelines

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