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

QI Multiple choice questions **20 M**

1. The … ……. provides guidance for impurities in new drug substances
a) ICH Q6A
b) ICH Q5
c) ICH Q3A
d) ICH Q2

2. _____is the statutory body formed by the act of Indian Parliament under the prevention of cruelty to animals
a) OECD
b) IAEC
c) IBSC
d) CPCSEA

3. _____ is a set of principles intended to assure the quality and integrity of non clinical laboratory studies
a) GDP
b) GMP
c) GLP
d) SMP

4. QSEM stands for
a) Quality, Efficacy, Safety and Multi effective
b) Quality, Efficacy, Safety and Multidisciplinary
c) Quality, Effective, Safety and Multidisciplinary
d) Quality, Efficiency, Safety and Multidisciplinary

5. —---------- is a process oriented document
a) Manual
b) Procedure
c) Records
d) Work instructions

6. The disposal of sewage & effluents from the manufacturing plant shall be in conformity with the requirements of ----------
a) EPCB (Environment pollution Control Board)
b) Central& state legislation
c) Biomedical waste Rule1996
d) FDA

7 ---------- is an important factor in selection of drug factory location
a) Availability of raw material
b) QAQC department
c) Availability of raw material
d) Transportation

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8. ---------- plays an important role in supply chain management.
a) Good manufacturing practices
b) Good warehousing practices
c) Good laboratory practices
d) Good hygiene practices

9. Which of the following is IPQC test for Parenteral preparations
a) Sedimentation test
b) Loss on drying test
c) Bloom strength test
d) Clarity test

10. ICH Q6 is related to
a) Analytical methods
b) Impurity profiling
c) Stability protocols
d) Specifications

11. The role of packaging material is ……..
a) Optimization
b) Product identification
c) Automization
d) Validation

12. Which of the following test is not applicable for testing quality of tablets
a) Hardness
b) Thickness
c) Viscosity
d) Dissolution

13. Which of the following document is required for submission to the drug regulatory body for its approval
a) SOP
b) BMR
c) CTD
d) MFR

14. Type III Drug Master file is related to ?
a) Drug Substance, Intermediate and Bulk Products
b) Manufacturing site and Facilities
c) Articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
d) FDA Accepted Reference Material

15. Specification of starting materials with their quantities is included in?
a) Specifications
b) Standard operating procedures
c) Master formula record
d) Batch records

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16. CAPA stands for……
a) Cumulative and proactive action
b) Creative and preventive action
c) Corrective and preferred action
d) Corrective and preventive action

17. _____ ensures that changes are implemented in a controlled manner
a) Out of specifications
b) Out of trend
c) Change control
d) Deviation

18. _____ is the variation in production or any other process from the predefined procedure.
a) Process control
b) Control deviation
c) Process deviation
d) Cross deviation

19. An effective HVAC system controls
a) Line clearance
b) Air borne contamination
c) Waste material treatment
d) Product deviation

20. _____ refers to freedom from cross contamination and also from mix-ups.
a) Identity
b) Purity
c) Strength
d) Safety

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

1. Discuss on the parameters for selection of drug industry location and give importance of gowning
2. What is IPQC and FPQC? Write a note on IPQC and FPQC tests for Parenterals
3. Elaborate on how documents are maintained, retained and retrieved in pharmaceutical industry

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

1. Elaborate on Sanitation of manufacturing premises
2. Explain the scope, advantages and disadvantages of GLP.
3. Write a note on analysis of raw materials.
4. Discuss the elements of Quality Audit.
5. Discuss IPQC in Manufacturing and Packaging
6. Write a note on good warehousing practices
7. Discuss ICH Q3 guidelines in detail.
8. Explain in detail Change Control in Pharmaceutical Manufacturing.
9. Describe the CPCSEA guidelines for animal house in detail.

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