Time: 3 Hours Total Marks: 75

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

I. Multiple choice questions 20

1. Which of the following is responsibility of Quality Assurance department

a. Internal Audit

b. Analytical testing

c. Procurement of raw materials

d. Vendor qualification

2. A suitable space is provided to raw material , handling of raw & packaging materials required for manufacturing including packaging of pharmaceuticals is known as _____

a. QCQA

b. Warehouse

c. Manufacturing area

d. F and D

3. _____ provides guidance for Drug Specifications

a. ICH Q3A

b. ICH Q 6

c. ICH Q 2

d. ICH Q 5

4. Module 4 of CTD relates to:

a. Clinical Study reports

b. Non-Clinical Study Reports

c. Quality Data

d. Region specific information

5. A systematic approach to managing chnges in products and systems is known as:

a. Deviation

b. Change control

c. Cross contamination

d. Out of trend

6. _____is the statutory body formed by the act of Indian Parliament under the prevention of cruelty to animals

a. CPCSEA

b. IAEC

c. OECD

d. IBSC

7. Airlockdoors should be equipped with systems that_____

a. Prevent simultaneous opening of both the doors

b. Allow simultaneous opening of both the doors

c. Prevent simultaneous opening of doors by unauthorized persons

d. Allow simultaneous opening of both the doors by authorized persons

8. Quality control involves

a. Product oriented activities

b. Process oriented activities

c. Managerial skills

d. Organizational skills

9. _____ is a set of written guidelines or instructions for the completion of a routine task, designed to increase performance, improve efficiency, and ensure quality

a. Master formula record

b. Batch records

c. Specifications

d. Standard operating procedures

10. Biomedical Waste Rule 1996 relates to?

a. Environment Pollution Control

b. Drug Licensing

c. Disposal of sewage & effluents from the manufactory

d. FDA

11. Which of the following is EMEA's mission statement?

a. Controlling the safety of medicines for humans and animals

b. Controlling the safety of medical devices

c. Controlling the safety of medicines intended for treatment

d. Controlling the safety of new medicines

12. The most preferred layout for large scale manufacturing is:

a. Product layout

b. Process layout

c. Fix position layout

d. Random layout

13. Photostability testing of Drug substances and Drug products are covered under

a. ICH Q1A

b. ICH Q1 B

c. ICH Q2 A

d. ICH Q2 B

14. Type I 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

15. Role of HVAC system is to _____

a. Prevent air borne contamination

b. Control impurities in raw materials

c. Prevent water contamination

d. Control pollution

16. Which of the following holds true for Quality Assurance?

a. Aims to Prevent defect

b. Aims to Identify defect

c. It's a proactive measure

d. It's a verification activity

17. CTD stands for?

a. Common Technical Document

b. Central Technical Document

c. Common Trade Document

d. Central Trade Document

18. Which of the following test is not applicable for finished product testing of capsules

a. Hardness

b. Viscosity

c. Friability

d. Disintegration time

19. Following are the responsibilities of warehouse management except

a. Transportation

b. Check on incoming and outgoing products

c. Marketing of product

d. Good supply chain

20. A market over which government bodies or, less commonly, industry or labor groups, exert a level of oversight and control is termed as _____

a. Non-regulated market

b. Free market

c. Regulated market

d. Semi regulated market

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

1. a. Write a note on the protocol for the conduct of non-clinical testing

b. Explain the terms: i. Quality audit ii. Reports

2. a. Write a detailed note on sanitation of manufacturing process

b. Compare CDER and CBER in terms of their roles and responsibilities

3. a. Write a note on ICH Q3 guidelines

b. How to calculate expiration date and yields

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

1. Discuss in detail plant layout, design and construction for liquid dosage forms.
2. Enlist the principles of GLP. Write a detailed note on any two principles
3. Discuss batch formula record and master formula record
4. Explain the term GMP. Write a detailed note on 'Sanitation and Hygiene'
5. Write a note on quality control tests for secondary packaging materials
6. Elaborate on the 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 Q6 guidelines in brief