Time: 3 hrs **Marks: 75**

I Multiple Choice question 20

1. GLP is a formal regulation created by USFDA as these regulations were proposed on November 19,1976 and designated as a new part of Chapter 21 of the Code of Federal Regulations(CFR) as .....in 1979.

a. 21 CFR Part 11

b. 21 CFR Part 58

c. 21 CFR Part 210

d. 21 CFR Part 56

2. IAEC under CPCSEA Guidelines stands for?

a. Institutional Animal Ethical Committee

b. International Animal Ethical Committee

c. Institutional Animal Ethical Convention

d. International Animal Ethical Convention

3. The ICH guidelines which deal with Impurities: Guidelines for Elemental Impurities are

a. ICH Q3D

b. ICH Q3A

c. ICH Q3B

d. ICH Q3C

4. The CTD module which is associated with Quality data is

a. Module 2

b. Module 3

c. Module 4

d. Module 5

5. The basic purpose of selection of vendor is

a. To evaluate that suppliers and manufacturers to assure regulatory compliance

b. To assures that suppliers product is manufactured in uncontrolled conditions

c. Designed to evaluate sales

d. To assure labelling of product

6. Air-borne contamination are controlled through effective ----------

a. HVAC system

b. Trained people

c. Line clearance

d. Production in segregated areas

7. Variation in the production or any other process from the predefined procedure is .....

a. Quality deviation

b. Cross deviation

c. Change control

d. Process deviation

8. The disposal of sewage & effluents from the manufacturer shall be in conformity with the requirements of ----------

a. EPCB (Environment pollution Control Board)

b. Central & state legislation

c. Biomedical waste Rules 1996

d. FDA

9. A solid waste that contains or may reasonably be expected to contain pathogens of sufficient virulence and quantify that exposure to the waste by a susceptible host could result in an infectious disease

a. Hazardous waste

b. Unwanted materials

c. Biohazardous waste

d. Used materials

10. The eCTD specification is organized into five modules. Module 5 is .....

a. Clinical study reports

b. Non-clinical study reports

c. Quality data

d. Region specific

11. Type III Drug Master File is related to?

a. Manufacturing site and Facilities

b. Drug Substance, Intermediate and Bulk Products

c. Packaging Material

d. FDA Accepted Reference Material

12. A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives is called as .....

a. Quality audit

b. Quality system

c. Internal audit

d. Regulatory audit

13. Raw Materials and WIP can be classified under _____

a. Direct Material

b. Indirect Material

c. Standard Parts

d. Finished Material

14. Good warehouse practices guide is intended for_____

a. Storage and transportation of pharmaceuticals

b. Stability testing of pharmaceutical products

c. Undesired introduction of impurities of a chemical or microbiological nature

d. Human use or veterinary product administered to food-producing animals

15. The ICH guidelines which deal with Impurities: Guidelines for Elemental Impurities are

a. ICH Q3A

b. ICH Q3B

c. ICH Q3C

d. ICH Q3D

16. Vendors Qualification is done by?

a. QC

b. QA

c. Production

d. Warehouse

17. PIC stands for

a. Pharmaceutical Inspection Conduction

b. Pharmaceutical Induction Convention

c. Pharmacy Inspection Conduction

d. Pharmaceutical Inspection Convention

18. Analyst Certification is done under?

a. cGMP

b. WHO Certification

c. GLP

d. TGA

19. Stock Monitoring of products and Management is a part of?

a. Good Laboratory Practice

b. Good Warehousing Practice

c. Good Clinical Practice

d. Good Cleaning Practice

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

a. OOT

b. OOS

c. Deviation

d. Change control

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

1. a. Elaborate the protocol for conduct of non-clinical testing

b. Write a note on mix-ups & cross-contaminations

2. a. Elaborate the protocol for conduct of non-clinical testing

b. Explain in detail about sanitation of manufacturing premises

3. a. How to calculate expiration date & yield

b. Write a note on three tier documentation

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

1. Describe animal handling as per CPCSEA guidelines

2. Discuss CBER guidelines as per USFDA in details

3. Describe in detail about ICH Q3 guidelines related to Impurities.

4. Explain IPQC tests for capsules.

5. Elaborate on processing of intermediate and bulk products

6. What is Drug Product Inspection? Give Layout of warehouse and discuss its activities.

7. Write a note on GLP components in detail.

8. Elaborate modules of CTD

9. Elaborate on the importance of documentation practices in the pharmaceutical industry.

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