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SUBJECT: BP-606, PHARMACEUTICAL QUALITY ASSURANCE

B.PHARM. SIXTH SEMESTER

UNIT V **QUESTION BANK**

MCQ

1. Essential characteristic of method validation is
a) Specificity
b) Range
c) Linearity
d) All of the above
2. Which of the following is not a type of process validation?
a) Prospective validation
b) Concurrent validation
c) Extrospective validation
d) Retrospective
3. The implementation of validation work requires consideration resources such as:
a) Time
b) Financial
c) Human
d) All of the above
4. Documentation associated with validation includes:
a) Validation master plan
b) Qualification protocols
c) Validation protocols
d) All of above
5. **Which of the following is not a general requirement in a cleaning validation program**
   a) **Written validation protocols in advance**
   b) **Written procedures on how cleaning process will be validated**
   c) **Validation report stating whether or not cleaning process is valid**
   d) **FDA approval of new drug application**
   6. **The current FDA Guideline for Industry addressing process validation was issued in**
   a) **2008**
   b) **2011**
   c) **2005**
   d) **2012**

7. **Process validation involves series of activities taking place over the entire lifecycle of a product & process. How many stages of activities have been identified in the FDA lifecycle approach to process validation**
    a) **Four**
    b) **One**
    c) **Two**
    d) **Three**
8. **According to USFDA guidelines the three stages of process validation involve**
    a) **Process qualification**
    b) **Process Design**
    c) **Continued Process validation**
    d) **All of the above**
9. **Pre market validation is also called as**
    a) **Design Qualification**
    b) **Concurrent validation**
    c) **Prospective validation**
    d) **Retrospective Validation**
10. **If a previously validated process is being transferred to a third party contract manufacturer or to another manufacturing site which type of validation can be done**
    a) **Design Qualification**
    b) **Concurrent validation**
    c) **Retrospective Validation**
    d) **Prospective validation**
11. **Documented validation of a proposed design's ability to meet the requirements it needs to fulfill is known as**
    a) **Operational qualification**
    b) **Design Qualification**
    c) **Performance qualification**
    d) **Installation qualification**
12. **A purchaser has specified 316 SS as the requirement material to the equipment manufacturer, which qualification will help them to verify the material.**
    a) **Design Qualification**
    b) **Performance qualification**
    c) **Installation qualification**
    d) **Operational qualification**
13. **If a purchaser has specified that the equipment is going to run in range of 50-150 rpm & will draw a specific amount of power, how will he verify that the equipment is achieving the operational requirements?**
    a) **Operational qualification**
    b) **Installation qualification**

c) **Design Qualification**
d) **Installation qualification**

14. **The closeness of agreement between the value, which is accepted either as a conventional true value or an accepted reference value & the value find is called as**
    a) **Precision**
    b) **Accuracy**
    c) **Ruggedness**
    d) **Robustness**
15. **Warehouse serves as a key connection between manufacturing and ____ for finished products**
    a) **Employees**
    b) **Customers**
    c) **Storage facilities**
    d) **Warehouses**
16. **Climate control in warehouse space include control of**
    a) **Relative Humidity**
    b) **Temperature**
    c) **Both a & b**
    d) **None**
17. **Many warehouses use____ to receive, store, retrieve products**
    a) **Serial process**
    b) **Bill of lading**
    c) **Storage system**
    d) **Warehousing Management system**
18. **At the time of transferring the goods the documents are signed by**
    a) **Person transferring the goods**
    b) **Person receiving the goods**
    c) **Both a & b**
    d) **None**
19. **During the distribution the ____ hand over the goods to the packers who verify the goods against the delivery note:**
    a) **Line manager**
    b) **Store keeper**
    c) **Analyst**
    d) **Gate keeper**
20. **FIFO stands for**
    a) **Far in Far out**
    b) **First invent first out**
    c) **Fist in first out**
    d) **First inventory first outstanding**

21. In the premises, following is prohibited:

a) **Eating**
b) **Chewing**
c) **Smoking**
d) **All**

22. A common saying in GMP is : If it is not documented it never

a) **Reported**
b) **Happened**
c) **Analysed**
d) **Taught**

23. Good distribution is a part of

a) **Quality control**
b) **Quality assurance**
c) **IPQC**
d) **None**

24. Storage area should be

a) **Filthy**
b) **Clean**
c) **Free from accumulated waste & vermin**
d) **Both b & c**

25. The documents should be retained for …… months after the expiry date of the product

a) **At least 12 months**
b) **6 months**
c) **5 months**
d) **3 months**

Q.1. Define validation. What is the scope & requirements for an effective validation program?

Q.2. Describe the types of process validation.

Q.3. Write a short note on validation master plan.

Q.4. Write a short note on validation protocol.

Q.5. What are the benefits of validation?

Q.6. Classify and discuss various types of validation.

Q.7. Define & discuss stages of qualification.

Q.8. Write note on Process validation.

Q.9. What os analytical method validation? Discuss how analytical method validation is performed?

Q.10. Explain procedure for pH meter calibration.

Q.11. Name the elements of Validation Protocol.

Q.12. Explain the strategy for Industrial process validation of solid dosage forms.

Q.13. What is validation protocol?

Q14. What are advantage of Good warehousing?

Q.15. What is stock verification?

Q.16. How analytical equipments can be validated?

Q.17. Write a detailed note on Good warehousing Practices.

Q.18. Discuss qualification of U.V. vis. Spectrophotometer.

Q.19. Write in detail description on Material management.

Q.20. Describe various methods of inventory control.

Q.21. Explain Calibration.

Q.22. Enlist types of validation in Pharmaceutical Industry.

Q.23. Explain equipment Validation.

Q.24. what is Qualification? Explain different types of qualifications.

Q.25. Explain different phases of validation.