KATHMANDU UNIVERSITY
End Semester Examination
February, 2025

Marks Scored:

Level : B.Pharm.
Year : III

Course : PHAR 326
Semester : II

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date 25 FEB 2025

SECTION "A"

[20 Q. × 1 = 20 marks]

Choose and encircle the most appropriate option from each set of choices

1. The term "stability" as one of the criteria for medicine quality in a dosage form indicates that the dosage form _____
   a. has presence of correct amount of active ingredient
   b. is not contaminated with potentially harmful substances
   c. has no variation in acceptable taste, consistency, color, shape and size of dosage form
   d. is ensured for expected activity until stated expiry in specified packs

2. _____ is a statement of a company of its overall intentions and direction relating to quality, formally expressed and authorized by top management.
   a. Quality management
   b. Quality policy
   c. Quality assurance
   d. Quality risk management

3. Which of the following statement about cleaning of production equipment and cleaning validation is false?
   a. The degree of cleaning depends on whether consecutive batch is of same or different product.
   b. All cleaning and disinfecting solutions should be carefully prepared and expiry dated.
   c. The final rinse of the equipment should be done with hot potable water.
   d. Cleaning validation program should be based on the worst case situation.

4. All of the following areas are included in ancillary area except_____
   a. raw material storage area
   b. animal house
   c. maintenance workshop
   d. rest and refreshment rooms

5. The introduction of a part of previous batch of required quality into another batch at a defined stage of manufacture is known as _____
   a. reprocessing
   b. recovery
   c. reworking
   d. reconciliation

6. Which of the following method is used for monitoring airflow visualization while testing HVAC system?
   a. Vane anemometer
   b. Inclined manometer
   c. Tracer thread
   d. Measuring hood

7. How SS grade 316L is different from SS grade 316?
   a. Presence of low carbon only
   b. Presence of molybdenum only
   c. Presence of molybdenum and low carbon
   d. Absence of nickel

8. Which of the following statement about control of document is false?
   a. Document should be regularly reviewed and kept up to date.
   b. After a document revision, a system should exist to prevent the use of superseded version.
   c. There should be a distribution list of the document.
   d. Superseded document should be retrieved and immediately destroyed.

9. A process validation approach that is carried out during routine production of products intended for sale is termed as _____
   a. prospective validation
   b. concurrent validation
   c. retrospective validation
   d. revalidation

10. Cleaning validation is necessary to provide clean equipment, suitable for its intended purpose when _____
   a. cleaning of floors, walls and ceiling
   b. cleaning the product non-contact parts of the equipment
   c. cleaning of equipment takes place between the batches of different product
   d. cleaning of equipment takes place between the batches of same product

11. All of the following are good practices in production except _____
   a. operation on different products should not be carried out simultaneously in the same area
   b. deviation in the manufacturing process can be permitted after approval from production head
   c. check on yields and reconciliation of quantities should be done
   d. non-medicinal product should not be produced with equipment that is used for pharmaceutical product

12. Despite the proper documented system, a non-conformity arising from the poor implementation of the system is termed as _____ non-conformity.
   a. isolated b. systemic c. critical d. major

13. Which of the following condition leads to voluntary recall of the marketed product?
   a. When there is import, distribution, storage, transportation and sale of prohibited drugs as per section 25 of Drug Act
   b. When the product manufacturing and/or marketing licenses are suspended from DDA
   c. When the product fails to meet the regulatory specification during the post marketing stability study
   d. When the drug product fails to meet the regulatory specification after the market sample analysis by DDA

14. In _____ order reaction, the shelf life is independent of the concentration of reactant.
   a. zero b. first c. second d. third

15. According to WHO guideline on stability testing, the pilot scale batch for oral solid dosage form means _____
   a. batch size of 5,000 tablets or capsules
   b. one-eight of a full production scale
   c. one-fifth of a full production scale
   d. one-tenth of a full production scale

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16. In _____ model, the cost of quality is categorized as cost of value-added activity and non-value-added activity
a. P-A-F b. Crosby's c. ABC d. Process cost

17. _____ observes the development of ISO standard and strategy by attending ISO technical and policy meetings as observer.
a. Subscriber member b. Correspondent member
c. Full member d. All of the above

18. The ICH _____ guidelines are concerned with the design, conduct, safety and reporting of clinical trials.
a. quality b. safety c. efficacy d. multidisciplinary

19. The formal recognition by an independent party that a certification body operates according to International Standard is known as _____
a. accreditation b. certification c. verification d. standardization

20. Suppose you are manufacturing 100 units of product and each unit has 4 parts. After checking, if 10 units are found to be defective, then the defect per opportunities (DPO) is calculated to be _____
a. 10 % b. 2.5 % c. 5 % d. 0.1 %

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SECTION "B"
[5 Q. × 3 = 15 marks]

Attempt ANY FIVE questions.

1. What are the strategies for fighting against substandard and falsified (SF) medical product?
2. How adequate sanitation and disinfection can be maintained in the production area?
3. Mention the good practices to be followed in quality control.
4. What is registration, release and in-house specification?
5. What are the WHO GMP requirements for starting and packaging materials?
6. What is analytical method validation? How accuracy and precision is performed during analytical method validation?
7. What are the requirements for testing frequency and storage condition for stability studies according to WHO guidelines?

SECTION "C"
[5 Q. × 5 = 25 marks]

Attempt ANY FIVE questions.

8. What is good manufacturing practice (GMP)? Give the basic requirements for GMP.
9. Discuss the WHO GMP requirements for premises in pharmaceutical industry.
10. What is qualification? Describe the stages of qualification.
11. What is quality audit? Write about the types of quality audit.
12. What is stability testing? How the shelf life of a product is determined by accelerated stability studies?
13. Describe the general principle of documentation in pharmaceutical industry.
14. What is cost of quality? Explain its various types.

P.T.O.

SECTION "D"

[2 Q. × 7.5 = 15 marks]

Attempt ANY TWO questions.

15. Discuss about six sigma and lean manufacturing as a quality management tools.

16. What are the common causes of product recall? Describe in detail about the product recall procedure. What are the steps to reduce product recall?

17. Why heating, ventilation and air-conditioning (HVAC) system is important in pharmaceutical manufacturing? Write about the design of HVAC system and its components.