KATHMANDU UNIVERSITY
End Semester Examination
June/July, 2023

Marks Scored:

Level : B.Pharm.
Year : III

Course : PHAR 326
Semester : II

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date : 30 JUN 2023

SECTION "A"
[20 Q. × 1 = 20 marks]

Encircle the correct option of the following multiple choice questions.

1. Which of the following is an example of substandard medicine?
   a. fake packaging + correct quantity of correct ingredients
   b. fake packaging + no active ingredient
   c. genuine packaging + incorrect quantity of active ingredient (deliberate)
   d. genuine packaging + incorrect quantity of active ingredient (not deliberate)

2. In a pharmaceutical company, who is responsible for the approval of release of finished products for sale or supply?
   a. Production head
   b. Quality control head
   c. Factory manager
   d. Authorized personnel

3. In a design of HVAC system, low level return air grill is preferred to ceiling return air because:
   a. it helps to achieve equal air distribution inside the cleanroom that allows good ventilation.
   b. it provides turbulent air flow pattern resulting displacement of dirty air.
   c. it requires higher air change rate to achieve specified clean area condition.
   d. it does not allow the exhaust air to be recirculated to save the energy.

4. Which of the following grade of water is commonly used for the preparation of oral and topical products?
   a. potable water
   b. purified water
   c. water for injection
   d. sterile water

5. The weighing area in pharmaceutical manufacturing premises:
   a. Should have accurate weighing scale but not special facilities for the protection of products
   b. Should have dispensing booth with Class 100 condition
   c. Should have dispensing booth with Class 100 to 1000 condition
   d. Should be done in any part of production area under the pharmacist's supervision

6. Which of the following statement about disinfectant used for cleaning and disinfection of pharmaceutical premise is true?
   a. Different disinfectants should be used on alternating basis to prevent microorganism resistance.
   b. Different disinfectants should be mixed to cover broad spectrum of microorganisms.
   c. Dilution of disinfectants is prepared once and can be stored for long period of time for future use.
   d. The dilution of disinfectants can be done in any proportion.

7. The starting materials may be used.....
   a. once the quality control department has sampled them.
   b. immediately after they have been labeled with all the details about receipt.
   c. only when released by quality control department and within their shelf life.
   d. immediately after the purchasing section has paid the supplier invoice.

8. Which of the following statement about production equipment is **FALSE**?
   a. The parts of equipment that come in contact with product must not be reactive, additive or absorptive.
   b. All parts of equipment should be made up of SS 304 to give durability and strength.
   c. Closed production equipment should be used whenever possible.
   d. The part of equipment that is difficult to remove of previous product should be dedicated to single product.

9. Which of the following document is useful for tracing the batch history of finished pharmaceutical product?
   a. site master file
   b. master formula
   c. batch processing record
   d. distribution record

10. Which of the following statement about retention sample is **TRUE**?
   a. Retention sample should be kept for at least one year after the expiry date.
   b. The size of retention sample should be sufficient to permit one full re-examination.
   c. The retention sample should be stored at 40°C ± 2°C/ 75% ± 5 % RH.
   d. The retention sample should be kept for only one batch of product per year.

11. The set of operations that establish relationship between value indicated by an instrument or system for measuring and the corresponding known value of reference standard is termed as.....
   a. validation b. qualification c. calibration d. verification

12. A document that describes in detail about the sequence of activities to be performed for specific validation program including the acceptance criteria is .....
   a. validation master plan
   b. validation protocol
   c. validation report
   d. SOP

13. Which of the following case results to mandatory recall?
   a. When the drug product fails to meet the requirements during stability study
   b. When the drug product fails to meet the requirements following market sample analysis by drug regulatory body
   c. When the batch is found to be defective during the investigation of market complaint
   d. When any unusual observation is noted during visual inspection of retention sample that indicate an impact on quality of product after investigation

14. The quality audit conducted by the customer or purchasing organization upon the supplier organization is known as.....
   a. first party audit
   b. third party audit
   c. second party audit
   d. fourth party audit

15. In first order reaction kinetics, the shelf life is.....
    a. dependent on the initial concentration of reactants
    b. dependent on the log of initial concentration of reactants
    c. dependent on the reciprocal of initial concentration of reactants
    d. independent of the initial concentration of reactants

16. Which of the following criteria is not the significant change criteria during stability studies?
    a. Assay values showing 5 % decrease as compared to initial assay value
    b. Any degradation product exceeding its acceptance criterion
    c. pH value exceeding its acceptance criterion
    d. Melting of creams or softening of suppositories on accelerated stability studies

17. Which of the following cost is highest among the four cost of quality categories?
    a. Preventive cost
    b. Appraisal cost
    c. Internal failure cost
    d. External failure cost

18. When a process is operating at six sigma level, the process variation is reduced to .....
    a. 3.4 defects per million opportunities
    b. 230 defects per million opportunities
    c. 6, 210 defects per million opportunities
    d. 99.977% defect free

19. Which of the following statement about ISO is **FALSE**?
    a. ISO develops international standard that are applicable to pharmaceutical company only.
    b. International standards are developed by the technical committees.
    c. ISO is not involved in the certification process.
    d. ISO certification is not a legal requirement.

20. Which of the following is not the founding member of ICH?
    a. EC, Europe
    b. FDA, USA
    c. MHLW/PMDA, Japan
    d. WHO

KATHMANDU UNIVERSITY
End Semester Examination
June/July, 2023

30 JUN 2023

Level : B.Pharm.
Year : III
Time : 2 hrs. 30 mins.

Course : PHAR 326
Semester : II
F. M. : 55

SECTION "B"
[5Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. Write about the anti-counterfeit technologies.
2. How sanitation can be maintained in the production area?
3. What are the biocontamination control measures for pharmaceutical water system?
4. Define the term DQ, IQ and OQ.
5. When the reduced design is applicable in stability studies? Give examples.
6. Describe briefly about self-inspection.
7. List down the various test parameters and their purpose for testing HVAC system.

SECTION "C"
[5 Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. Describe about the lean production as a quality management method.
9. How do a pharmaceutical company handle a complaint about their product?
10. Write short notes on the following:
    a. Specification
    b. Master formula
11. What are the good practices to be followed in production?
12. Explain any two of the quality cost models.
13. Discuss about the requirements for equipment in pharmaceutical company.
14. Describe about the quality management principles on which ISO 9000 is based.

SECTION "D"

[2 Q. × 7.5 = 15 marks]

Attempt *ANY TWO* questions.

15. What is quality risk management? Explain in detail about the various steps in quality risk management process.

16. What is cleaning validation? Describe the elements of cleaning validation.

17. What is stability testing of pharmaceutical products? Give requirements for selection of batches, testing frequency, storage condition and stability commitment according to the WHO guidelines on stability study.