

KATHMANDU UNIVERSITY  
End Semester Examination [C]  
November/December, 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

07 DEC 2023

SECTION "A"

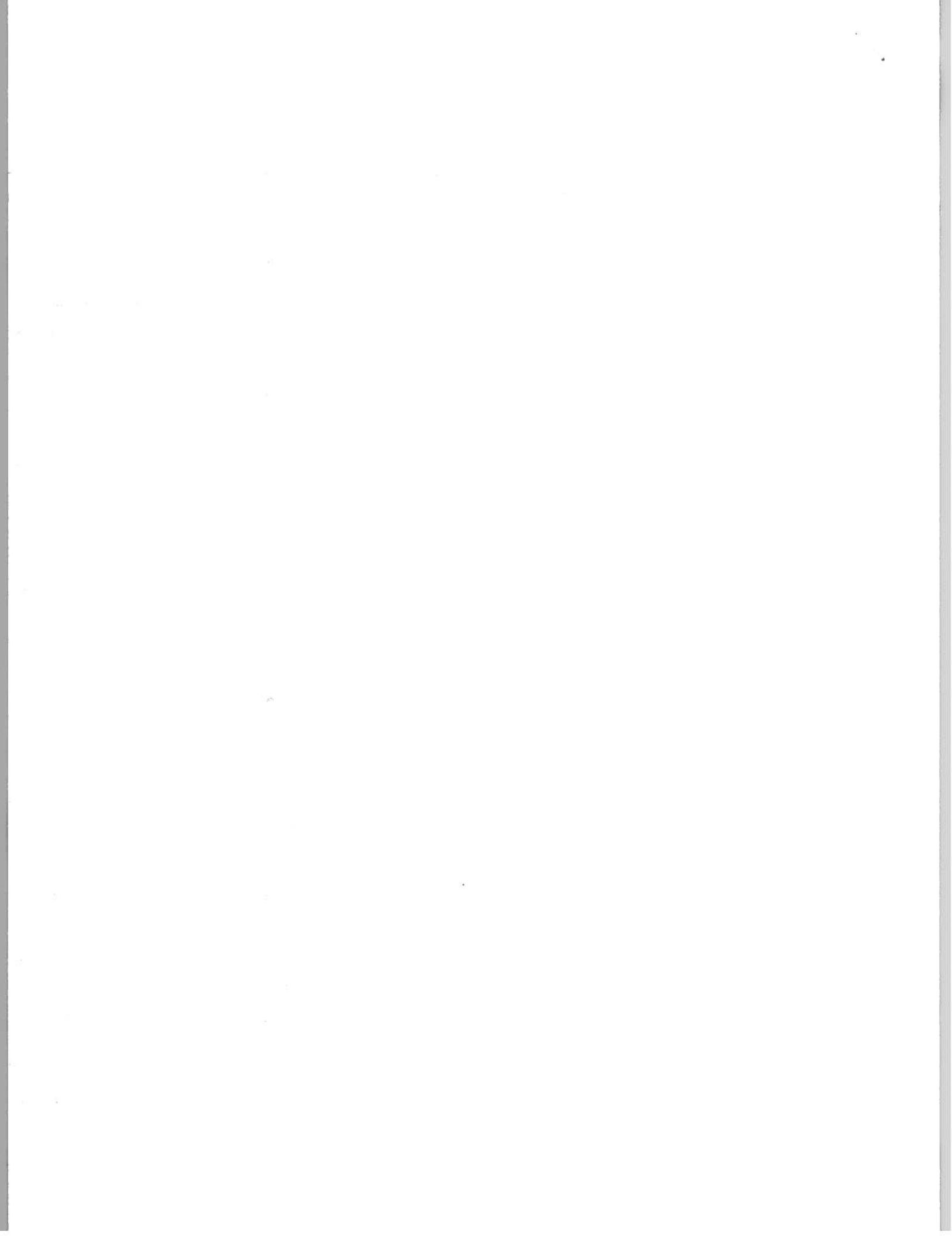
[20 Q. × 1 = 20 marks]

Choose and encircle the most appropriate option.

- The use of hologram in a product is an example of .....
  - overt technology
  - covert technology
  - product engineering
  - none of the mentioned
- The risk product number (RPN) in quality risk management is calculated as .....
  - RPN = Severity X Detectability X Safety
  - RPN = Severity X Probability X Efficacy
  - RPN = Severity X Detectability X Purity
  - RPN = Severity X Probability X Detectability
- The responsibility of production head is to ensure.....
  - analytical method validation and calibration of analytical procedure
  - release of batch after review of BMR and analytical report
  - product production and storage according to appropriate documentation
  - approval of sampling instruction, specification and test methods
- A clean room (5m × 2m × 5m) is supplied with clean air at the velocity of 5m/min by a single air filter having face area of 5m<sup>2</sup>. What is the air change rate of that room?
  - 0.5/hour
  - 6/hour
  - 25/hour
  - 30/hour
- The suitable lighting level requirement in visual inspection area is .....
  - 20 lux
  - 100 lux
  - 500 lux
  - 1000 lux
- Bulk water for injection is .....
  - used in the preparation of oral product
  - highest quality of water for pharmaceutical use
  - used as a final dosage form
  - produced by deionization technique
- A comparison between the theoretical quantity and the actual quantity is termed as .....
  - recovery
  - reprocessing
  - reconciliation
  - reworking
- In production area, the pipeline supplying the purified water should be made up of .....
  - mild steel
  - SS 304
  - SS 304L
  - SS 316L

9. .... provides the list of detailed requirements with which the product has to conform to be acceptable for its intended use.
- a. SOP                      b. Specification              c. Master formula              d. BMR
10. All of the following activities prevent the cross contamination **EXCEPT**
- a. producing every product in segregated area  
b. cleaning non-dedicated production equipment with validated cleaning procedure  
c. relying only on the status labelling of the equipment  
d. operating properly designed air handling unit and dust extraction system
11. Validation carried out during routine production of products intended for sale is .....
- a. prospective validation                      b. concurrent validation  
c. retrospective validation                      d. re-validation
12. For the analytical method validation of content uniformity analysis, the minimum specified range is .....
- a. 90 to 110 % of test concentration              b. 80 to 120 % of test concentration  
c. 70 to 130 % of test concentration              d.  $\pm$  20 % over specified range
13. The drug regulatory body is planning to conduct quality audit of a newly established pharmaceutical industry. What type of audit is recommended?
- a. Routine audit              b. Concise audit              c. Special audit              d. Follow up audit
14. During the technical investigation of product complaint, if the complaint sample showed OOS result, which is clearly a single unexplained failing product and the retained sample is within the specification, then the complaint is .....
- a. confirmed complaint                      b. non confirmed complaint  
c. tamper suspicion                      d. irrational
15. The expenses incurred while doing the quality testing of raw material and finished product is an example of .....
- a. preventive cost                      b. appraisal cost  
c. internal failure cost                      d. external failure cost
16. When post approval stability commitment is **NOT** necessary?
- a. When the submission includes long term stability data from two primary batches covering the proposed shelf life  
b. When the submission includes long term stability data from three primary batches covering the proposed shelf life  
c. When the submission includes long term stability data from two production batches covering the proposed shelf life  
d. When the submission includes long term stability data from three production batches covering the proposed shelf life
17. Nepal is the ..... of ISO.
- a. full member                      b. correspondent member  
c. subscriber member                      d. unclassified

18. The ICH guideline on "Bracketing and Matrixing Design for Stability Testing of New Drug Substance and Product" comes under..... guideline.  
a. Safety                      b. Quality                      c. Efficacy                      d. multidisciplinary
19. The quality management method that focuses on reducing process variation and defect rate in production process through statistical analysis is .....  
a. six sigma method                      b. lean manufacturing  
c. just in time manufacturing                      d. Kaizen method
20. The waste due to unnecessary movement of goods from one location to another is an example of ..... waste.  
a. Defect                      b. Transportation                      c. Motion                      d. extra-processing



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10.7 DEC 2023

Level : B.Pharm.  
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Course : PHAR 326  
Semester : II  
F. M. : 55

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SECTION "B"  
[5 Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. How can you classify quality audit?
2. Write a brief note on cost of quality.
3. What do you understand by accuracy and precision of analytical method?
4. List down the requirements for applying the marketing authorization of a product in Nepal.
5. Prepare a label for starting material and reference standard.
6. What are the requirements for personal hygiene in production area?
7. Write about the qualitative test for identification of SS 316 grade.

SECTION "C"  
[5 Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. Define medicine quality, counterfeit and substandard medicine. List down the main criteria for medicine quality in a dosage form.
9. What is quality assurance? Write down the basic requirements for quality assurance.
10. What are the conditions for voluntary recall of the product? Describe the depth of product recall.
11. Compare traditional organization with total quality management organization.
12. Explain ISO certification process.
13. What are the good practices to be followed in quality control?
14. Discuss about the requirements for premises in pharmaceutical company.

**SECTION "D"**  
**[2 Q. × 7.5 = 15 marks]**

Attempt *ANY TWO* questions.

15. What is the purpose of documentation? Explain the general principle of documentation in pharmaceutical quality system.
16. Describe the various approaches for manufacturing process validation.
17. What is stability testing of pharmaceutical product? When it is done? Explain the shelf-life determination from accelerated stability studies of a product.