

KATHMANDU UNIVERSITY  
End Semester Examination [C]  
July, 2024

Marks Scored:

Level : B.Pharm.  
Year : III

Course : PHAR 326  
Semester : II

Exam Roll No. : Time: 30 mins.

F. M. : 20

Registration No.:

Date : 28 JUL '16

SECTION "A"  
[20 Q. × 1 = 20 marks]

Choose and encircle the most appropriate option.

- Which of the following is an example of covert type of anti-counterfeit technology?  
a. hologram  
b. barcodes  
c. chemical markers  
d. tamper proof labels
- ..... is a wide ranging concept covering all matters that individually or collectively influence the quality of a product.  
a. Quality policy  
b. Quality assurance  
c. Quality control  
d. Quality risk management
- Which of the following area is included in ancillary area?  
a. maintenance workshop  
b. raw material storage area  
c. material weighing area  
d. production area
- Subjecting an in-process or bulk process intermediate or final product of a batch to an alternate manufacturing process due to failure to meet specification is referred to as.....  
a. rejecting  
b. reprocessing  
c. reworking  
d. recovery
- The specification that is based on official compendia or as authorized by the regulatory authority is ..... specification.  
a. registration  
b. release  
c. in-house  
d. stability
- Which of the following measure is recommended to avoid cross-contamination of penicillin products?  
a. Conducting campaign production  
b. Using dedicated and self-contained areas for producing penicillin products  
c. Cleaning of equipment after use in multiproduct facility  
d. Using cleanliness status label on equipment
- What should be done after the receipt of incoming starting material in pharmaceutical industry?  
a. The material should be labelled and used for the production of drug product  
b. The container should be cleaned and used for the production of drug product.  
c. The material should be sampled for quality control and used for the production of drug product.  
d. The container should be thoroughly checked, cleaned and quarantined until they are released for use by quality control.



17. Which of the following is an example of transportation waste in lean manufacturing?
- a. Producing the defective product
  - b. Producing the product parts in one location and shipping them to assemble in different location
  - c. Producing the product in excess quantities than the market demands
  - d. Poor teamwork and minimal training of employees
18. ICH ..... is responsible for developing the harmonized guidelines.
- a. auditor
  - b. management committee
  - c. coordinator
  - d. working group
19. When a product 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. 99.997 % defect free
20. Nepal is a .....member of ISO.
- a. part time
  - b. correspondent
  - c. subscriber
  - d. full



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

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

28 JUL 2024

SECTION "B"

[5 Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. Define medicine quality, counterfeit medicine and substandard medicine.
2. Write about the sampling methods for cleaning validation.
3. What is overage? Why overage is added to a pharmaceutical formulation?
4. What are the key principles involved in standard development by ISO?
5. What are the requirements for production equipment?
6. Describe briefly HVAC system and its components with well labelled schematic representation.
7. Write about the purpose of dispensing booth in pharmaceutical industry.

SECTION "C"

[5 Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. What is quality control? Give the requirements for quality control in pharmaceutical industry.
9. How do a pharmaceutical company handle a market complaint related to their product?
10. Write about the requirements for batch selection, testing frequency and storage condition according to WHO guideline for stability studies.
11. Explain about different types of quality related costs.
12. Discuss about Six Sigma as a Quality Management tool.
13. Discuss the WHO GMP requirements for personnel in pharmaceutical industry.
14. Write short notes on:
  - a. Standard operation procedure
  - b. Batch manufacturing record

P.T.O.

SECTION "D"  
[2 Q. × 7.5 = 15 marks]

Attempt *ANY TWO* questions.

15. What is analytical method validation? Discuss the various parameters studied for analytical method validation.
16. What are the benefits and types of quality audit? How quality audit is conducted in a pharmaceutical industry?
17. Write about good practices in production and quality control.