KATHMANDU UNIVERSITY
End Semester Examination [C]
April, 2023

Marks Scored:

Level : B.Pharm.
Year : IV

Course : PHAR 406
Semester : I

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date 09 APR 2023

SECTION "A"
[20Q. × 1 = 20 marks]

Encircle the most appropriate alternative from each set of choices.

1. Risk priority number (RPN) in quality risk management approach is calculated as.....
   a. RPN= Severity × Detectability × Safety
   b. RPN= Severity × Probability × Efficacy
   c. RPN= Severity × Detectability × Purity
   d. RPN= Severity × Probability × Detectability

2. The overall quality management policies and GMP related activities carried out by pharmaceutical manufacturer are included in.....
   a. batch manufacturing record
   b. stock control record
   c. site master file
   d. distribution record

3. In production unit, the pipes used for supplying purified water should be made up of .....
   a. SS 304
   b. SS 304L
   c. SS 316
   d. SS 316L

4. Subjecting an in-process intermediates of a single batch to an alternate manufacturing process due to failure to meet specification is termed as.....
   a. recovery
   b. reworking
   c. reprocessing
   d. reconciliation

5. The responsibility of head of production is.....
   a. ensure initial and continuous training of production personnel
   b. evaluation of batch records for batch release
   c. approval of the release of finished product for sale
   d. supervision of contract analysis

6. Cross contamination may occur due to .....
   a. presence of foreign matter in purified water
   b. presence of dust particle in production area
   c. presence of microorganism in production area
   d. insufficiently cleaned equipment

7. Hologram used in the HHAll of the following is true about sampling except .....
   a. Every sampling equipment should be cleaned and sterilized as necessary.
   b. Every container should be sampled and marked accordingly.
   c. A consignment containing two batches/lots is given same control number.
   d. Sample should be representative of the batch of material.

8. Which of the following statement is **false** about good laboratory practice?
   a. Primary reference standard should be used for the routine analysis of identification, purity and assay.
   b. The reagents and media prepared in the laboratory should not be used after its shelf life period.
   c. All analytical procedure must have reference of origin and issue date before its application in routine testing.
   d. Every equipment usage should be recorded in the respective equipment log book.

9. A clean room (5 m × 2 m × 5 m) is supplied with clean air at 5 m/min by a single air filter having face area of 5 m^2. Calculate the air change rate of that room.
   a. 0.5/hour b. 6/hour c. 25/hour d. 30/hour

10. In vitro and in-vivo preclinical studies are covered under .....
   a. efficacy guideline b. safety guideline
   c. quality guideline d. multidisciplinary guideline

11. Which of the following represent ISO in Nepal?
   a. Federation of Nepalese Chamber of Commerce and Industry
   b. Nepal Bureau of Standard and Metrology
   c. Department of Drug Administration
   d. Nepal Medicine Laboratory

12. Which of the following statement about ISO 9001:2015 certification process is false?
   a. The first step of certification process is gap assessment via quality audit.
   b. Accreditation bodies prepare a contract and propose an audit team for conducting audit.
   c. Audit is always performed at the manufacture's premises.
   d. The ISO 9001:2015 certification process is voluntary.

13. In Nepal, the condition for real time stability testing is .....
   a. 25^{O} C ± 2^{O} C/ 65% RH ± 5% RH b. 30^{O} C ± 2^{O} C/ 65% RH ± 5% RH
   c. 30^{O} C ± 2^{O} C/ 75% RH ± 5% RH d. 40^{O} C ± 2^{O} C/ 75% RH ± 5% RH

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

15. The purchase specification, drawings, manuals, spare parts lists and vendor details are verified during .....
   a. design qualification b. installation qualification
   c. operational qualification d. performance qualification

16. Which of the following parameter expresses the precision of the analytical procedure carried out in different laboratories?
   a. Reproducibility b. Specificity
   c. Robustness d. Intermediate precision

17. The focus, extent and boundary of an audit is specified by .....
   a. audit plan b. audit scope c. audit criteria d. audit evidence

18. The highest among the four quality related cost is.....
    a. preventive cost
    b. appraisal cost
    c. internal failure cost
    d. external failure cost

19. The guidelines "Specifications: test procedures and acceptance criteria for biotechnological/biological products" is not applicable to.....
    a. protein, polypeptides and their derivative
    b. protein and polypeptide obtained from recombinant and non-recombinant cell-culture expression systems
    c. proteins and polypeptides isolated from tissues and body fluids.
    d. synthetic peptides and polypeptides

20. Acceptance criteria for the biotechnological/biological products should be established and justified based on.....
    a. data from stability studies and relevant development data.
    b. data obtained from lots used in preclinical and/or clinical studies.
    c. data from lots used for demonstration of manufacturing consistency.
    d. all of the above.

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SECTION "B"
[5Q. × 3 = 15 marks]

Attempt *ANY FIVE* questions.

1. Write about the main criteria for medicine quality in dosage form.
2. Define at rest, as built and in operation condition.
3. Explain about the filter integrity test (DOP test).
4. What is overage? Why overage is added in pharmaceutical formulation?
5. Describe briefly about the categories of ICH guidelines.
6. What is cleaning validation? Mention the commonly used acceptance criteria for cleaning validation.
7. List down the key principles involved in ISO standard development.

SECTION "C"
[5Q. × 5 = 25 marks]

Attempt *ANY FIVE* questions.

8. What is quality assurance (QA)? Discuss the basic requirements of QA.
9. What is specification? Describe about the specification preparation for starting and packaging materials.
10. Write short notes on the following:
    a. Good practices in production
    b. Weighing area
11. Discuss about various types of cost of quality.
12. Write about the purity, impurities and contaminants characterization of biological product.
13. Describe about the HVAC system and its components with suitable diagram.
14. Explain the procedure of conducting quality audit in pharmaceutical industry.

SECTION "D"
[2Q. × 7.5 = 15 marks]

Attempt *ANY TWO* questions.

15. What are the types and purpose of documentation in quality assurance system? Describe in detail about the general principle involved in documentation.

16. Why validation is considered as essential part of Good Manufacturing Practice (GMP)? Discuss about the various approaches by which a pharmaceutical manufacturing process can be validated.

17. How shelf life of finished pharmaceutical product is determined by accelerated stability studies? Write about testing frequency and storage condition requirements for stability studies according to WHO guidelines.