KATHMANDU UNIVERSITY
End Semester Examination [C]
May/June, 2019

Mark scored:

Level : B.Pharm.
Year : IV

Course : PHAR 406
Semester : I

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date 0 5 JUN 2019

SECTION "A"
[20 Q × 1 = 20 marks]

*Choose the correct answer from given options and* ***encircle*** *the letter of your choice.*

1. Starting material 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 the quality control department and within their shelf-life.
   [d] Immediately after the purchasing section has paid the supplier's invoice

2. The term "Potency" as one of the criteria for medicine quality in a dosage from indicates that the dosage form
   [a] Has presence of correct amount active ingredient
   [b] Is not contaminated with potentially harmful substance
   [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 the specified packs

3. SS grade 316L is different form SS grade 304 in the following aspects
   [a] Presence of low Carbon only
   [b] Presence of Molybdenum only
   [c] Presence of Molybdenum and low carbon
   [d] None of the above

4. Risk priority number (RPN) in risk management approach refers to
   [a] RPN= Severity x Detectability x Safety
   [b] RPN= Severity x Probability x Efficacy
   [c] RPN= Severity x Detectability x Purity
   [d] RPN= Severity x Probability x Detectability

5. Reverse Osmosis (RO) is a water purification process where through a semi permeable membrane water flows from
   [a] Higher concentration to lower concentration without pressure
   [b] Higher concentration to lower concentration under pressure
   [c] Lower concentration to higher concentration without pressure
   [d] Lower concentration to higher concentration under pressure

6. As-built condition is a condition where
   [a] The installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present.
   [b] The installation is functioning in the specified manner, with specified number of personnel present and working in the manner agreed upon.
   [c] The installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
   [d] All above

7. Hologram used in the product represents one of the following product security technologies used
[a] Covert Features [b] Overt Features
[c] Product Engineering [d] None of above

8. Stability cushion is the difference betweenHologram used in the HHStability
[a] Release limit and in-house limit at higher side
[b] Release limit and in-house limit at lower side
[c] Registration limit and release limit at higher side
[d] None of above

9. The responsibility of head of production isHologram used in the HHThe ttt
[a] Ensures initial and continuous training of production personnel
[b] Evaluation of batch records
[c] Approval of the release of finished product for sale
[d] All of above

10. The room air changes per hour for a room of L=10 ft x B=10 ft x H=10 ft with air supply form a filter grill of L=2 ft x B=1 ft with air velocity of 12000 ft/hr is
[a] 20 per hour [b] 22 per hour [c] 24 per hour [d] 26 per hour

11. In stability studies, reduced design(bracketing and matrixing) is not applicable to :
[a] Capsules of different strengths made with different fill plug sizes from the same powder blend
[b] Tablets of different strengths manufactured by compressing varying amounts of the same granulation
[c] Tablets of same strength containing same excipients and different active ingredients
[d] Oral solutions of different strengths with formulations that differ only in minor excipients like colourants or flavourings

12. Which of the following statement about validation is not true?
[a] Validation ensures that any process, procedure or method actually and consistently leads to the expected results
[b] Process validation is a part of qualification process
[c] Validation should be done according to approved validation protocol
[d] Any deviations found during the validation process should be acted upon and documented

13. Cost incurred in measuring and inspecting activities related to the quality comes under
[a] Preventive cost [b] Appraisal cost
[c] Internal failure cost [d] External failure cost

14. When an organization conducts an audit on its own quality system by hiring external consultants or using its own staff , the audit is known as
[a] First party audit [b] Second party audit
[c] Third party audit [d] All of the above

15. Which of the following represent ISO in Nepal?
[a] Department of Drug Administration
[b] Federation of Nepalese Chamber of Commerce and Industry
[c] Nepal Bureau of Standard and Metrology
[d] None of the above

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

17. The ICH guidelines on "Biopharmaceutics Classification System-based Biowaivers" is classified under
[a] Quality guideline
[b] Safety guideline
[c] Efficacy guideline
[d] Multidisciplinary guideline

18. During the production of biotechnological product, all introduced materials not intended to be part of the manufacturing process are.....
[a] Product related substances
[b] Product related impurities
[c] Process related impurities
[d] Contaminants

19. All of the following are the requirement of Good Laboratory Practice except
[a] All equipment must be serviced and calibrated at specified intervals by a competent service engineer
[b] Primary reference standard should be used for all the routine analysis of drug product
[c] Sampling should be done by trained personnel
[d] The analysis should be done by using validated analytical procedure

20. Which of the following statement about documentation is not true?
[a] Documents should be approved, signed and dated by the appropriate responsible persons.
[b] No document should be changed without authorization and approval.
[c] Documents should be regularly reviewed and kept up to date.
[d] Superseded documents should be destroyed immediately to prevent its use.

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## SECTION "B"

[5Q. × 3 = 15 marks]

Answer *ANY FIVE* questions.

1. Describe safety, potency and stability about medicine quality in dosage form.
2. Write down the process flow for quality risk management (QRM).
3. Describe the Heating ventilation and air conditioning (HVAC) requirements for oral solid dosage form at rest condition.
4. Differentiate between internal failure cost and external failure cost.
5. Explain briefly about the mission and purpose of ICH guidelines.
6. What is meant by overage? How can you calculate the amount of overage to be added in the formulation?
7. How do you monitor the air quality and ventilation in the production area?

## SECTION "C"

[5Q. × 5 = 25 marks]

Answer *ANY FIVE* questions.

8. Discuss about the seven steps of effective hand washing.
9. Discuss the basic principles of premises.
10. Write notes on the following (*ANY TWO*)
    a. Overt and Covert features of product security technologies
    b. Sampling and dispensing booth
    c. Quality assurance (QA) and quality control (QC)
11. Why quality audit is important in pharmaceutical manufacturing? Write about the types of quality audit.
12. What is ISO? Explain briefly about the key principles involved in standard development.
13. Write about the storage conditions and testing frequency for stability studies.
14. Explain in detail about the drug product specification of the biological/biotechnological products.

## SECTION "D"

[2Q. × 7.5 = 15 marks]

Answer *ANY TWO* questions.

15. Describe the basic requirements for Good Manufacturing practices (GMP).
16. What is the purpose of documentation? Explain about the types of documents prepared in pharmaceutical manufacturing.
17. Why analytical method validation is important? Describe in detail about the parameters to be evaluated for analytical method validation with suitable examples.