KATHMANDU UNIVERSITY
End Semester Examination [C]
July, 2017

Mark scored:

Level : B. Pharm.
Year : IV

Course : PHAR 406
Semester : I

Exam Roll No. :

Time: 30 min.

F. M. : 20

Registration No. :

Date JUL 14 2017

SECTION "A"
[20 Q × 1 = 20 marks]

Check (√) the correct answer of the following multiple choice questions. There may be one or more than one correct answer for some questions. In case of a mistake, draw a line through the incorrect answer and √ mark the correct one.

1. Quality assurance is a:
   [a] Narrowly based concept that covers only the administrative arrangements relating to product quality.
   [b] Limited activity relating to the product release procedures only.
   [c] Philosophy that gives general guidance only and is issued by top management.
   [d] Wide-ranging concept covering all matters that influences product quality.

2. Good manufacturing practices are directed primarily at:
   [a] Ensuring that all products are tested according to specifications.
   [b] Ensuring that all products are made in accordance with the formula.
   [c] Minimizing risks inherent in production that cannot be prevented through testing of finished products.
   [d] Preventing cross-contamination only.

3. The basic element of validation is:
   [a] Evidence that all aspects of a manufacturing process achieve the expected result.
   [b] Documented evidence that all aspects of systems, facilities, equipment and manufacturing processes achieve the expected result.
   [c] Documented evidence that the equipment used in manufacturing works as it is intended to.
   [d] A record of how a manufacturing process works.

4. Retrospective validation is carried out
   [a] Periodically and/or after major changes.
   [b] For a production processes that have been used on a routine basis, based on analysis of accumulated data.
   [c] During the development phase.
   [d] Whilst a new product is being commissioned on the plant.

5. The role of a self-inspection process is:
   [a] To detect any shortcomings in implementation of GMP.
   [b] To evaluate all aspects of a manufacturer's compliance with GMP.
   [c] To recommend corrective actions.
   [d] All of the above.

6. Arrhenius equation is expressed by
   [a] $\log A = \log k - Ha/2.303RT$
   [b] $\log k = \log A - Ha/2.303RT$
   [c] $k = \log A - Ha/2.303RT$
   [d] $\log k = A - Ha/2.303RT$

7. Starting materials may be used:
[a] Once they have been sampled by the quality control department.
[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.

8. The "Efficiency" mentioned in the specification limit indicates
[a] Difference between release limit and in-house limit at lower side.
[b] Difference between release limit and in-house limit at higher side.
[c] Difference between registration limit and in-house limit at lower side.
[d] Difference between registration limit and in-house limit both at lower and higher side.

9. Six Sigma (6σ) level indicates the process variation with
[a] 233.00 ppm defects
[b] 2.33 ppm defects
[c] 3.40 ppm defects
[d] 98.99966% defect free

10. 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.

11. SS grade 316 is different form SS grade 304 in the following aspects
[a] Presence of low Carbon
[b] Presence of Molybdenum
[c] Presence of Silicon
[d] All of the above

12. 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

13. 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.

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

15. The real time stability testing condition for Nepal is
[a] 30°C ± 2°C/65% RH ± 5% RH
[b] 30°C ± 2°C/60% RH ± 5% RH
[c] 40°C ± 2°C/75% RH ± 5% RH
[d] 30°C ± 2°C/75% RH ± 5% RH

16. A substandard medicine is a
[a] fake packaging + correct quantity of correct ingredient.
[b] genuine packaging + incorrect quantity of ingredient (deliberate).
[c] genuine packaging + incorrect quantity of ingredient (not deliberate).
[d] genuine packaging + correct quantity of ingredient.

17. Which of the following is not the requirement of WHO GMP
[a] Customer Feedback
[b] Calibration of Monitoring & Measuring Devices
[c] Process Validation
[d] Control of Documents & records

18. Which is correct as "Accurate but imprecise".

(A) 

(B) 

(C) 

(D)

None of them

19. Dose response studies comes under ..... topic of ICH.
[a] Quality
[b] Safety
[c] Efficacy
[d] Multidisciplinary

20. All introduced materials not intended to be part of the manufacturing process, such as chemical and biochemical materials, and/or microbial species is referred as.....
[a] Product related substance
[b] Process related substance
[c] Contaminants
[d] Process related impurities

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SECTION "B"

[5 Q. × 3 = 15 marks]

Answer *ANY FIVE* questions.

1. How is ISO different from GMP certification?

2. List down some basic rules for conducting the quality audit. What is the mission of ICH?

3. Discuss about the concept of medicine quality in a dosage form.

4. Define the term specification mentioning registration, release and in-house specifications.

5. Describe the concept of total quality management (TQM).

6. Discuss general concept of water for pharmaceutical use.

7. A blister packing room of 12 ft long, 10 ft wide and 10 ft height is supplied with the HEPA filtered air through 2 grills each of 3.0 ft long and 1.5 ft wide. Calculate the room air changes per hour if the air is supplied at each grill at 75 ft/min.

SECTION "C"

[5 Q × 5= 25 marks]

Answer *ANY FIVE* questions.

8. Write about specifications for purities and impurities related to drug substance of biological products. In which condition we can replace biological assay by physicochemical test? [4+1=5]

9. Write in detail about process validation. Define linearity and accuracy of analytical method. [4+1=5]

10. Discuss about the concept of Premises. [5]

11. Discuss about the concept of quality assurance. [5]

12. Describe the basic requirements for GMP. [5]

13. Write notes on the following (*ANY TWO*) [2.5 × 2=5]
    a. Equipment
    b. Error cause removal
    c. Effective hand washing

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SECTION "D"

[2 Q × 7.5= 15 marks]

Answer *ANY TWO* questions.

14. Describe about the quality assurance management including the concept of quality risk management and product quality review.

15. Write down the storage condition and time period required to conduct various level of stability studies. Write a note on bracketing. [2.5+2+3=7.5]

16. Describe the concept of general principle of documentation including different types of documentation as per GMP requirements.