Mark scored:

KATHMANDU UNIVERSITY
End Semester Examination
February/March, 2019

Level : B. Pharm.
Year : IV
Course : PHAR 406
Semester : I

Exam Roll No. :
Time: 30 mins.
F. M. : 20

Registration No.:
Date : 11 MAR 2019

SECTION "A"
[20 Q × 1 = 20 marks]

Encircle the correct answer.

1. 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

2. 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.

3. 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

4. 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] 99.95% defect free

5. Which of the following is not the requirement of WHO GMP?
   [a] Customer Feedback
   [b] Calibration of Monitoring & Measuring Devices
   [c] Management Responsibility
   [d] Control of documents & records

6. "At-rest" 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

7. "Fresh Air" in the different types of air mentioned in HVAC system is also called as
[a] supply air [b] make-up air [c] returned air [d] exhaust air

8. Weighing areas
[a] must have very accurate weigh scales but not special facilities for protection of the product.
[b] must have dispensing booth with class 1000 condition
[c] must have dispensing booth with class 100 condition
[d] do not need any written procedures for operation if controlled by a pharmacist

9. Quality control laboratories should be
[a] in the production areas to be sure that there is a close overview of production.
[b] should be separated from production areas.
[c] kept very small because it is very expensive, non-productive space.
[d] all in one area because there is no risk of cross-contamination or mix-up.

10. Which of the following document is useful in material management process?
[a] Distribution record [b] Stock control record
[c] Packaging instruction [d] Specification

11. For the climatic zone IVB (hot and very humid), the long term storage condition is.....
[a] 25°C ± 2°C/60% RH ± 5% RH [b] 30°C ± 2°C/65% RH ± 5% RH
[c] 30°C ± 2°C/75% RH ± 5% RH [d] 40°C ± 2°C/75% RH ± 5% RH

12. Documented evidence that utilities systems or equipment and all its components operated in accordance with operational specifications is.....
[a] design qualification [b] installation qualification
[c] operational qualification [d] performance qualification

13. Which of the following parameter is not normally evaluated during the analytical method validation of assay?
[a] Linearity [b] Range [c] Specificity [d] Limit of detection

14. The cost incurred during the recall of product comes under.....
[a] preventive cost [b] appraisal cost
[c] internal failure cost [d] external failure cost

15. Statement that specifies the focus, extent and boundary of a particular audit is .....
[a] audit plan [b] audit scope
[c] audit evidence [d] none of the above

16. Who is responsible for developing ICH harmonized guidelines?
[a] ICH secretariat [b] ICH coordinator
[c] ICH Management committee [d] ICH working group

17. All of the following are safety guidelines except.....
[a] mutagenic impurities
[b] reproductive Toxicology
[c] genotoxicity Studies
[d] pharmacology Studies

18. Molecular variants arising during manufacture and/or storage, which do not have properties comparable to those of the desired product with respect to activity, efficacy, and safety are.....
[a] product related substances
[b] product related impurities
[c] process related impurities
[d] contaminants

19. ..... influence ISO standards development and strategy by participating and voting in ISO technical and policy meeting.
[a] Correspondent members
[b] Member bodies
[c] Subscriber members
[d] All of the above

20. The role of accreditation body is .....
[a] to provide ISO certification
[b] to provide certification to the ISO certification body
[c] to develop ISO standards
[d] none of the above

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SECTION "B"
[5 Q. × 3 = 15 marks]

Answer *ANY FIVE* questions.

1. Discuss on the concept of medicine quality in a dosage form.
2. Define the term specification mentioning registration, release and in-house specifications.
3. Describe the concept of total quality management (TQM).
4. Justify the statement "Highest quality is the lowest cost".
5. Describe the different categories of ICH guidelines.
6. Why bracketing is done in stability studies? In what conditions, bracketing is applicable?
7. List out the various parameters studied during the environment monitoring of production areas.

SECTION "C"
[5 Q. × 5 = 25 marks]

Answer *ANY FIVE* questions.

8. Discuss on the concept of personnel hygiene.
9. Write notes on the following (*ANY TWO*)
   a. Electrodeionization (EDI)
   b. Six Sigma
   c. Quality Risk Management (QRM)
10. Discuss the basic requirements of Quality Control (QC).
11. What is quality audit? Explain the procedure for conducting quality audit.
12. Describe the seven quality management principles on which ISO 9001:2008 is based.
13. Describe the parameters for the characterization of biotechnological products.
14. Why documentation is important in pharmaceutical manufacturing? Explain the general principles involved in documentation.

SECTION "D"
[2 Q. × 7.5 = 15 marks]

Answer *ANY TWO* questions.

15. Describe the concept in designing premises and role of heating ventilation and air conditioning (HVAC) system for practical implementation of Good Manufacturing Practice (GMP) norms.
16. What do you mean by stability of drug? Write the purpose of the stability studies. How would you determine the shelf life of drug product by stability studies?
17. What is cleaning validation? Discuss in detail on the elements of cleaning validation.