Mark scored:

KATHMANDU UNIVERSITY
End Semester Examination
February/March, 2018

Level : B. Pharm. | Course : PHAR 406
Year : IV | Semester : I
Exam Roll No. : | Time: 30 mins. | F. M. : 20
Registration No.: | Date : MAR 07 2018

SECTION "A"
[20 Q × 1 = 20 marks]

Tick (√) the correct answer. In case of a mistake, strike the mistake with single line and tick (√) mark the correct one.

1. ..... is a documented verification that the system or subsystem performs as intended over all anticipated operating ranges.
   [a] Design qualification
   [b] Installation qualification
   [c] Operational qualification
   [d] Performance qualification

2. ..... expresses within-laboratories variations like different days, different analysts, different equipment, etc.
   [a] Reproducibility
   [b] Intermediate precision
   [c] Repeatability
   [d] Intra-assay precision

3. Which statement regarding OVERAGE is **FALSE**?
   [a] It should be included in the amount of drug substance listed in the batch formula.
   [b] It might compensate for loss during manufacture.
   [c] Its use to extend shelf- life or to compensate for degradation during manufacturing is encouraged.
   [d] Justification for overage is mandatory.

4. A biological assay to measure the biological activity of the product may be replaced by physicochemical tests only when:
   [a] Biological assay is time consuming and expensive than physicochemical test.
   [b] There exist a well-established manufacturing history
   [c] Relevent corelation to biologic activity can be demonstrated.
   [d] Both [b] and [c]

5. Cost for process validation comes under .....
   [a] Preventive cost
   [b] Appraisal cost
   [c] Internal failure cost
   [d] External failure cost

6. It is responsibility of .....to organize and co-ordinate the Internal Quality Audit.
   [a] Factory Manager
   [b] Quality Assurance
   [c] Production
   [d] Quality Control

7. Guidelines for Good clinical practices come under the topic of ..... of ICH guideline.
   [a] Quality
   [b] Safety
   [c] Efficacy
   [d] Multidisciplinary

8. Which of the following statement is **TRUE** regarding GMP and ISO certification?
   [a] Both focus on role and responsibility of quality control unit.
   [b] Both describe in detail the requirement for a management review.
   [c] Both are mandatory according to DDA
   [d] Both require proper documentation to be maintained.

9. System Suitability test is performed to ensure that-
   [a] The result obtained are suitable for submission to Drug authorities
   [b] The test procedure fulfils the acceptance criteria established during test method validation
   [c] Same test method is suitable for testing bulk, intermediate and finished products
   [d] The system is acceptable for all types of test

10. Air born contaminants are controlled through-
   [a] Effective circulation in HVAC equipment
   [b] Effective monitoring in HVAC system
   [c] Effective filtration, airflow and ventilation in HVAC system design
   [d] Controlled filtration and extraction in HVAC design

11. Control sample is-
   [a] Samples kept under lock & key by Quality Control department
   [b] Samples kept in controlled area
   [c] Samples used for testing the continued accuracy and precision of the procedure
   [d] Samples used for assuring the validation of the test method.

12. Out of Specification result is -
   [a] Test results that fall outside the legal requirement of DDA
   [b] Test results that fall outside the acceptance criteria in drug master file or product dossiers
   [c] Test results that fall outside the acceptance criteria of the medical practitioners
   [d] Test results that are not accepted by the top management of the company.

13. Calibration is -
   [a] An evidence to establish that the instrument is producing correct results
   [b] The set of operations that establish the relationship between vales indicated by an instrument and the corresponding known value of a reference standard
   [c] A relationship between expected value and obtained value
   [d] All of above

14. Critical operation in Pharmaceutical Manufacturing process is -
   [a] An operation which is carried out in a complicated equipment
   [b] An operation that needs strict monitoring
   [c] An operation that may cause impact on quality of the product
   [d] An operation that needs approval from top drug regulatory authorities.

15. An authorized person in Pharmaceutical Manufacturing set up is -
   [a] Persons appointed by the top management for QA, QC & production activities
   [b] A person recognized by the national regulatory authority for ensuring that the product has been manufactured, tested & approved in compliance with law & regulation of the country
   [c] A person who is qualified and knowledgeable to ensure that the products manufactured are safe, efficacious and suitable for intended use
   [d] A person having sufficient qualification and experience in assuring the quality of the product produced under his/her supervision.

16. Acceptance criterion for an analytical result is -
   [a] The limits indicated in the specification set by drug regulatory authority of Nepal
   [b] Predefined & documented indicators by which a result is considered to be within the limits
   [c] Documented specification which is authorized by QA clearly indicating the variation
   [d] Documented specification supplied by the material supplier applicable to that particular item

17. Sewage, refuse and other waste (solid, Liquid and other by-products from Manufacturing site must be -
    [a] Kept inside the factory premises for couple of years
    [b] Disposed off in a safe, timely and sanitary manner
    [c] Disposed off in a landfill site
    [d] Dump in a riverside where garbage is dumped by public too.

18. Self Inspection should be conducted -
    [a] In order to monitor the implementation and compliance with Good Manufacturing Practices and to propose necessary corrective measures
    [b] In order to collect the documents to show to the external inspectors and regulatory authorities
    [c] In order to find out the shortcuts and mistakes committed by various functional departments
    [d] In order to collect information and submit the same to top management for their confidence that Quality management system is in place.

19. Product Quality Review [PQR] should normally be done -
    [a] Annually to verify the consistency of the manufacturing process
    [b] Monthly to find out the effect of deviation incorporated in the process
    [c] Once in three month as a surprise checks on manufacturing process
    [d] Every six month to keep a tract of compliance.

20. Validation Protocol should specify -
    [a] Critical process steps and acceptance criteria as well as the type of validation to be conducted i.e. prospective, concurrent, retrospective etc.
    [b] All the steps of manufacturing process and their acceptance criteria and type of validation [prospective, concurrent, retrospective].
    [c] Only the steps identified as critical for prospective validation during Process development
    [d] Critical process steps and acceptance criteria for prospective & concurrent validation.

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Level : B. Pharm.
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Semester : I
F. M. : 55

SECTION "B"
[5 Q. × 3 = 15 marks]

Answer *ANY FIVE* questions.

1. What are the conditions for performing routine audit? In what frequency audit should be performed?
2. How is standard developed for ISO certification? List down the quality management principles on which ISO 9001:2015 standard is based.
3. Differentiate between Calibration and Validation in the context of Pharmaceutical Quality Assurance.
4. Why the provision of Product Recall is kept in GMP guideline for Pharmaceutical production?
5. Define the role of Quality Control (QC) and Quality Assurance (QA).
6. List down the 'procedure characteristics' [parameters] to consider during validation of analytical procedures.
7. Differentiate between Primary and Secondary reference materials.

SECTION "C"
[5 Q × 5= 25 marks]

Answer *ANY FIVE* questions.

8. What changes are considered as "significant change" during stability testing? Mention the provisions to follow if it occurs. Write down the detailed procedure for stability testing as per DDA.
9. Write about specifications for purities and impurities related to drug substance of biological products. What is the difference between process related impurities and contaminants?
10. What are the different types of water used in Pharmaceutical Manufacturing process? Briefly explain the techniques of preparing Purified Water.
11. What is the significance of statement "Do what is written and write what is done" in the context of Good Manufacturing Practices [GMP].
12. Which "In-Process Quality Control [IPQC]" parameters need to be checked while manufacturing Tablets and why such IPQC checks are important?
13. Why HEPA filters are used in the HVAC system in process areas? How is the integrity of HEPA established?
14. What are the information deemed most important while preparing product specification [analytical work sheet] as per the Good Laboratory Practice [GLP] guidelines?

SECTION "D"

[2 Q ×7.5= 15 marks]

Answer *ANY TWO* questions.

15. What value of R^2 (coefficient of determination) and Relative Standard Deviation (RSD) is desired to validate the linearity and precision of analytical method respectively. Explain about Robustness of analytical method. Give a detailed account on Process Validation. [1+2+4.5]

16. What are the major contaminations which must be controlled in Pharmaceutical manufacturing premises?

17. Describe seven basic requirements of Pharmaceutical Quality Control [QC].