Marks Scored:

KATHMANDU UNIVERSITY
End Semester Examination [C]
June, 2018

Level : B.Pharm.
Year : IV

Course : PHAR 406
Semester : I

Exam Roll No. :

Time: 30 mins.

F. M. : 20

Registration No.:

Date JUN 15 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. The term "**Purity**" 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, colour, shape and size of dosage form
   d) Is ensured for expected activity until stated expiry in the specified packs

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. 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

4. Cost for process validation comes under .....
   a) Preventive cost
   b) Appraisal cost
   c) Internal failure cost
   d) External failure cost

5. 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.

6. 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

7. 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.

8. 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.

9. Accelerated stability testing condition is
   a) 40°C ± 2°C/75% RH ± 5% RH for 6 months
   b) 40°C ± 2°C/65% RH ± 5% RH for 6 months
   c) 30°C ± 2°C/60% RH ± 5% RH for 12 months
   d) 40°C ± 2°C/75% RH ± 5% RH for 3 months

10. 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.

11. The Production head is responsible to
   a) Ensure process validation and calibration performed, recorded, and reports are made available
   b) Ensure analytical procedure validation and calibration of control equipment
   c) Ensure initial and continuous training of quality control personnel
   d) All of above

12. A person releasing the batch should ensure
   a) Each batch meets manufacturing and marketing authorization requirements
   b) Planned changes and deviations reported - including where necessary to drug regulatory authority
   c) All production and control documents are completed and endorsed
   d) All of above

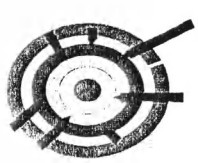
13. "**In-Operation**" is a condition where
   a) The installation is complete with all services connected and functioning but with no production equipment, materials, or personnel present.
   b) The installation is complete with equipment installed and operating in a manner agreed upon by the customer 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

14. Which is correct as "**Accurate but imprecise**".

a) 

b) 

c) 

d) 

15. 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.

16. 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 thorough testing of finished products.
    d) Preventing cross-contamination only.

17. Mistakes made in filling in documentation:
    a) Should be neatly covered by white correcting fluid.
    b) Should be completely covered over with a dark black pen.
    c) Should be crossed through with a single line and initialed or signed, dated, and if appropriate, the reason recorded.
    d) Should be reported to the supervisor at once.

18. ICH guideline on stability testing Q1A (R2) refers to
    a) Photostability Testing of New Drug Substances and Products
    b) Stability Testing for New Dosage Forms
    c) Stability Testing of New Drug Substances and Products
    d) Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products

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

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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F.M. : 55

SECTION "B"
[5 Q. × 3 = 15 marks]

Answer ***ANY FIVE*** questions

1. Discuss about the concept of medicine quality in a dosage form.
2. How is standard developed for ISO certification? List down the quality management principles on which ISO 9001:2015 standard is based.
3. Define the term specification mentioning registration, release and in-house specifications.
4. Define quality assurance (QA), good manufacturing practices (GMP) and quality control (QC).
5. Describe the concept of total quality management (TQM).
6. Discuss the need for conception of ICH guidelines with its mission.
7. Discuss general principles of documentation.

SECTION "C"
[5 Q. × 5 = 25 marks]

Answer ***ANY FIVE*** questions

8. Describe in brief about the parameters to consider during validation of analytical procedures.
9. Write about specifications for purities and impurities related to drug substance of biological products.
10. Describe the basic requirements for GMP.
11. Discuss general concept of water for pharmaceutical use.
12. Which "In-Process Quality Control [IPQC]" parameters need to be checked while manufacturing Tablets and why such IPQC checks are important?
13. Describe the concept of Product Recall based on GMP guideline for Pharmaceutical production.
14. Describe the concept of HEPA filters are used in the HVAC system in process areas.

SECTION "D"
[2 Q. × 7.5 = 15 marks]

Answer ***ANY TWO*** questions

15. Describe basic requirements of Pharmaceutical Quality Control [QC].
16. Describe general principle of premises and discuss in detail about location, design and construction of a premises based on GMP norms.
17. Explain in detail about the concept of product stability (shelf-life) studies based on GMP.