BIRLA INSTITUTE OF TECHNOLOGY, MESRA, RANCHI
(END SEMESTER EXAMINATION)

CLASS: B.Pharm. **SEMESTER: VI**
BRANCH: PHARMACY **SESSION: SP2022**

SUBJECT: BP606T Pharmaceutical Quality Assurance

TIME: 3.00 Hours **FULL MARK: 75**

INSTRUCTIONS:

1. **The missing data, if any, may be assumed suitably.**
2. **Before attempting the question paper, be sure that you have got the correct question paper.**
3. **Tables/Data hand book/Graph paper etc. to be supplied to the candidates in the examination hall.**
4. **This question paper consists of (03) three parts. Read the part wise instructions before attempting the questions.**

PART-I
Multiple choice questions (Instruction: Answer all questions)

Q1. (20 x 1 = 20 Marks)

A. ISO 14000 FAMILY stands for:
a) quality management.
b) environment management.
c) digital security.
d) medical devices — Quality management systems.

B. SOPs doesn't include:
a) protocol.
b) sign.
c) procurement price.
d) model and make.

C. Quality assurance process does **NOT** include:
a) In process quality checking in manufacturing
b) Complaint handling
c) Warehousing of raw materials
d) Storage of quality records and control samples

D. Quality control head and production head share which of the following responsibility?
a) Approval of production process
b) Approval or rejection of starting material
c) Monitoring and approval of material supplier
d) Testing parameter decision for finished product

E. GLP governs
a) test and control articles.
b) raw material selection.
c) approval of manufacturing process.
d) environmental controls.

F. Q1C guidelines is for
a) stability testing of new drug product.
b) photostability testing.
c) text on validation of procedures.
d) validation of analytical procedure: methodology.

G. According to ICH guidelines for stability study, temperature and relative humidity (RH) condition for Zone III are:

a) 21°C± 2°C , 45% ± 5% RH
b) 25°C ± 2°C, 60% ± 5% RH
c) 30 C ± 2°C, 35% ± 5% RH
d) 30 C ± 2°C, 65% ± 5% RH

H. For purchasing raw material what should **NOT** be in the specification list?

a) Cost of raw material.
b) Identity, purity and quality of raw material
c) Date of manufacture and date of expiry
d) Date of release of product from manufacturing department

I. GMP is related to Schedule
a) Q
b) M
c) R
d) U

J. NABL accreditation is for:
a) standards for product.
b) ICH.
c) testing labs.
d) Pharma industrial manufacturing unit.

K. Which of the following statements are **CORRECT** related to master formula records?
I. It is prepared by the production team.
II. It is a master document for a pharmaceutical product.
III. This written document contains the entire manufacturing process.
IV. Batch manufacturing records follows this master formula records.

a) I and II only
b) II and III only
c) I, II and III only
d) II, III and IV only

L. Which of the following statements related to maintenance of electronic data is **NOT TRUE**?
a) Any changes to these electronic data should be recorded and detected.
b) Access of the documents should be restricted by password.
c) It will be accessible to everyone freely.
d) These documents are protected by back-up transfer

M. Calibration of instrument is an important consideration in measurement system. The errors due to instruments being out of calibration can be rectified by:
a) increasing the temperature coefficient
b) increasing the frequency of recalibration
c) increasing the susceptibility of measuring instrument
d) increasing the productivity of the instrument

N. Historical data is used to process:
a) Prospective validation
b) Retrospective validation
c) Concurrent validation
d) Revalidation

O. _____ is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.
a) Range
b) Specificity
c) Robustness
d) Linearity

P. Which of the following signal-to-noise ratio of analyte to blank samples is **CORRECT** for limit of quantitation assay?
a) 1:10
b) 2:3
c) 3:2
d) 10:1

Q. Which of the following quality control tests can be performed for glass containers of pharmaceutical products?
I. Light transmission test
II. Chemical resistance test
III. Leakage test
IV. Test for arsenic

a) I and II only
b) II and III only
c) I, II and IV only
d) I, III and IV only

R. Which of following quality control tests is used as confirmatory tests of Class II and Class III?
a) Surface etching test
b) Surface glass test
c) Glass grain test
d) Light transmission test

S. Which of the following statements is **FALSE** regarding precautions during vending scrap materials from the pharmaceutical industries?
a) Labels of the containers should be defaced.
b) Residual solvent containers must be emptied.
c) Authorised records should be maintained for the disposal process.
d) Extra labels should be pasted to the respective bottles before disposal.

T. "Controlled copy" stamp is pasted on which of the following documents?
a) Master copy of standard operating procedure
b) Copies of master copy of standard operating procedure
c) Superseded copies of standard operating procedure
d) Drafted copies of standard operating procedure during revision

PART-II
Short Answers
(Instruction: Answer seven out of nine questions)

(7 x 5 = 35 Marks)

Q2. Write a short note on total quality management.

Q3. Elaborate the tools of QbD and their significance.

Q4. Detail about ICH stability testing guidelines for accelerated stability testing.

Q5. Define QA and QC. Write about quality management concept.

Q6. Describe the process of handling returned products in pharmaceutical industries.

Q7. List the personnels responsible for calibration of instruments in industry. Described the roles of any one of them.

Q8. Discuss about precision in analytical method validation process.

Q9. Write a short note on installation qualification.

Q10. Define revalidation. Categorize the conditions where revalidation is necessary.

PART-III
Long Answers
(Instruction: Answer two out of three questions)

(2 x 10 = 20 marks)

Q11. Discuss in detail about premise layout plan for pharma industry. Describe about maintenance of sterile area.

Q12. Explain the process of surface etching test and briefly interpret the possible findings. Describe the consequences of disqualification of a testing facility.

Q13. Outline different components of complaints handling standard operating procedure.

:::::02/05/2022:::::