DR. BABASAHEB AMBEDKAR TECHNOLOGICAL UNIVERSITY, LONERE

End Semester Examination – Summer 2022

Course: B. Pharmacy **Sem: VI**

Subject Name: Pharmaceutical Quality Assurance **Subject Code: BP606T**

Max. Marks: 75 **Date: 28/07/2022** **Duration: 3.45 Hrs.**

Instructions –

1. **All questions are compulsory**
2. **Answers to MCQs should be written in full sentences**
3. **Draw diagrams / figures wherever necessary**
4. **Figures to right indicate full marks**

Q. 1. Multiple Choice Questions (MCQs) = 20 x 1 = 20 (All the questions are compulsory)

1) NABL accreditation has a validity period of _____ years.

   a) 1 b) 2 c) 3 d) 4

2) The …… is a process of assurance that the specific system, premises or equipment are able to achieve the predetermined acceptance criteria to confirm the attributes.

   a) Validation master plan b) Calibration

   b) Evaluation d) Qualification

3) ISO Certification is valid for _____ years.

   a) 1 b) 2 c) 3 d) 4

4) Which guideline stands for evaluation of stability data?

   a) Q1B b) Q1C c) Q1D d) Q1E

5) P-D-C-A stands for…..

   a) Proceed-Do-Check-Act b) Plan-Do-Check-Act

   c) Plan-Do-Correct-Act d) Prepare-Do-Check-Act

6) Physical dimension of equipment and accessories comes under which qualification?

   a) Operational qualification (OQ) b) Installation qualification (IQ)

   c) Performance qualification (PQ) d) Design qualification (DQ)

7) _____ airlock is mainly used in Parenteral manufacturing areas.

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a) Cascade airlock b) Sink airlock

c) Bubble airlock d) Hermetical airlock

8) For Hydrolytic resistance test, at least ____ number of containers to be used for the 5 ml capacity glass containers.

a) 20 b) 10 c) 5 d) 3

9) Fragmentation test applicable to butyl rubber closures, the total number of fragments is NMT____.

a) 5 b) 10 c) 15 d) 20

10) As per USFDA, Microbiological limit for clean area class 1000 is _____ cfu/ft^3.

a) <1 b) <2 c) <3 d) <5

11) Non-clinical laboratory study records must be retained for at least ____ years, when application for research is approved by FDA.

a) 1 b) 2 c) 3 d) 5

12) _____ validation is performed on already completed process.

a) Prospective b) Concurrent c) Retrospective d) Qualification

13) Non-clinical laboratory study protocol is signed and approved by _____

a) Study Director b) Sponsor c) QA Unit d) Both a & b

14) ____ is degree of closeness of a series of measurement obtained using multiple samples of same substance.

a) Accuracy b) Precision c) Specificity d) Linearity

15) Waste which is potentially dangerous to human health is called as.....

a) Non-hazardous waste b) Hazardous waste

b) Inert substances waste d) Biomedical waste

16) _____ means an action taken to resolve a problem with therapeutic goods having deficiencies in quality, efficacy or safety.

a) Qualification b) Drug recall c) Quality review d) Complaint

17) As per CDSCO, Class II Drug recall should be completed within _____

a) 3 days b) 10 days c) 30 days d) 7 days

18) _____ audit is performed to assess the GMP & cGMP compliance.

a) External audit b) Internal audit c) Regulatory audit d) Operational audit

19) Product quality complaint should be investigated within_____ days

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a) 5 b) 3 c) 10 d) 7

20) Only complaint sample shows OOS result, due to improper storage and retained sample meets specifications, this complaint is categorized as_____

a) Confirmed complaint b) Non-confirmed complaint

c) Counter complaint d) Tamper complaint

Q. 2. Long Answers = 2 x 10 = 20 (Answer 2 out of 3)

1. Describe process of harmonization and elaborate the ICH stability testing guidelines.
2. Write in detail about Analytical Method Validation. Give process of Calibration of pH meter.
3. Explain the quality control tests for glass containers and rubber closures.

Q. 3. Short Answers = 7 x 5 = 35 (Answer 7 out of 9)

1. Explain the process of Complaint Handling.
2. Describe Elements of QbD.
3. Explain principles and procedure for NABL accreditation.
4. Write a note on Training and Personnel health and hygiene. Explain in short Maintenance of sterile areas.
5. Give an account of purchase specifications and maintenance of stores for raw materials.
6. Discuss the Protocol for Conduct of a Nonclinical Laboratory Study and Records and Reports per GLP.
7. Write a note on Quality Audit and Master Formula Record.
8. Differentiate between QA & QC. Enlist the steps for registration for ISO 9000.
9. Write a short note on Good Warehousing Practice.

------END OF THE PAPER------

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