647510 **MSC3AnaC302x** **Seat No :_____**

M.Sc.(Chem.) Semester - 3 (*CBCS*) Examination
OCT/NOV-2025 (AS PER SYLLABUS YEAR JUNE-2019)
Pharma Regulatory Affairs (Core(New))

Time: 2:30 Hours **Marks:70**

Instructions:

1. All questions are compulsory.
2. Figures to the right indicate marks.

Q.1 (A) **Answer the following question** **(04)**

(1) What is SOP? Give the list of SOPs for QC department.

Q.1 (B) **Answer any two questions out of three.** **(10)**

(1) Give an account on SOP writing style and its benefits.
(2) Prepare SOP for operation and calibration of digital pH meter.
(3) Explain following in short:
   a) Control copy and master copy of SOP
   b) Supersedes date of SOP.

Q.2 (A) **Answer the following question** **(04)**

(1) Prepare table indicating various validation parameters and its acceptance criteria.

Q.2 (B) **Answer any two questions out of three.** **(10)**

(1) Write the process to calibrate analytical balance.
(2) How would you calibrate TDS meter and pH meter?
(3) Explain robustness and ruggedness with suitable example.

Q.3 (A) **Answer the following question** **(04)**

(1) What is qualification? Discuss objectives and scope of qualification.

Q.3 (B) **Answer any two questions out of three** **(10)**

(1) What is performance qulification? How it is conducted for TDS meter?
(2) Distinguish between qualification, calibration and validation.
(3) Give detailed account on analyst qualification.

Q.4 (a) **Answer the Following Question** **(04)**

(1) Mention Any Two Factors Affecting Drug Stability.
(2) What Is Self-Life of a Drug?

Q.4 (b) **Answer Any Two Questions Out Of Three** **(10)**

(1) Answer the Following
   (a) Explain About Frequency of Stability Testing.
   (b) Describe the Effect Of Temperature, Light, And Humidity On Drug Stability.
(2) Write A Note on Accelerated Stability Testing and Its Significance.
(3) Give an Account of Packing Materials for Stability Studies and Discuss Its the Role in Drug Stability.

Q.5 (A) **Answer the following question** **(04)**

(1) Expand the following terms: OEDC, USFDA
(2) State any two differences between GLP and GMP.

Q.5 (B) **Answer any two questions out of three** **(10)**

(1) Discuss the essential requirements under the criteria 'Personal' to maintain GLP.
(2) State any ten major GLP non-compliant (violations) observations.
(3) Answer the following:
   a) What is Quality as per GLP
   b) Write elements of GLP

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