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

M.Sc.(Chem.) Semester - 3 (*CBCS*) Examination
OCT/NOV-2024 (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 documentation? Give the examples of major documents in pharmaceuticals and discuss importance of documentation

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

1) Give an account on SOP of SOP.
2) Prepare SOP for operation and calibration of digital pH meter in standard SOP format.
3) Answer the following
   (A) Give blank format of SOP
   (B) What is Specification?

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

1) Draw master calibration schedule
2) Define: Calibration

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

1) Give the stepwise process to calibrate flame photometer.
2) Discuss calibration criteria for UV-Viz Spectrophotometer.
3) Explain Traceability and Tolerance Limit with 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) Explain performance qulification taking suitable example
2) Write a not on Installation Qualification highlighting its purpose.
3) Explain facility qualification and analyst qualification in brief

Q.4 (A) **Answer the following question** **(04)**

1) Note the requirements of container closer for stability studies of API.
2) what is Shelf-life in stability studies?

Q.4 (B) **Answer any two questions out of three** **(10)**

1) Explain the following in brief
   (A) Various climatic zones, countries, temperature and %RH values
   (B) Stability testing frequency
2) Explain stress testing with suitable example and conditions.
3) Prepare storage conditions table for stability studies of APIs.

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

1) Give brief introduction of GLP and list out key components of a GLP-compliant laboratory?

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

1) Discuss the essential building and infrastructure requirements for compliance with GLP standards
2) Provide examples of GLP violations related to calibration and validation practices."
3) Answer the following:
   (A) What is 21CFR?
   (B) Differentiate between GLP and GMP.

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