

M.Sc.(Chem.) Semester - 3 (CBCS) Examination
Oct/Nov. -2019 - [NEW COURSE]
Pharma Regulatory Affairs (Core (New))

Time: 2:30 Hours

Marks: 70

Instructions:

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

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- Q1 (A) Answer the following Question** **04 Marks**
- 1 Give standard and blank format of SOP and specification.
- Q1 (B) Answer any two questions out of three** **10 Marks**
- 1 Discuss purpose and benefits of SOP.
- 2 Prepare SOP for calibration of Polari meter.
- 3 What is SOP of SOP and what are the benefits of SOP?
- Q2 (A) Answer the following Question** **04 Marks**
- 1 Give an account of Robustness studies with example.
- Q2 (B) Answer any two questions out of three** **10 Marks**
- 1 Explain Traceability in calibration and give Traceability chart.
- 2 Enlist objectives of validation studies and prepare characteristics chart for validation parameters.
- 3 Write calibration procedure and prepare daily calibration format for conductivity meter.
- Q3 (A) Answer the following Question** **04 Marks**
- 1 Define the term 'shelf life'
- 2 Prepare stability testing schedule for long term and accelerated stability studies.
- Q3 (B) Answer any two questions out of three** **10 Marks**
- 1 Give an account of various stability zones as per ICH guidelines.
- 2 Discuss the objectives and purpose of stability studies.
- 3 Explain the following for stability studies.
i) selection of batches ii) Testing frequency
- Q4 (A) Answer the following Questions** **04 Marks**
- 1 Explain following terms with example
(i) Static Documents (ii) Dynamic Documents
- Q4 (B) Answer any two questions out of three** **10 Marks**
- 1 Give brief details of qualification of analyst and explain when does the qualification of analysts should be done?
- 2 Enlist phases of qualification and discuss the difference between operational qualification and performance qualification.
- 3 Give an account of facility qualification.
- Q5 (A) Answer the following Question** **04 Marks**
- 1 What is GLP? Enlist the topics covered under the GLP
- Q5 (B) Answer any two questions out of three** **10 Marks**
- 1 Describe requirements of Infrastructures and Personal under GLP.
- 2 Explain violation of GLP with suitable example in each element.
- 3 Discuss minimum criteria required for Calibration and Validation under GL.
