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

M.Sc.(Chem.) Semester - 3 (*CBCS*) Examination
DEC/JAN. - 2020 - [NEW COURSE]
Pharma Regulatory Affairs(Core (New))

Time: 1:30 Hours **Marks: 42**

Instructions:

1. Figure to the right indicate marks.
2. There are five questions in the question paper.
3. Answer any three of the following questions.

Q.1 (a)	**Answer the following question**	**4**
(1)	Prepare blank format of SOP, discuss its elements in brief.	
Q.1 (b)	**Answer any two questions out of three**	**10**
(1)	Prepare SOP for Operation and Calibration of Conductivity meter.	
(2)	What is SOP? briefly explain about general writing style and importance of SOP.	
(3)	Answer the following (i) Prepare Specification for AR Grade methanol (ii) What is Documentation? Enlist most knowns and important QC documents	
Q.2 (a)	**Answer the following questions**	**4**
(1)	Define the term Validation, enlist various validation parameters with passing criteria.	
(2)	Briefly differentiate between Calibration and Validation	
Q.2 (b)	**Answer any two questions out of three**	**10**
(1)	Explain calibration of glassware by taking example of 5.0 mL volumetric flask.	
(2)	What is calibration? Give brief Outline on Calibration activity.	
(3)	Illustrate LOD and LOQ with equation and representative figure.	
Q.3 (a)	**Answer the following question**	**4**
(1)	Classify various instruments by group under qualification	
Q.3 (b)	**Answer any two questions out of three**	**10**
(1)	Give an account of Qualification of Analyst	
(2)	What is Instrument Qualification? Enlist phases of qualification and draw qualification chart	
(3)	Explain Operational qualification and Performance qualification with suitable example	
Q.4 (a)	**Answer the following question**	**4**
(1)	Explain the following terms in brief (i) Expiry date (ii) Shelf Life	
Q.4 (b)	**Answer any two questions out of three**	**10**
(1)	Give an account of Climatic zones for stability studies.	
(2)	What is Short term stability study? Discuss merits and demerits of Short term stability study.	
(3)	Explain about packing and container closure system for stability studies.	
Q.5 (a)	**Answer the following questions**	**4**
(1)	What is GLP? List out its major elements	
(2)	Draw organogram for Quality Control Department	
Q.5 (b)	**Answer any two questions out of three**	**10**
(1)	Give an account of violation of GLP.	
(2)	How will you maintain GLP in Instrument Lab of a Pharma company?	
(3)	Discuss requirements of facility and infrastructure as per GLP.	

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