647510 **MSC4AnaC402x** **Seat No :_____**

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
August/September -2020 [NEW COURSE]
Regulatory Affairs-II (Core)

Time: 2:00 Hours **Marks: 56**

Instructions:

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

Q1 (A)	**Answer the following questions.**	**04 Marks**
1	Give short explanation about 21 CFR.	2
2	Write the detailed name of following: (i) CDSCO (ii) FSSAI.	2
Q1 (B)	**Answer any two questions out of three.**	**10 Marks**
1	What is GMP? Discuss requirements of GMP under the criteria of Personal.	5
2	Draw the organogram of QC department and discuss responsibilities of Quality Head	5
3	Explain the following terms with example a) Blending of Batch b) Reprocessed Batch	5

Q2 (A)	**Answer the following questions.**	**04 Marks**
1	Define the term quality control as per GMP.	2
2	What is quarantine area?	2
Q2 (B)	**Answer any two questions out of three.**	**10 Marks**
1	Give an outline of sampling in quality control department.	5
2	Give an account of vendor qualification activity.	5
3	Draw following labels with brief introduction a) Calibration label b) Status label c) Quarantine label	5

Q3 (A)	**Answer the following questions.**	**04 Marks**
1	Discuss requirements of finished goods storage in terms of space and infrastructure	04
Q3 (B)	**Answer any two questions out of three.**	**10 Marks**
1	Give an account of finished goods sampling and testing.	5
2	Write a detailed note on violation of GMP practices.	5
3	What is warehouse? Briefly explain about types of warehouse.	5

Q4 (A)	**Answer the following questions**	**04 Marks**
1	Which ICH guidelines provide the base of QbD approach?	2
2	Define the term quality by design and enlist its elements.	2
Q4 (B)	**Answer any two questions out of three**	**10 Marks**
1	Explain the concept of critical quality attributes (CQA) with examples.	5
2	Give detailed out line on quality by design approach.	5
3	Write a note on critical material attributes (CMA) with examples.	5

Q5 (A)	**Answer the following questions**	**04 Marks**
1	Write the detailed names of following: 1) USFDA 2) PIC/S 3) TGA 4) MHRA	4
Q5 (B)	**Answer any two questions out of three**	**10 Marks**
1	Discuss preparation of Site Master File in detail.	5
2	Give the importance and role of regulatory agencies.	5
3	Briefly discuss preparation of Drug Master File in detail.	5

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