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

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
Oct/Nov -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	Define the term: GMP.	2
2	Write the full forms of following: (i) NDA, (ii) ANDA	2
Q1 (B)	**Answer any two questions out of three**	**10 Marks**
1	What is GMP? Discuss the requirements of GMP under the criteria of personal.	5
2	Draw the organogram of QC and discuss the responsibilities of QC Head.	5
3	Explain the following terms with example (i) Rejected material (ii) Recalled material.	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 QC department.	5
2	Draw following labels with brief introduction (i) Calibration label (ii) Status Label.	5
3	Discuss briefly about documentation and storage in QC department.	5
Q3 (A)	**Answer the following questions**	**04 Marks**
1	Define the term: Quarantine area	2
2	What is FIFO & FEFO?	2
Q3 (B)	**Answer any two questions out of three**	**10 Marks**
1	What is Warehouse? Briefly explain about types of Warehouse.	5
2	Give an account of finished goods sampling and testing.	5
3	Write a detailed note on violation of GMP Practices.	5
Q4 (A)	**Answer the following questions**	**04 Marks**
1	Define the terms: Quality by Design	2
2	Which ICH guidelines provide the base of QbD approach?	2
Q4 (B)	**Answer any two questions out of three**	**10 Marks**
1	Write a note on risk assessment tools a per QbD.	5
2	Explain the concept of critical quality attributes (CQA) with example.	5
3	Discuss benefits and outcomes of quality by design.	5
Q5 (A)	**Answer the following questions**	**04 Marks**
1	Write the full forms of following: (i) TGA (ii) MHRA.	2
2	Who prepares Site Master File? Which guidelines should follow for preparation of Site Master File?	2
Q5 (B)	**Answer any two questions out of three**	**10 Marks**
1	Discuss preparation of Drug Master File in detail.	5
2	Write a note on Site Master File.	5
3	Explain the importance and role of regulatory agencies in brief.	5

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