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

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
May/June-2021 (NEW COURSE)
Regulatory Affairs-II(Core)

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

Instructions:

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

Que-1(A) Draw detailed organogram of a pharmaceutical manufacturing unit. (04)

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

1. Briefly discuss the role and work of personal department.
2. Discuss violations of GMP in terms of equipment and instruments.
3. Give an outline of sampling process in Quality Control Department.

Que-2(A) Briefly explain the difference between RMQC, IPQC and FPQC. (04)

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

1. Discuss responsibilities of Quality Control Department as per GMP.
2. Give an outline and importance of Labels, draw following labels with necessary details. (i) Calibration Label, (ii) Approved Label
3. Discuss basic requirements of quality control area in terms of space & infrastructure.

Que-3(A) **Answer the following questions.** (04)

1. What is Quarantine area?
2. Give the full forms of FIFO and FEFO

Que-3(B) **Answer any two questions out of three.** (10)

1. Discuss the basic requirements of Raw Material warehouse and Finished Product warehouse in terms of Infrastructures and Facility.
2. Briefly explain the following terms with example
   (a) Blanding of Batch (b) Reprocessing of Batch
3. Give an account of handling of return goods and product complaints.

Que-4(A) Give brief introduction and historical account of QBD approach. (04)

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

1. Explain interpretation of Quality as per QBD with suitable examples.
2. Enlist elements and benefits of QBD approach.
3. Give an account of Critical Material Attributes (CMA) and Critical Process Parameters (CPP).

Que-5(A) Give the full forms of followings (04)

(i) ANDA, (ii) NDA, (iii) USFDA, (iv) TGA

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

1. Enlist the elements of DMF covered in the open part and close part of DMF.
2. Give detailed account Site Master File (SMF).
3. Discuss the broad role of national regulatory agency in terms of manufacturing and marketing of pharmaceutical products.

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