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

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
March/April - 2025 (As Per Syllabus Year June-2019)
Regulatory Affairs-II(Core)

Time: 2:30 Hours **Marks: 70**

Instructions:

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

Que-1(A) **Answer the following question** **(04)**

(1) Draw detailed organogram of a pharmaceutical manufacturing unit.

(2) What is cGMP?

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

(1) Briefly discuss the role and work of personal department.

(2) Explain with examples: non GMP compliances in equipment.

(3) Discuss the general requirement for premises as per GMP guideline

Oue-2(A) **Answer the following questions** **(04)**

(1) Briefly explain about Quarantine area and Auxiliary area.

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

(1) Discuss responsibilities of Quality Control Department as per GMP.

(2) Discuss in detail about packing and labelling control including objectives and types.

(3) Distinguish between following pairs in brief

1) Blending of batch and Reprocessing of batch
2) Batch Manufacturing Record (BMR) and Batch Formula Record.

Que-3(A) **Answer the following question** **(04)**

(1) What to be audited in self-audit?

(2) What is product recall?

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

(1) Discuss the requirements of finish goods sampling and testing.

(2) Define the term audit and explain types of audits.

(3) Give an account of handling of return goods and product complaints.

Que-4(A) **Answer the following question** **(04)**

(1) Introduce QBD approach.

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

(1) Enlist elements and benefits of QBD approach.

(2) Explain interpretation of Quality as per QBD with suitable examples.

(3) Give an account of Critical Material Attributes (CMA) and Critical Process Parameters (CPP).

Que-5(A) **Answer the following questions** **(04)**

(1) What is DMF? Briefly explain its type.

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

(1) Enlist and explain open part and close part elements of DMF.

(2) What are ICH guidelines? Give the names of all Quality guidelines.

(3) Discuss objectives and function of National Regulatory Agencies

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