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

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
March/April - 2026 (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.

Q.1 (A) **Answer the following questions** **(04)**

(1) Where personal hygiene concern most in pharmaceutical manufacturing and testing

(2) What is GMP? Who provides certificate for GMP in Gujarat?

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

(1) What is Schedule-M? Explain its types.

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

(3) What is vendor qualification? State its objectives and benefits.

Q.2 (A) **Answer the following questions** **(04)**

(1) Prepare master calibration schedule.

Q.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) Explain following in brief

i) Retain Samples Room

ii) Quarantine Area

Q.3 (A) **Answer the following question** **(04)**

(1) Who Schedule and initiate self-audit? What to be audited in self-audit?

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

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

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

(3) Give examples of non-compliances observed in raw material and finished Good storage

Q.4 (A) **Answer the following question** **(04)**

(1) Define Quality by Design (QbD)

(2) What is a Quality Target Product Profile (QTPP)?

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

(1) Enlist elements and benefits of QBD approach.

(2) Discuss the importance of risk assessment in QbD with suitable examples.

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

Q.5 (A) **Answer the following questions** **(04)**

(1) Define Drug Master File (DMF)

(2) What are the types of DMF?

(3) Who submits a DMF?

(4) State the purpose of DMF.

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

(1) Introduce ICH guidelines; state all Quality guidelines.

(2) Discuss objectives and function of National Regulatory Agencies

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

****