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

M.Sc.(Chem.) Semester - 4 (*CBCS*) Examination
March/April - 2024 (NEW COURSE)
Regulatory Affairs-II(Core)

Time: 02:30 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) Introduce CDSCO.
(2) Write the basic principle of GMP.

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

(1) Give an account on personnel qualification and responsibilities under GMP.
(2) State the basic requirements for building and premises to follow GMP.
(3) Discuss various stages of raw material handling.

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

(1) Draw the following labels:
(a) Calibration status label (b) Approved label for Finished Goods
(2) Prepare Master Calibration Schedule for QC Lab.

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

(1) Explain i) Blending of batch, ii) Reprocessing of batch, iii) Reworking of batch with suitable example.
(2) Write a note on GMP violations observed in production area.
(3) Define the term quality control; enlist sampling and testing responsibilities of quality control department.

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

(1) What to be audited in self inspection?
(2) Explain FIFO and FEFO in brief.

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

(1) Stateexamples for violation of GMP practices in quality control area.
(2) Discuss the basic requirements for finished goods sampling and finished goods storage.
(3) Briefly explain about returned goods and product recall

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

(1) Give introduction and historical account of QbD approach.

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

(1) Prepare comparative Quality Target Product Profile (QTPP) and Critical Quality Attributes (CQAs) for injectables and tablet dosage form.
(2) Define QbD and state basic elements and benefits of QbD.
(3) Give an account on risk assessment for QbD.

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

(1) Give full forms of following: MHRA, PMDA, TGA, 21CFR

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

(1) What is DMF? discuss its types in brief.
(2) Introduce ICH and list out ICH quality guidelines.
(3) Answer the following in brief:
a) State objectives of FDA
b) Give brief account on CDSCO

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