Seat No. _____

HB-003-1104005

M. Sc. (Sem. IV) (CBCS) (W.E.F. 2016) Examination

April - 2023

Chemistry : (CPA) 403

(Pharma Regulatory Affairs)

(New Course)

Faculty Code : 003
Subject Code : 1104005

Time : $2\frac{1}{2}$ / Total Marks : **70**

Instructions :

(1) All questions are compulsory.

(2) All questions carry equal marks.

1 Answer the following : (any seven)

(a) List the parameters of regulatory affairs.

(b) Define SOP. Who should write SOPs ?

(c) Enlist S_1 to S_{10} ICH guideline.

(d) Explain : Master formula record and BPR.

(e) Differentiate AQ and QC.

(f) What is process validation ?

(g) Define : Herbal product, placebo, drug substance and specified impurities.

(h) What is robustness study ?

(i) Give the full form of following :

(i) MHRA

(ii) C-GMP

(iii) CDSCO

(iv) USFDA

(j) What is calibration ? Why it is required ?

2 Answer the following : (any two)

(a) Discuss Q8 to Q14 ICH guideline in detail.

(b) Discus regulatory affairs in clinical trials, product management and R&D.

(c) What are residual solvents ? Classify them with examples.

3 Answer the following :

(a) Explain qualification documents. Describe DQ, IQ, OQ and PQ in detail.

(b) Discuss stability study in detail/

OR

(a) Describe SOP of SOP.

(b) Explain various components of GLP in detail.

5 Answer the following : (any two)

(a) Give the classification and discuss the impurity with their examples.

(b) Discuss the working of regulatory affairs in detail.

(c) Write note on GMP.

(d) Enlist the various techniques for isolation of impurities.

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