



MBU-003-1104005 Seat No. _____

M. Sc. (Chemistry) (Sem. IV) (CBCS) Examination

April / May - 2018

CPA - 403 : Pharma Regulatory Affairs

(New Course)

Faculty Code : 003

Subject Code : 1104005

Time : $2\frac{1}{2}$ Hours]

[Total Marks : 70

Instructions :

- (1) All questions carry equal marks.
- (2) All questions are compulsory.

1 Answer the following : (any **seven**)

- (a) What is calibration ? Give its importance.
- (b) Define : QA, Impurity profile, API, QC.
- (c) What is objective of stability testing ?
- (d) List the steps used in the ICH process ?
- (e) What is analytical method validation ? Give name of parameters of drug validation.
- (f) What is source of SOP and who write it ?
- (g) Give bracketing in stability study with example.
- (h) Explain LOD, LOQ, accuracy and precision.
- (i) Explain schedule-M, WHO-GMP and 7QA.
- (j) What is certified reference material ? Give their role.

2 Answer the following : (any **three**)

- (a) What is GLP ? Compare the main features of GMP and GLP.
- (b) Discuss primary features of well organised quality assurance system.
- (c) Classify the solvent as per ICH guideline with example.
- (d) Give the safety guidelines and discuss in detail.

3 Answer the following :

- (a) Describe the quality guidelines in detail.
- (b) List the documents require for calibration. How will you calibrate gas chromatograph ?

OR

- (a) As per ICH, describe multidisciplinary guidelines in detail.
- (b) How will you calibrate UV spectrophotometer and analytical balance.

4 Answer the following : (any **two**)

- (a) Write SOP of SOP.
- (b) Give detail description of method validation.
- (c) Explore cleaning validation and revalidation.

5 Answer the following : (any **two**)

- (a) Explain in detail DQ, IQ, PQ and OQ.
- (b) What is GMP ? What are major aspects of GMP ?
- (c) Describe and classify stability study according to climatic zones with advantages.
- (d) Write note on Quality control.
