DO-003-1104005 Seat No. _____

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

March / April - 2022

Chemistry : C(PA)-403

(Pharma Regulatory Affairs)

Faculty Code : 003

Subject Code : 1104005

Time : $2\frac{1}{2}$ Hours] [Total Marks : **70**

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

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

(a) What is ICH ? Who are the members of ICH ?

(b) What is C-GMP ? Why it is important ?

(c) Define regulatory affairs and on which issues does RA department provide assistance ?

(d) What is SOP ? Give the types of SOP' name.

(e) Give definition, significance and objectives of GLP.

(f) List the types of analytical procedures to be validated ?

(g) What is the difference between linearity and range ?

(h) List the steps of calibration programme.

(i) What is the scopes and objectives of SOP ?

(j) What are the main ICH guideline and which topic included in it ?

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

(a) Explain general work profile of regulatory affairs professional in an API manufacturing company.

(b) Discuss the steps that need to be followed in case of regulatory landscape and product development.

(c) Describe the SOP writing style in detail.

3 Answer the following :

(a) Write down an SOP for the calibration of pH meter and glass wares.

(b) Describe the ICH guidelines in detail.

OR

3 Answer the following :

(a) What is stability study ? Discuss the design of stability program in detail with steps in it.

(b) Explain the residual solvents with its classification included their acceptable limits.

4 Answer the following :

(a) Discuss GMP in detail.

(b) Explain the term precision in detail with its types.

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

(a) What is qualification documents ? Discuss IQ, DQ, OQ and PQ documents.

(b) Describe the calibration of analytical balances.

(c) Discuss quantitative limit with its different measurement methods.

(d) Discuss the process of SOP in detail.
