PT-003-1104005 Seat No. _____

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

August - 2020

C(PA) - 403 : Pharma Regulatory Affairs

(New Course)

Faculty Code : 003

Subject Code : 1104005

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

Instruction : (1) All questions are compulsory.

(2) All questions carry equal marks.

1 Answer the following : (any **seven**) **14**

(a) What is Calibration ? Why is it necessary ?

(b) What are the goals and objectives of ICH ?

(c) Give the full form of the following :

(i) NDA

(ii) DMF

(iii) ASMF

(iv) BLA

(d) List the types of SOP.

(e) List the step for the calibration program.

(f) Define :

(i) Genetic drug and ethical drug.

(ii) Active subastance and clinical trial.

(g) What is revalidation ? When is it required ?

(h) What is GMP and its application ?

(i) Give the role of chemist and pharma industry.

(j) What are the options for describing limits of class-2 solvents ?

2 Answer the following : (any **two**) **14**

(a) Describe the ICH guidelines in detail.

(b) What is regulatory affairs ? Discuss the origin and goals of regulatory affairs.

(c) What is residual solvent ? Describe its classification in detail.

3 Answer the following : **14**

(a) Discuss the calibration of analytical balances.

(b) Discuss in detail the process of SOP.

OR

3 (a) Describe the general work profile of regulatory affairs in an API manufacturing company.

(b) Write a SOP for cleaning and operation of p^H meter.

4 Answer the following : **14**

(a) Discuss method validation parameters in detail.

(b) What are qualification documents ? Duiscuss IQ, OQ, PQ and DQ documents in detail.

5 Answer the following (any **two**) : **14**

(a) Write note on calibration of melting point apparatus and glasswares.

(b) Write note on GMP.

(c) Write note on GLP.

(d) Explain LOD and LOQ in detail.