



BBC-003-1104005

Seat No. _____

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

July - 2021

C(PA)-403 : Chemistry

(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) Attempt any five questions out of ten.

1 Answer the following :

- Give the objectives of regulatory affairs.
- Enlist the types of ICH guidelines.
- Give the standard format of SOP.
- What is impurity ? Explain organic impurity.
- Enlist the component of GMP.
- What is calibration ? Why it is require ?
- Differentiate LOD and LOQ.

2 Answer the following :

- Give the historical overview of regulatory affairs.
- Describe the benefits of SOP.
- Enlist the area covered by M and S guidelines.
- Give the name of techniques for the isolation and characterization of impurities.
- Enlist the component of GLP.
- Explain CRM and VMP.
- Give the calibration of pH meter.

3 Answer the following :

- Write note on SOP.
- Classify and discuss the impurity.

- 4 Answer the following :
- (a) Discuss the ICH guidelines for Q₁ to Q₇.
 - (b) Give the role of regulatory affairs in product management, clinical trial and R&D.
- 5 Answer the following :
- (a) Write note on QA.
 - (b) Discuss analytical method validation for linearity, LOD and LOQ study.
- 6 Answer the following :
- (a) Explain the following components of schedule-M series:
 - (i) Self inspection and quality audit
 - (ii) QC system
 - (iii) MFR
 - (iv) Packing record
 - (v) BPR
 - (vi) SOP
 - (vii) Batch processing and recoveries
 - (b) Describe the requirements and task performed by QC development.
- 7 Answer the following :
- (a) Describe the principle of GLP.
 - (b) Write note on stability.
- 8 Answer the following :
- (a) Write calibration of UV-visible spectrophotometer and glasswares.
 - (b) Give calibration of IR spectrophotometers and weighing balance.
- 9 Answer the following :
- (a) Discuss the analytical method validation for linearity and range.
 - (b) Describe photolytic and thermal degradation study.
- 10 Answer the following :
- (a) Write note on SMF.
 - (b) Discuss the principle of GMP.