



NBW-003-010409 Seat No. _____

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

April / May - 2017

Chemistry : C(PA)-403

(Pharma Regulatory Affairs)

(New Course)

Faculty Code : 003

Subject Code : 010409

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) 14

- (a) Write a short note on quality assurance.
- (b) Differentiate ruggedness and robustness.
- (c) Discuss different zones according to their climate condition with reference to Q1 guideline.
- (d) Describe personnel and hygiene as per GMP.
- (e) Explain OOS, OOT and OOSC.
- (f) Write a note on NABL, BIS, AGMARK with their use and importance.
- (g) Explore re-validation.
- (h) Define the following terms :
 - (1) Drug product
 - (2) Drug self life.
- (i) Explain the terms repeatability and reproducibility.
- (j) Differentiate working standard and certified reference material.

- 2** Answer the following : (any **three**) **14**
- (a) What is calibration failure ? Why calibration is necessary ?
 - (b) Describe process validation with its types.
 - (c) Explain matrixing protocol for stability study.
 - (d) Give solvent classification with their acceptable limits.
- 3** Answer the following : **14**
- (a) Discuss in detail ICH guideline Q1B.
 - (b) Write short note on impurity profiling.
- OR**
- (a) Discuss in detail cleaning validation.
 - (b) What is analytical method validation ? Writ a detailed procedure for precision study.
- 4** Answer the following : (any **two**) **14**
- (a) Describe in detail any five ICH guidelines.
 - (b) Write note on bracketing phenomena for stability guideline with its importance.
 - (c) What is qualification documents ? Discuss about IQ, OQ, PQ and DQ documents.
- 5** Answer the following : (any **two**) **14**
- (a) Define the following terms :
 - (i) Specification
 - (ii) Stability
 - (iii) System suitability test
 - (iv) Content uniformity
 - (b) Write about different types of LOD measurement method in detail.
 - (c) Discuss in detail recovery study with suitable example as a validation parameter.
 - (d) What is stability study ? Describe main objective and factor affecting to stability study.