

Shree Manibhai Virani and Smt. Navalben Virani Science College (Autonomous), Rajkot
Affiliated to Saurashtra University, Rajkot

SEMESTER END EXAMINATION APRIL - 2018

M.Sc. Chemistry (Analytical Chemistry)

16PCEAC07 – ANALYTICAL METHOD DEVELOPMENT, VALIDATION & STABILITY STUDIES

Duration of Exam – 3 hrs

Semester – IV

Max. Marks – 70

Part A (5x2= 10 marks)

Answer **ALL** questions

1. Define the term LOD.
2. Explain methodology for determination of Robustness.
3. What are the objectives of cleaning validation?
4. What are the scope of validation?
5. Give difference between validation and qualification.

Part B (5x5 = 25 marks)

Answer **ALL** questions

- 6a. Write a note on sterile process validation.

OR

- 6b. Describe various storage conditions used for stability study of drug product.

- 7a. Discuss the different phases of validation.

OR

- 7b. Explain the validation of API.

- 8a. Specify types of method transfer. Explain any one from them in detail.

OR

- 8b. Write a note on stability testing protocol of the drug substance.

- 9a. What is MKT? Give the importance of the same in the stability study? How it can be calculated?

OR

- 9b. Describe validation master plan.

- 10a. Explain sampling process in cleaning validation.

OR

- 10b. What is the full form of ICH? Explain in brief about guidelines used for stability study.

Part C (5x7 = 35 marks)

Answer **ALL** questions

11a. Discuss in detail: ICH guidelines of analytical method validation.

OR

11b. Which factors are affecting on degradations of drugs? Give detail explanation.

12a. Write a note on process validation.

OR

12b. How accelerated stability study is carried out using Arrhenius equation? What are its limitations.

13a. Give detail importance of validation.

OR

13b. Discuss in detail about various climatic zones in stability testing as per WHO guidelines.

14a. Write a note on non sterile product process validation

OR

14b. Write a note on validation of water system.

15a. Enumerate parameters of analytical method validation. Explain any three in detail.

OR

15b. Explain method for carrying out stability study using thermal degradation and photo stability testing.
