Total No. of Questions : 8] *[Total No. of Printed Pages : 1*

Roll No .....

MPY-QA(C)

M.Pharmacy III Semester Examination, June 2020

Analytical Method and Equipment Validation (Elective)

Time : Three Hours

Maximum Marks : 70

Note : i) Attempt any five questions.

ii) All questions carry equal marks.

1. What are bio-analytical methods? Describe study parameters for bio-analytical method validation as per FDA guidelines.

2. What is the importance of Standard Operating Procedure (SOP) in pharma industry? Write a model SOP for operation of UV spectrophotometer.

3. What do you understand by method transfer? Write about documentation required in method transfer for ANDA filing as per USFDA.

4. What is User Requirement Specification? Prepare the URS for procurement of a GMP model tablet compression machine.

5. Discuss regulatory aspect of stability testing. Explain the stability testing of pharma products as per ICH guidelines.

6. Describe Bracketing and Matrixing designs in stability study of pharmaceutical products.

7. Describe salient features of Q1C: ICH guidelines for stability testing for new dosage form.

8. Write short note on **any two** of the followings:
   a) Application of Process Analytical Technology (PAT) in quality assurance.
   b) PAC-ATLS (Post Approval Changes - Analytical Testing Laboratory Site).
   c) SOP of Differential Scanning Calorimetry in pharma industry.

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