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Roll No. .....

341817(41)

B. Pharmacy (Eighth Semester) Examination, April-May 2018

(New Scheme)

(Pharmacy Branch)

PHARMACEUTICAL ANALYSIS-IV

(Quality Assurance and Drug Regulatory Affairs)

Time Allowed : Three hours

Maximum Marks : 70

***Note** : Attempt any **five** quesitons. Each question carries equal marks.*

1. Discuss the basic concept of Quality Control (QC) and Quality Assurance (QA) with special reference to GMP. 14

2. What is Validation? Enlist all the important parameters or process validation of analytical procedures. 14

3. Explain various stability testing protocols of drug product as per ICH guidelines. 14

4. Explain followings : 7×2

(a) Quality audits and batch release documentations

(b) Role of regulatory affairs departments

5. Explain the types of water used in pharmaceuticals. Discuss in brief about the validation fo water system for sterile and non-sterile products. 14

6. What is TQM? What are the basic principles of TQM? Why TQM is important to an organisations? 14

7. Write short notes : (any **two**) 7×2

(a) Quality Control Responsibilities

(b) Cleaning Validation

(c) Regulatory Drug Analysis