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B. Pharmacy (Eighth Semester) Examination, Nov.-Dec. 2017

(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. What is Validation? Describe process validation and equipment validation with suitable examples. 14

2. Write the differences between QC & QA. Discuss the total quality management system. 14

3. Elaborate the role of regulatory affairs departments with refereene to quality control of drugs. 14

4. Discuss the stability protocols of drug as per ICH quide lines. 14

5. Write a detail note on sampling plans and quality audits. 14

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

(a) Sterile product validation

(b) ICH quide lines

(c) Q.C. responsibilities

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

(a) Regulatory drug analysis

(b) GLP and ISO

(c) Interpretation of analytical data