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B. Pharmacy (Eighth Semester) Examination, April-May 2016

(New Course)

(Pharmacy Branch)

PHARMACEUTICAL ANALYSIS-IV

(Quality Assurance and Drug Regulatory Affairs)

Time Allowed : Three hours

Maximum Marks : 70

***Note** : Attempt any five questions. All questions carry equal marks.*

1. Recall the basic concept of quality assurance and quality control in pharmaceutical industry. 14

2. Describe the concept of Validation in Pharmaceuticals with special reference to Process Validation. 14

3. Explain the role of documentations like INDA and NDA required for the approval of a new drug. 14

4. Write a note on working of quality control department in pharmaceutical Industries in detail. 14

5. Write in detail about the stability testing protocols of drug products as per ICH guidelines. 14

6. Describe the procedure for filing investigational new drug applications in US FDA. 14

7. Write short note on any **two** : 2×7=14

   (a) CFR (Code of Federal Regulation)

   (b) TQM (Total Quality Management)

   (c) GMP