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**B. Pharmacy (Eighth Semester) Examination,  
April-May 2017**

(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. Each question carries equal marks.*

1. (a) Define QA and QC. Differentiate between QA and QC. 7

341817(41)

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| 2 |

- (b) Discuss the philosophy of GMP. Write a note on CGMP. 7
2. Define Total Quality Management. Discuss the strategies, approaches and philosophies of TQM. 14
3. (a) Discuss the role of regulatory affairs department in India, US and EU. 7
- (b) Write exhaustive note on cleaning validation. 7
4. What is sampling? Discuss the methods of sampling and sampling plans in details with example. Add a note on sampling curves. 14
5. (a) Discuss the validation of water system for sterile and non-sterile products. 7
- (b) Explain the validation of analytical procedures in detail. 7
6. Write short notes on : 2x7
- (any two)
- (a) ISO
- (b) GLP

(c) Quality Reviews and Quality Audits

7. What are ICH guidelines? Discuss the stability testing protocols of drug products as per ICH guidelines. 14

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