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341817(41)

B. Pharmacy (8th Semester)
Examination, Nov.-Dec., 2016

(New Scheme)

Pharmaceutical Analysis-IV
(Quality Assurance and Drug Regulatory Affairs)

Time Allowed : 3 hours *Maximum Marks :* 70

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

1. What are ICH guidelines? Discuss it with special reference to analytical method validation of drugs.
2. Discuss validation and its importance. Describe validation of sterile and non-sterile products.
3. How will you perform the routine quality control of instruments? Discuss SOP's and standard protocol for control of instruments.
4. Write a detailed note on general philosophy of GMP and CGMP.

(Turn Over)

5. Explain in brief about role, nomenclature an salient features of USFDA.
6. Write short notes on the following (any *two*) :
   (*a*) Sampling plan
   (*b*) TQM
   (*c*) Batch release documents
7. Explain following :
   (*a*) Cleaning validation
   (*b*) Stability testing protocols.