

QP Code: 106329

Reg No: .....

**First Year M.Pharm Degree Examinations – July 2015**

**(Pharmaceutical Analysis)**

**Paper II - Quality Control and Quality Assurance**

**Time: 3 hrs**

**Maximum Marks: 100**

- *Answer all questions*
- *Draw diagrams wherever necessary*

**Essays:** **(2x20 =40)**

1. Explain in detail validation of equipment. Explain the location, design & layout, construction and control of contamination of manufacturing premises
2. Explain in detail
  - raw material purchase specification
  - maintenance of stores.
  - standard operating procedure for coating of tablets and membrane filtration

**Short Essays:** **(6x10=60)**

3. Discuss in detail
  - reconciliation of labels
  - master and batch formula record
4. Discuss about the quality control tests for plastic containers and closures
5. Explain quality review of finished product and preparation of analytical report
6. Explain the procedure involved in handling complaints and recalls.
7. Explain
  - Reprocessing
  - waste disposal records
8. Explain salient features of GMP.

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