

QP Code: 106329

Reg No:

First Year M.Pharm Degree Examinations- February 2013

(2011 Admn- New Scheme)

(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 the concept & types of validation and discuss the following • Salient features of ISO 14,000 • Training of personnel • personal hygiene
2. Explain in detail • Equipment purchase specification • Vendor selection. • Standard operating procedure for sterilization • Auditing of manufacturing facility.

Short Essays:

(6x10=60)

3. Discuss in detail • Line clearance • Master formula record
4. Discuss about the types and tests assuring quality of glass
5. Explain in details the controls that must be in place for animal house.
6. Explain the procedure involved in handling returned goods and recovered materials
7. Explain evaluation of complaints and recall procedure
8. Explain the procedure involved in disposal of waste and scrap material
