

Q.P Code:3293

Reg No:

M Pharm Part I Degree Examinations-June 2012

(Pharmaceutical Analysis)

Paper III - Quality Assurance

Time:3hrs

Maximum Marks: 100

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

Essays:

(2x20 =40)

1. Explain the concept of TOM. Describe distribution and batch formula records.
2. Describe various types of validations. Explain various types of protocols used in Validation. Explain any validation process for any two equipments used in pharmaceutical manufacturing with procedure.

Short Essays:

(6 x10=60)

3. Explain the SOP for cleaning , filling and sterilization procedures .
4. Describe about selection of vendors. Add a note on good warehouse practice.
5. Discuss evaluations of complaints and recall procedures.
6. Describe in detail quality audit.
7. Explain various packaging tests performed to ensure the quality of packaging materials
8. Explain briefly organization and personnel in pharmaceutical industries.
