

QP Code: 103329

RegNo:.....

First Year M.Pharm Degree supplementary Examinations-July 2013
(2010 Scheme)

(PHARMACEUTICAL ANALYSIS)

Paper III - Quality Assurance

Time: 3 hrs

Maximum Marks: 100

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

Essays:

(2x20=40)

1. Explain in detail about quality audit and batch release document. Add a note on sterile areas and control of contamination.
2. Explain the concepts and philosophy of TQM. Mention about the master formula records. Add a note on manufacturing documents.

Short Essays:

(6 x10=60)

3. What are the procedures for evaluation of complaints and recall of distributed products.
4. Explain briefly organization and personnel in a pharma company.
5. Good warehousing practice and material management.
6. Explain briefly about export of drugs and import policy.
7. Discuss handling of returned goods, recovered materials and reprocessing.
8. Mention the standard operating procedures for compression and sterilization.
