

QP Code: 106329

Reg No:

First Year M.Pharm Degree Examinations August 2017

(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 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 (total quality management). 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 the responsibilities and importance of training of personnel.
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.
