M.Pharm. Second Semester (Quality Assurance)

35238 : Quality Assurance Techniques : MQA 201

P. Pages : 1 | **AU - 0743**

Time : Three Hours | Max. Marks : 70

* 0 4 9 5 *

Notes : 1. All question carry equal marks.
2. Answer **any five.**
3. Illustrate your answer necessary with the help of neat sketches.
4. Use of pen Blue/Black ink/refill only for writing the answer book.

1. Define validation. Describe validation of solid dosage forms. **14**

2. Explain steps involved in pharmaceutical manufacturing documentation. **14**

3. Explain concept of 'Total Quality management' & write note on ISO 9001 : 2000. **14**

4. Write note on.
   a) Method development protocol for UV. **7**
   b) Validation of water & air handling system. **7**

5. Discuss statistical methods for uniformity and dissolution testing. **14**

6. Discuss documentation requirement for GMP compliance. **14**

7. Write short note on **any two.** **14**
   a) Method development protocol for FTIR.
   b) Retrieval and disposal of documents.
   c) Master formula record. Batch record.

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