

M. Pharm. Second Semester (Quality Assurance) (Old)
35238 : Quality Assurance Technique : MQA-201

P. Pages : 1

Time : Three Hours



AW - 2383

Max. Marks : 70

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- Notes :
1. All question carry equal marks.
 2. Answer **any five** questions.
 3. Use of pen Blue/Black ink/refill only for writing the answer book.

1. Discuss the concepts : Quality Assurance & quality control in detail. **14**
2. Write in detail about quality control documentation, batch release documents, distribution & recall records. **14**
3. Explain the concept of TQM in relation to pharmaceutical industry. Add a note on ISO:14000. **14**
4. Discuss various aspects that should be considered during validation of solid dosage form specifically tablets. **14**
5. Discuss method development protocols with reference to HPLC & FIIR methods. **14**
6. Discuss statistical methods for uniformity & dissolution testing. **14**
7. Write notes on **any two**. **14**
 - i) ISO 9001:2000.
 - ii) Steps involved in retrieval & disposal of documents in pharmaceutical Mfg units.
 - iii) SUPAC & PAT.
