MPY - 103

M.Pharmacy I Semester

Examination, December 2014

DRA, Intellectual Property Rights and Quality Assurance

Time : Three Hours

Maximum Marks: 70

Note : Attempt any *five* questions. All questions carry *equal* marks.

1. Discuss the standard operating procedures for different dosage forms.

2. Discuss the preparation of documents for new drug approval and export registration.

3. Discuss the requirements of GMP as per USFDA guidelines.

4. Write short notes on (any two):
   a) ICH guidelines
   b) Forms and maintenance of records in pharmaceutical industry
   c) Intellectual property rights
   d) Source and control of quality variation of raw materials, containers and closures

5. Write a detail note on sewage disposal and pollution control.

6. Write a detailed note on In process quality control tests and IPQC problems in pharmaceutical industries.

7. Write short notes on (any two):
   a) Analytical process validation and its application
   b) Sampling and characteristic curves
   c) Master formula generation and maintenance

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