M.Pharm. Semester - I (Common For All Branches)

35205 : MC-104 : Drug Regulatory Affairs - IV

P. Pages : 1 | AR - 1756

Time : Three Hours | Max. Marks : 70

* 0 6 4 5 *

Notes : 1. All question carry equal marks.
2. Answer **any five** question.
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. Give the detail account of New Drug Application. **14**

2. Discuss Australian TGA guidelines in details. **14**

3. Discuss the pollution and Environmental Control Act. **14**

4. Discuss the salient features of D & C Act, 1940. **14**

5. Comment on followings – **14**

a) Preparation of patent proposal.

b) Registration of patent in India.

6. Discuss the ICH Guidelines for TDM & Bioequivalence. **14**

7. Write short notes on **any two**. **14**

i) Drug Master file

ii) Prevention of food Adulteration Act, 1954.

iii) Master formula Record.

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