

Section B

3. What is Patent Infringement ? Discuss criteria for patent infringement with the help of a case study. **12**
4. Write notes on the following : **6,6**
- (a) Intellectual Cooperation
- (b) The Patent Rules, 2005

Section C

5. Elaborate the terms and conditions for drugs under schedule Y of Drugs and Cosmetics Act. **12**
6. Write note on the following : **6,6**
- (a) Different Phases of clinical trials
- (b) Data Monitoring Committee

Section D

7. Elaborate various regulatory requirements under GLP of drugs and pharmaceuticals. **12**
8. Write notes on the following : **6,6**
- (a) Accelerated stability testing of new drug substances
- (b) Shelf life and expiry date of products.

Roll No.

Total Pages : 02

LMDQ/M-24

7530

PHARMACEUTICAL CHEMISTRY

SPECIAL-V

CHEM-403

(OBES/LOCF)

Time : Three Hours]

[Maximum Marks : 60

Note : Attempt *Five* questions in all, selecting at least *one* questions from each Section. All questions carry equal marks.

Section A

1. Explain the following with examples : **6,6**
- (a) TRIPS
- (b) WTO
2. How do Intellectual Property Rights play a role in protecting novel inventions ? With the help of a case study, discuss its role in protecting living species. **12**