

ONE YEAR LL M DEGREE FIRST SEMESTER EXAMINATION, JULY 2021

LAW RELATING TO DRUGS AND CLINICAL TRIALS

Duration: 10.00am - 1.45 pm

Maximum Marks: 50

Question carry Ten marks

Module 1 Time 10 a.m-10.45 a.m (35 minutes for writing and 10 minutes for uploading)

1.a Give a brief overview of Indian pharmaceutical industry.

OR

b. Explain MCI regulations on drug prescription in India

Module 2 Time 10.45 a.m-11.30 a.m (35 minutes for writing and 10 minutes for uploading)

2.a Give a brief account of Good Manufacturing Practices relating to drugs

OR

b. Write notes on (i) Indian Pharmacopoeia Commission (ii) Central Drugs Standard Control Organization

Module 3 (Time 11.30 a.m-12.15 p.m (35 minutes for writing and 10 minutes for uploading)

3.a Examine the object and significance of the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

OR

b. Explain 'compulsory licensing' and its impact on pharmaceutical industry in India.

Module 4((Time 12.15 p.m-1.00 p.m (35 minutes for writing and 10 minutes for uploading)

4.a.Explain “essential drugs” and regulation on pricing of essential drugs

OR

b. Explain the scope and challenges for implementing ‘digital health’ in India

Module 5(Time 1.00 p.m-1.45 p.m (35 minutes for writing and 10 minutes for uploading)

5.a Explain Schedule Y requirements and guidelines for permission to import or manufacture of new drugs for sale under Drugs and Cosmetic Rules

OR

b. Give an overview of the New Drugs and Clinical Trials Rules, 2019