

Q.P. Code : 502301

(2 Hours)

[Total Marks : 40

- N.B. :** (1) Question No. 1 is compulsory.
(2) Attempt any three questions from the remaining questions.
(3) Figures to the right indicate full marks.

1. (a) Define the following terms (**any five**):

- (i) 'New drug' as per D & C act.
- (ii) 'Bonded manufactory' under MTP (ED) act
- (iii) 'Food' under PFA act
- (iv) 'Coca leaf' under NDPS act
- (v) 'Invention' under Patent act
- (vi) 'Scheduled formulation' under DPCO 1995.

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(b) Answer **any two** of the following:

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- (i) What do the following schedules to D & C rules state.
 - (a) Schedule Y
 - (b) Schedule K
 - (c) Schedule N
 - (d) Schedule H
 - (e) Schedule O
- (ii) Give different types of intellectual property rights. Give criteria for patentability in India.
- (iii) Who was the chairperson of drug enquiry committee (DEC)? Give the recommendation of DEC.

2. Answer **any four** of the following:

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- (a) Write note on welfare measures for women and children under Factories Act.
- (b) Give the powers and duties of public analyst.
- (c) Discuss the pricing of bulk drugs as per DPCO.

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- (d) Give general requirements for labelling of medicines as per D & C act.
- (e) Give offences and penalties under D & C act.

3. Answer **any four** of the following:

- (a) Give functions of central drugs laboratory
- (b) What are the qualifications for entry in the first and subsequent registers of pharmacist.
- (c) Write short note on loan license.
- (d) What is DTAB ? Give its constitution.
- (e) What are prohibited advertisements under DMR(OA) Act.

4. Answer **any four** of the following:

- (a) Give the requirements for warehouse and production area as per schedule M.
- (b) Enlist offences and penalties under NDPS Act.
- (c) What are cognizable and non-cognizable offences?
- (d) Give the legislative intent of insecticide act and Bombay Shops and Establishment Act.
- (e) Describe requirements to be followed for wholesale and retail sale of schedule C & C₁ drugs.

5. Write short note on (**any two**):

- (a) Pharmacy council of India
- (b) Manufacture of alcoholic preparation as per MTP (ED) act.
- (c) Import of drugs under D & C act.
