B. Pharm/Sem – VII CBS gs/

sub :– Pharmaceutical Jurisprudence.

QP Code : 21809

(3 Hours) [Total Marks :70

N.B. : (1) **All** questions are **compulsory.**
(2) Answers all sub qustions together.
(3) Figures to the Right Indicate full marks.

1. (a) Define the following. (Any five) 5
   (i) **Displaced person** under Pharmay Act.
   (ii) **Manufacture** under D and C Act.
   (iii) **Advertisment** under DMR (OA) Act.
   (iv) **Opium derivatives** under NDPS Act.
   (v) **Dealer** under DPCO 2013.
   (vi) **Adulterent** under Food Safety and Standard Act 2006.
   (b) What is the objective behind MTP (ED) Act and Define Dutiable goods, Denatured spirit and Spirit store under MTP (ED) Act. 5
   (c) Differentiate between Bailable and non-bailable offences And cognizable and non-cognizable offences. 5

2. (a) Explain the process to calculate the ceiling price of a scheduled formulation under DPCO 2013. 4
   (b) What process to be followed by an inventor to register a patent in India. 4
   (C) Explain the procedure for issuing licence for manufacturing medicinal and toilet preparations under MTP (ED) Act. 3

   OR

   (c) Give the composition of Drug Technical Advisory Board. 3

3. (a) Describe the process and control of cultivation of opium. 4
   (b) Elaborate on different types of licenses that can be granted for manufacturing of drugs and write a note on loan license for manufacturing of drug. 4
   (c) Comment on need of ICH guidelines and describe the steps of Initiation of ICH guidelines. 3

   OR

   (c) Define **Relay and Shift**. Enlist offences under factories Act. 3

4. (a) Write a note on manufacture and sale of Ayurevedic and Unani drugs as per D and C Act. 4
   (b) Write a note on Joint state Pharmary council. 4

TURN OVER

OR

(b) State legislative Intention of D and C Act and give contents of following schedules. 4

(i) Schedule M (ii) Schedule X
(iii) Schedule D (iv) Schedule FF

(c) State qualifications and powers of food safety officer. 3

5. (a) Describe labelling directions for ophthalmic ointments. 4
(b) What are the savings as per DMR(OA) Act? 4

OR

(b) Describe labelling directions for food as per Food Satety and Standard Act & rules thereunder.
(c) State recommendations of Haathi committee w. r. t. development of Indian Pharma and small sector Industry. 3

6. (a) (I) Define "Spreadover" as per Bombay shops and establishment Act. What are the rules to be followed for working hours in any establishment. 2
(II) Give qualifications for entry into subsequent register before and after ER came in force 2
(b) Enlist powers of drug inspector. Describe procedure to be followed for inspection. 4
(c) A pharmacy is ready to provide Alprazolam Tablets without prescription but would not provide with receipt. what is your opinion ? Justify. 3