

SUBJECT: DRUG REGULATORY AFFAIRS

Day: Sunday
Date: 05/05/2019

S-2019-4465

Time: 02.00 PM TO 05.00 PM
Max. Marks: 80

N.B.:

- 1) Q. No. 1 and Q. No. 5 are **COMPULSORY**. Out of remaining attempt any **TWO** questions each from **SECTION-I** and **SECTION-II**.
- 2) Answers to both the sections should be written in the **SAME** answer books.
- 3) Figures to the right indicates **FULL** marks.

SECTION – I

- Q.1** Attempt **ANY FIVE** of the following (10)
- a) Describe the objectives of Pharmacy Act 1948.
 - b) What is “First register” and “Subsequent registers” under Pharmacy Act 1948?
 - c) Name different types of licenses for retail and wholesale of drugs.
 - d) Define Schedule A, H, K, and R.
 - e) Discuss offences and penalties under Pharmacy Act 1948.
 - f) Define the terms Spurious drugs and Patent & Proprietary Medicines.
- Q.2** a) Discuss in detail qualification, powers and duties of Drug Inspector, add a note on procedure of Inspection. (8)
- b) Discuss in detail constitution and functions of Pharmacy Council of India. (7)
- Q.3** a) What are the educational qualifications for appointment as Government Analyst? Explain duties and procedure to be followed by Government Analyst. (8)
- b) Discuss in detail the constitution and functions of Drugs Technical Advisory Board (DTAB) and Central Drugs Laboratory (CDL). (7)
- Q.4** Write short notes on **ANY THREE** of the following. (15)
- a) Labeling conditions for Ophthalmic preparations
 - b) Labeling requirements of Schedule X drugs
 - c) General conditions required for grant or renewal of license to manufacture of drugs other than those specified in Schedule C, C1 and X
 - d) Schedule Y

SECTION – II

- Q.5** Attempt **ANY FIVE** of the following (10)
- a) Define Psychotropic substances and Narcotic drugs.
 - b) Enlist different mechanisms of Intellectual Property Rights (IPR).
 - c) What are the objectives of Medicinal and Toilet Preparations Act 1955?
 - d) Discuss in brief about Patent Agents.
 - e) Define Advertisement and Magic Remedy.
 - f) What are Non-patentable inventions?
- Q.6** a) Discuss in detail provision of Compulsory license and Exclusive marketing rights under Indian Patent Act 1970. (8)
- b) Discuss the powers of Central Government to permit, control and regulate certain operations relating to Narcotic Drugs and Psychotropic Substances Act 1985. (7)
- Q.7** a) Describe the provisions for classes of Prohibited advertisements and Exempted advertisements. (8)
- b) Discuss salient features of Indian Patent Act 1970 with latest amendments. (7)
- Q.8** Write short notes on **ANY THREE** of the following. (15)
- a) Code of ethics of Pharmacists in relation to his profession
 - b) European Medicines Evaluation Agency (EMA)
 - c) Manufacturing outside bond (Non-bonded manufactory)
 - d) US Food and Drug Administration (USFDA)
