

(3 Hours)

(Total Marks : 80)

Please check whether you have got the right question paper.

N.B.: (1) All questions are compulsory.

(2) Figures to the right indicate full marks.

1. a) Define the following (Any five) 5
- (i) Adulterated Drug under Drugs & Cosmetics Act 1940.
 - (ii) Ceiling price under DPCO 2013.
 - (iii) Registered pharmacist under Pharmacy Act 1948.
 - (iv) Food under Food Safety & Standards Act 2006.
 - (v) Opium under the Narcotic Drugs & Psychotropic Substances Act & Rules 1985.
 - (vi) Advertisement under Drug & Magic Remedies (Objectionable Advertisements) Act 1954.
- b) I) i) Differentiate between cognizable and non-cognizable offences. 2
- ii) Explain the terms nonbonded manufactory, denatured spirit and spirit store under Medicinal & Toilet preparations act & rules. 3
- II) What are the measures taken by the Central Government to prevent illicit traffic of narcotic drugs under Narcotic Drugs & Psychotropic Substances Act & Rules 1985? 5
- c) Give the constitution, terms of office and functions of the DTAB. 5
2. a) Outline the newer initiatives of the Pharmaceutical Policy 2017. 4
- b) What are the general principles applicable to working of patented inventions? 4
- c) Give the salient features of manufacture in bond under the Medicinal & Toilet preparations act & rules. 4
3. a) List any two narcotic drugs. Enlist offences and penalties w.r.t narcotic drugs as per Narcotic Drugs & Psychotropic Substances Act & Rules 1985. 4
- b) Enlist different types of drugs prohibited to be imported into India. Elaborate on the import of drugs by government hospitals or autonomous medical institutions for the treatment of patients. 4
- c) What are the objectives of ICH? Describe in brief the ICH process for harmonisation of guidelines. 4
- OR**
- c) Define Factory. Enlist offences under Factories Act. 4

4. a) Describe in brief the different types of licences granted for the sale of drugs (other than homeopathic medicines). 4
b) Give composition and functions of PCI. 4
- OR**
- b) Write note on Schedule Y as per the Drugs and Cosmetics rules 1945. 4
c) Give composition and functions of central advisory committee established under FSSAI. 4
5. a) Write the special labelling instructions as per Drugs and Cosmetics Act, 1940 and Rules for the following : 4
i) Ciprofloxacin Eye Drops I. P.
ii) Metformin hydrochloride Tablets I.P. 500mg
b) Discuss the prohibited advertisements under Drugs and Magic Remedies (Objectionable Advertisements) Act. 4
- OR**
- b) Describe the labelling and packaging provisions of food articles as given in Food Safety and Standards Act. 4
c) i) Discuss the preparation of First Register of pharmacists as per Pharmacy Act. 2
ii) Briefly discuss the offences and penalties under Pharmacy Act. 2
6. a) i) What is the objective of Bombay Shops and Establishments Act? Define 'Spread over' and 'Child' as per Bombay Shops and Establishments Act. 2
ii) Discuss some salient features of Mashelkar Committee Report. 2
b) What is the procedure to be followed by the Drug Inspector while taking a sample from a licensee? Discuss the powers of the Drug Inspector under Drugs and Cosmetics Act & Rules. 4
c) i) An advertisement for a herbal product was shown on TV channels. Using celebrity models, the advertisement claimed a cure for arthritis by application of the product on the joints. 4
ii) An advertisement for treatment of malaria fever was published by Government of India on postcards. Analyse the above cases and give your comments.