

[Time: Three Hours]

[Marks:70]

Please check whether you have got the right question paper.

- N.B:
1. All questions are compulsory.
 2. Answer all sub questions together.
 3. Figures to right indicate full marks.

Q.1

A. Define the following (Any Five) 5M

- i. Registered Pharmacist as per Pharmacy act
- ii. Misbranded cosmetics as per D & C Act
- iii. Advertisement as per DMR (OA) Act
- iv. Opium as per NDPS Act
- v. Ceiling price of medicine as per DPCO 2013
- vi. Adulterant as per FSSA

B. Define Denatured spirit, restricted preparation and medicinal preparation. Differentiate between manufacture in bond and manufacture outside bond as per MTP (ED) Act 1955. 5M

C. Answer the following

- i. Define Bail, differentiate between Cognizable and Non-cognizable offences. 3M
- ii. Discuss measures taken for preventing and combating abuse of narcotic drugs and illicit traffic. 2M

Q.2

A. Explain key principles of National Pharmaceutical Pricing policy 2012 4M

B. Define Patent and explain the criteria for Patentable Inventions. 4M

C. Explain the functions of CDL as per D & C Act 3M

OR

C. Write the process of appointment, qualification and duties of Government analyst as per D & C Act 3M

Q.3

A. Elaborate on powers of central government for the control and regulation of operations relating to narcotic drugs and psychotropic substances. 4M

B. Enlist the different types of manufacturing licenses and State the conditions for license for manufacturing of drugs other than those included in Sch C, C1 and X. 4M

C. What are the objectives of ICH? Write a note on ICH Process for Harmonization of major topics 3M

OR

Comment on provisions for welfare of women and children under Factories Act. 3M

Q.4

A. What are the different types of licenses and forms for sale of drugs as per D and C Act. Write a note on restricted licenses. 4M

B. Give composition and function of PCI 4M

OR

B. State the provisions for Import and manufacture of Cosmetics as per D and C Act. 4M

C. State the functions of Commissioner of Food Safety. 3M

Q.5

A. Describe complete labeling directions of ophthalmic preparations. 4M

B. Elaborate on Savings under DMR(OA) Act. 4M

OR

B. Describe labelling directions for Milk and milk products and canned products as per FSSAI and rules thereunder 4M

C. Under whose chairmanship was drugs enquiry committee established? Give terms of reference of DEC. 3M

Q.6

A.

(I) Define 'Shop' as per Bombay Shops and Establishments act. What is the objective of Bombay Shops and Establishments act? 2M

(II) Describe procedure for preparation of First Register under Pharmacy Act. 2M

B. Explain powers and duties of drug inspector under D and C act. 4M

C. Nirmal Baba claiming as "Representative of God" is treating cases of cancer. Comment on it. 3M