

[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. Repatriate as per Pharmacy act
- ii. Spurious drugs as per D & C Act
- iii. Advertisement as per DMR (OA) Act
- iv. Manufactured drugs as per NDPS Act
- v. Maximum retail price as per DPCO 2013
- vi. Food additives as per FSSA

B. Write legislative intent behind MTP(ED) Act 1955. Define Dutiable goods, Restricted preparation and Denatured spirit 5M

C. Answer the following

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

**Q.2**

A. Describe the objectives and features of NPPP 2012. 4M

B. Explain the terms Patent and Copyright with one example of each. 4M

C. Enlist the various administrative bodies under D & C Act and write the functions of DTAB and DCC. 3M

**OR**

C. Write a short note on manufacture outside bond. 3M

**Q.3**

A. How is the cultivation of Opium controlled and regulated as per NDPS Act? 4M

B. Enlist the different types of import licenses and Elaborate on import of drugs for examination, test or analysis. 4M

C. Describe in brief the role and responsibility of European Medicine Agency in regulating the quality of medicines 3M

**OR**

Define Factory. Describe the process for licensing of Factories.

**Q.4**

- A. Write a note on General Conditions of license for sale as per D and C Act. 4M
- B. Describe in brief the Education Regulations laid down by PCI as per Pharmacy Act. 4M
- OR**
- B. Write a note on Schedule Y as per D and C Act. 4M
- C. State the powers of food safety officer. 3M

**Q.5**

- A. Elaborate on special labelling directions for 4M
- (i) Medicines for internal use and
- (ii) Patent and proprietary medicines containing vitamins.
- B. Elaborate on exempted advertisements as per DMR(OA) Act. 4M
- OR**
- B. Describe labelling directions for pre-packaged food as per FSSAI and rules thereunder 4M
- C. State recommendations of Chopra committee. 3M

**Q.6**

- A.
- (I) Describe procedure for registration of establishment as per Bombay Shops and Establishments act. 2M
- (II) Enlist offences under Pharmacy Act. 2M
- B. Explain procedure for inspection by drug inspector under D and C act. 4M
- C. Ms. Amruta was carrying 500 doses of antidepressant tablets and was caught at Mumbai Airport. Comment on the situation. 3M
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