

[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. Displaced Person as per Pharmacy act
- ii. Misbranded drugs as per D & C Act
- iii. Magic remedies as per DMR (OA) Act.
- iv. Cannabis as per NDPS Act
- v. Generic version of medicine as per DPCO 2013
- vi. Food as per FSSA

B. What are the objectives of MTP(ED) Act? Define Alcohol, Spirit store and substandard preparation.

5M

C. Answer the followings

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

3M

2M

Q.2

A. Explain the process of calculation of MRP for scheduled formulation as per DPCO 2013.

4M

B. Define Invention and write any six inventions which are not patentable as per the provision of Indian patent act.

4M

C. Give the composition of DTAB as per D & C Act

3M

OR

Write a short note on Manufacture in bond

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. Describe the process of application for import of drugs as per D and C Act.

4M

C. Describe in brief the role and responsibility of US FDA in regulating the quality of medicines.

3M

OR

Comment on various provisions for safety of workers under Factories Act.

3M

Q.4

A.State the provisions for Ayurvedic, Sidha and Unani drugs as per D and C Act. 4M

B. How are the institutions providing courses of study and examination approved under Pharmacy Act? 4M

OR

Give the contents of following schedules 4M

1. Schedule V
2. Schedule H
3. Schedule FF
4. Schedule Y

C. State the duties and functions of Food safety and standards authority of India 3M

Q.5

A. Discuss on manufacture and sale of Homeopathic medicines as per D and C Act. 4M

B. Elaborate on Advertisements prohibited as per DMR (OA) Act. List offences under DMR(OA) Act. 4M

OR

B. Describe labelling directions for Food as per FSSAI and rules thereunder 4M

C. State recommendations of Haathi committee. 3M

Q6.

A. (I) Define Spreadover as per Bombay Shops and Establishments act. Elaborate on rules and regulations regarding spreadover as per Bombay Shops and Establishments act. 2M

(II) Enlist any four special provisions for registration of certain persons as per Pharmacy Act 2M

B. Explain role of Licensing authority, controlling authority and customs collectors in efficient running of D and C act. 4M

C. Ms. Amita has filed provisional specifications for patent on 10th January 2018. Her study needs 2 more months to complete from now. Comment on her filing grant of patent. 3M