

[Time: 3 Hours]

[Marks:70]

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**.

Q.1 A Define any five:

- i. 'Repatriate' as per Pharmacy act
- ii. 'New drug' as per D & C act.
- iii. 'Advertisement' as per DMR (OA) act.
- iv. 'Manufactured drugs' as per NDPS act
- v. 'Formulation' as per DPCO
- vi. 'Contaminant' as per food safety and standards act.

5

B Define 'Medicinal preparations', 'Alcohol' and 'Restricted preparation' as per MTP(ED) act. Distinguish between 5 manufacture in bond and manufacture outside bond

- C**
- i. What do you mean by bail? What do you understand by bailable offences?
 - ii. Elaborate on Narcotic Drugs and Psychotropic Substances consultative committee.

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Q.2 A Explain the process and calculation of fixation of ceiling price of scheduled formulations

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B Define 'Patent' as per Indian Patent act. Elaborate on process of grant of patent in India.

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C Enlist duties of government analyst.

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OR

C Write note on export under bond.

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Q.3 A Enlist the various offences and penalties under NDPS act.

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B Write a note on labelling and packaging of cosmetics.

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C Describe role of ISO

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OR

C Comment on special provision under the 'factories act'.

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Q.4 A Write a note on manner of labeling and packaging of ayurvedic drugs.

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B Write a note on 'forms and manners of manufacture of drugs for sale or distribution'.

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OR

B Write a note on PCI: compositions and functions.

4

C Write the duties and functions of food authority under FSSA 2006.

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Q.5 A Give the additional labelling for following as per D & C Act.

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- 1) Schedule O
- 2) Schedule FF
- 3) Schedule X
- 4) Schedule G

B Elaborate on savings on advertisements as per DMR (OA) act.

OR

B Give the general labelling of tin packed food articles as per FSSAI.

C Who was the chairman of DEC? Describe recommendations given by DEC.

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Q.6 A i. Define spread over. How is the registration of establishment done as per Bombay shop establishment act?

ii. State the offences and penalties under Pharmacy act.

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B Elaborate on qualifications and functions of drug inspector

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C Mr XYZ was caught at Mumbai airport along with 500 doses of medicines to cure depression. Comment on above situation.

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