

**Birla Institute of Technology and Science, Pilani**

**PHA F343: Forensic Pharmacy**

**Comprehensive Examination**

**Second Semester 2022-23**

**Date: 17/05/2023**

**Duration: 3hrs**

**Max. Marks: 40 M**

**Closed book**

**Note:** Write the answer in the questions sequence.

**Q1. Write specific answers: [8M]**

- a) Write name and year of commencement of scheme in India promoting the generic medicine by Govt of India? This scheme launched by which department and ministry. [1.5]
- b) Name the enforcing and approval agency in India who is responsible for clinical trial of innovator product and approval of generic medicine. [1]
- c) Define 'Scheduled drugs' and 'Scheduled formulations' as per Drug Price Control Order. [1]
- d) Name of Act, regulating authority, and ministry which regulate the registration of pharmacist in India. [1.5]
- e) Write the objective of Drugs and Cosmetics Act 1940 and Rules 1945. [1]
- f) How many medicines are listed in National List of Essential Medicines 2015 and 2022? [1]
- g) Name of department .....ensure availability of safer and effective pesticides through regulatory measures under the.....Act .....Year. [1]

**Q2. Write short answers: [8M]**

- a) When does an Advertisement become "Misleading"? Give two suitable examples. [2M]
- b) What is the reason of addiction of narcotic drugs? [2]
- c) In what conditions, a pharmaceutical company can go for 505(b)(2) application in USFDA. [2]
- d) Write the name of governing body, department and its ministry which are directly responsible for manufacture, sale and export/import of opium and its alkaloids, as well as all commercial transactions in India and abroad. Write the Name of nodal agency on the matter of narcotics drug law enforcement in India. [2]

**Q3. (A)** Discuss with suitable example about the classes of drugs and disease advertisement which are not prohibited as per Drugs and Magic Remedies (Objectionable Advertisements) Act 1954.

Why such advertisements are not prohibited? [2]

**(B)** If you see any advertisement in newspaper which claim 80% cure of diabetes using herbal powder to be taken for 30 days twice a day. Give your opinion and action plan on the above case as per the Drugs and Magic Remedies (Objectionable Advertisements) Act with proper justifications. [3]

**(C)** Write Salient features of Medical Termination of Pregnancy (Amendment) Bill, 2021. [3]

**Q4. (A)** Write the objective of insecticide act 1968. Write the benefits or importance of this act for farmers and citizens of India. What are the improvement proposed in Pesticide management bill 2020 to increase the effectiveness of the insecticide act? [5]

**(B)** Write the Objective of DPCO and Main Features of the DPCO 2013. [3]

**Q5.** Discuss the objective and contribution of 'The Drug Price Competition and Patent Term Restoration Act'. In what aspects the 505(j) application is different with New Drug Application (NDA)? Write about the drug approval process under the para IV ANDA. Write various 'market exclusivity' of a new drug to extend its market benefits. [8]