

THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

MODEL QUESTION PAPER

B.PHARM. DEGREE EXAMINATION

PCI Regulation – SEMESTER V

PAPER V – PHARMACEUTICAL JURISPRUDENCE (UNIT I: DRUGS AND COSMETICS ACT, 1940 AND ITS RULES 1945)

Q.P. Code: 562058

Time: Three hours

Maximum: 75 Marks

I. Elaborate on: Answer any TWO questions. (2 x 10 = 20)

1. Explain in detail about the conditions of license for manufacture of drugs under Drugs and Cosmetics Act, 1940 and its rules 1945.
2. Discuss about the conditions of license for manufacture of drugs for test, examination and analysis.
3. Give an account of Import of drugs under Drugs and Cosmetics Act, including classes of drugs and cosmetics prohibited from import.
4. Write in detail about manufacture of drugs specified in Schedule C, C1 and X.

II. Write notes on: Answer any SEVEN questions. (7 x 5 = 35)

1. Discuss the rule relating to import of drugs as per Drugs and Cosmetics Act.

2. Conditions for grant of license for wholesale of Schedule C and C1 drugs.
3. Loan license and repacking license.
4. Classes of drugs prohibited to sale.
5. Repacking licenses and their conditions.
6. What are the conditions for the issue of import license?
7. Describe the Classes of drugs and cosmetics prohibited from import.
8. Write a note on Supply of Schedule H and X Drugs.
9. Elaborate on i) Manufacture of New Drugs ii) Loan Licenses.

III. Short answers on: Answer ALL questions.

(10 x 2 = 20)

1. Adulterated drugs.

2. Schedule H.
3. Spurious drug.
4. Define Misbranded Drugs.
5. What is Schedule P?
6. Master Formula Records.
7. Define the term misbranded and adulterated drug.
8. Explain the term new drug.
9. Define Spurious Drugs.
10. Schedule C and C1.
11. Labeling condition for ophthalmic preparations.
12. Misbranded cosmetics.
13. Schedule 'X' Drugs.
14. Define Manufacture of drugs.
15. What is central register?
16. Subsequent registers.
17. Labeling condition for Schedule G.
18. Define Rectified spirit.
19. Define Repacking License.
20. What is third party license?