Total No. of Questions: 6

Total No. of Printed Pages:2



### Enrollment No.....

# Faculty of Pharmacy End Sem Examination Dec-2023

#### PY3CO22 Pharmaceutical Jurisprudence

Programme: B. Pharm. Branch/Specialisation: Pharmacy

Duration: 3 Hrs. Maximum Marks: 75

Note: All questions are compulsory. Internal choices, if any, are indicated. Assume suitable data if necessary. Notations and symbols have their usual meaning.

|                |       | ·   |    |
|----------------|-------|---|----|
| Q.1            | i.    | Name the law which classify a drug under "Essential Commodity" which was vital to the health, formed in 1955? | 2  |
|                | ii.   | Define the term drugs and substances.   | 2  |
|                | iii.  | Define the term misbranded drugs.   | 2  |
|                | iv.   | Define the term patent or proprietary medicines.  | 2  |
| v.<br>vi<br>vi | v.    | Write the key role of registered pharmacist.  | 2  |
|                | vi.   | How many consecutive members form PCI?  | 2  |
|                | vii.  | Write the full form of CPCSEA and its role.   | 2  |
|                | viii. | Write the two names of essential medicines as NLEM.   | 2  |
|                | ix.   | In which year Bengal chemical and pharmaceutical works established?   | 2  |
|                | х.    | In 1927, under whose chairmanship Chopra committee formed.  | 2  |
| Q.2            |       | Attempt any two:  |    |
|                | i.    | Explain Schedule M (Good Manufacturing Practices) in detail.  | 10 |
|                | ii.   | Explain drug and cosmetics act 1940 in detail.  | 10 |
|                | iii.  | (a) Explain general labelling requirements with suitable example of Schedule G drugs.                         | 5  |
|                |       | (b) Write a note on administration of the act and rule, how different agencies form and explain their role.   | 5  |
| Q.3            |       | Attempt any seven: Two questions from each section is compulsory.  Section - A                                |    |
|                | i.    | Explain the various work done by PCI in pharmacy.   | 5  |
|                | ii.   | Why Pharmacy Act 1948 is essential? Highlight relevant point with valid reasons.                              | 5  |

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| 111.  | write a note on penalties for falsely claiming to be registered    | 5 |
|-------|--|---|
|       | pharmacist.  |   |
|       | Section - B  |   |
| iv.   | Write the salient features of Drug and Magic remedy act.           | 5 |
| v.    | Write the right procedure for performance of experiments on animal | 5 |
|       | as per CPCSEA.   |   |
| vi.   | Explain offences and penalties as per CPCSEA guidelines.           | 5 |
|       | Section - C  |   |
| vii.  | Explain future trends in Drug Legislation.                         | 5 |
| viii. | Write a note on medical termination of Pregnancy act.              | 5 |
| ix.   | What is Patent Act 1970? Explain the impact of IPR in pharma       | 5 |
|       | industry.  |   |
|       |  |   |

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## **Marking Scheme**

## PY3CO22 Pharmacuetical Jurisprudence

| Q.1 | i)      | Essential Commodities Act 1955-                        | 2 Marks        | 2  |
|-----|---------|--|----------------|----|
|     | ii)     | Definition of drug- 1 mark, definition of substances   | s- 1Marks      | 2  |
|     | iii)    | Definition of misbranded drug-                         | 2 Marks        | 2  |
|     | iv)     | Definition of patent or proprietary drugs-             | 2 Marks        | 2  |
|     | v)      | At least 2 roles-                                      | 2 Marks        | 2  |
|     | vi)     | 3 Members -  | 1 Mark         | 2  |
|     |         | Name-  | 1 Mark         |    |
|     | vii)    | Full form of CPCSEA-                                   | 1Mark          | 2  |
|     |         | 1 role-  | 1 Mark         |    |
|     | viii)   | 2 names of essential medicines as per NLEM-            | 2 Marks        | 2  |
|     | ix)     | 1901, Acharya P.C. Ray-                                | 2 Marks        | 2  |
|     | x)      | Col. R.N. Chopra-                                      | 2 Marks        | 2  |
| Q.2 |         | Attempt any two:                                       |                |    |
|     | i.      | Schedule- M –  | 6 Marks,       | 10 |
|     |         | Specifications-  | 4 Marks        |    |
|     | ii.     | Defination-  | 2 Marks        | 10 |
|     |         | Act, rules and schedules-                              | 4 Marks        |    |
|     |         | Scope and explanation of rules-                        | 4 Marks        |    |
|     | iii. A) |  | 3 Marks,       | 5  |
|     | ,       | Label with specifications-                             | 2 Marks        |    |
|     | B)      | Name of agencies (advisory, analytical and executive   | ve) - 3 Marks, | 5  |
|     |         | role and applications-                                 | 2 Marks        |    |
| Q.3 |         | Attempt any seven: Two questions from each compulsory. | section is     |    |
|     |         | Section - A  |                |    |
|     | i.      | PCI- 1 marks, constitution-                            | 1 Marks        | 5  |
|     |         | work done-   | 3 Marks        |    |
|     | ii.     | Pharmacy act-  | 2 Marks        | 5  |
|     |         | 3 reasons with examples-                               | 3 Marks        |    |
|     | iii.    |  | 3 Marks        | 5  |
|     |         | terms-   | 2 Marks        |    |
|     |         | Section - B  |                |    |

| iv.   | 5 features with explanation-             | 5 Marks    | 5 |
|-------|--|------------|---|
| v.    | animal handling-                         | 2.5 Marks, | 5 |
|       | storage and precautions-                 | 2.5 Marks  |   |
| vi.   | Offences –                               | 2.5 Marks, | 5 |
|       | Penalties-                               | 2.5 Marks  |   |
|       | Section - C                              |            |   |
| vii.  | Drug legislation-                        | 2 Marks,   | 5 |
|       | Importance-                              | 1 Marks,   |   |
|       | future trends-                           | 2 Marks    |   |
| viii. | Termination of Pregnancy act-            | 3 Marks,   | 5 |
|       | Qualification of RMP and penalties-      | 2 Marks    |   |
| ix.   | Definitions-                             | 1 Marks    | 5 |
|       | Patent act, 1970-                        | 2 Marks    |   |
|       | highlights of impact on pharma industry- | 2 Marks    |   |

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