

**Time: Three Hours**

**Max. Marks: 75 Marks**

**Regulations Legislations for Food PMBC in India**

**Q.P. CODE: 5122**

Your answers should be specific to the questions asked.

Draw neat, labeled diagrams wherever necessary.

**LONG ESSAY (Answer any Three)**

**3 X 10 = 30 Marks**

1. Write in detail about import, manufacture, sale and packing of drugs as per D&C Act 1940.
2. Write in detail on rationale for conducting animal studies.
3. Describe ICMR-DBT guidelines for stem cell research.
4. What are Intellectual Property Rights? Write in detail about industrial designs and geographical indications.

**SHORT ESSAY (Answer any Nine)**

**9 X 5 = 45 Marks**

5. BCS classification of drugs.
6. Ethical guidelines for human participants in clinical studies
7. Write a note on ICH stability requirements.
8. Write a note on fixed dose combinations.
9. FNPCMB approval procedures.
10. Indian Pharmacopoeial Standards.
11. Write a note on Indian patent scenario.
12. Guidelines for regulatory filing of FPMB.
13. Bioavailability and Bioequivalence data requirements
14. Write a note on patent and trademark.

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