



JBW-104-T

Seat No. _____

Master of Pharmacy (Sem. I) Examination

January - 2020

**MRA - 104 T : Regulations & Legislation For Drugs
& Cosmetics, Medical Devices, Biologicals &
Herbals, & Food & Nutraceuticals In India &
Intellectual Property**

Time : 3 Hours]

[Total Marks : 75

1 Answer the following questions : 20

- (1) What is BIS standard ?
- (2) What is GI? Who can apply for GI ?
- (3) What is rationale for conducting animal testing ?
- (4) Define : Trademark and Copyright.
- (5) What is non-patentable invention? Give examples.
- (6) Give difference between provisional and complete patent application.
- (7) What are the functions of pharmacy council of India ?
- (8) What is intellectual property? What is its importance ?
- (9) Write functions of animal welfare board of India.
- (10) What is an ISO standard? Classify it.

2 Answer the following questions : (Any Two) 20

- (1) Write about different types of patent and write in detail about procedure for grant of patent.
- (2) Write BCS classification of drugs. Write an informative note on regulatory requirements for bioequivalence study.
- (3) Discuss prohibited and exempted advertisements with conditions as per Drugs and Magic Remedies Act.

3 Answer the following questions : (Any Seven)

35

- (1) Write organization chart and functions of CDSCO.
 - (2) Write functions of state licensing authority.
 - (3) Which are different types of opposition during patent filling process? Discuss different ground of opposition.
 - (4) Write in detail about following schedules as per Drug and Cosmetic Act.
 - (i) Schedule C
 - (ii) Schedule F
 - (iii) Schedule M
 - (5) Write and explain formulae for calculating retail prices of formulations. Write in brief about prices of essential bulk drugs.
 - (6) Discuss manufacture of ayurvedic, homeopathic & patent and proprietary preparations as per the medicinal and toilet preparations Act.
 - (7) Write constitution of Central Pharmacy Council.
 - (8) Compare the ICH & WHO stability guideline.
 - (9) Which is licensing authority for medical devices in India? Classify medical devices with examples.
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