

**PARUL UNIVERSITY**  
**FACULTY OF PHARMACY**  
**M.Pharm. Winter 2022-23 Examination**

**Semester: 1****Subject Code: MIP104T****Subject Name: INTELLECTUAL PROPERTY RIGHTS****Date: 20/03/2023****Time: 10:00am to 1:00pm****Total Marks: 75****Instructions:**

1. Figures to the right indicate maximum marks.
2. Make suitable assumptions wherever necessary.

**Q.1 Essay Type Questions. (any 2 out of 3) (15 Marks Each) (30)**

1. A) Explain what is Patent, What are the essentials of patentable invention and which inventions are not patentable under Indian Patent Act.  
B) Explain in detail GATT.
2. A) Write down the need and significance of intellectual property right protection for an industrial design.  
B) Explain brief on TGA regulatory guideline.
3. What is CRO? Write the roles of CRO in clinical trials and explain regulatory requirement for CRO.

**Q.2 Short Essay Type Questions. (any 5 out of 6) (5 Marks Each) (25)**

1. What is importance of intellectual property rights? Explain in detail.
2. Explain in detail TRIPS.
3. Explain about new developments in trademark law.
4. Explain in detail about USFDA guidelines
5. Discuss the regulatory requirements for biosimilars.
6. Explain in brief the Patent filing procedure. What are the differences between Product Patents and Process Patents?

**Q.3 Short Answers. (2 Marks Each) (20)**

1. What do you mean by invention? Give an example
2. What are the objectives of IPR?
3. Explain in brief WIPO.
4. Define WIPO copyright treaty and article 10.
5. What are the objectives of copyrights?
6. Enlist major bodies regulating Indian Pharmaceutical sector.
7. What is yellow card scheme?
8. What is orange book and What are the contents of Orange Book?
9. Mention exclusive criteria for conducting bioequivalence study.
10. What is difference between biosimilar and generic drug.