

7th Semester	RBM7D003	Biosafety and Bioethics	L-T-P 3-0-0	3 Credits

Module-I:**(10 hours)**

Concept of property, rights, duties and their correlation; Intellectual property rights and its types- Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications, Protection of new GMOs; Process patent vs product patent; International framework for the protection of IP; IP as a factor in R&D; IPs of relevance to Biotechnology and few Case Studies; Introduction to History of GATT, WTO, WIPO and TRIPS.

Module-II:**(10 hours)**

Basic requirement of a patentable invention- novelty, inventive step, Prior art and State of art; Patent databases; Searching International Databases; Analysis and report formation; Indian Patent Act 1970 and Recent Amendments; Filing of a patent application; Precautions before patenting- disclosure/non-disclosure; WIPO Treaties; Budapest Treaty; PCT and Implications; Role of a Country Patent Office; Procedure for filing a patent, International patenting requirement, Patent infringement- meaning, scope, litigation, remedies; Case studies and examples-Rice, Neem etc

Module-III:**(10 hours)**

Introduction to Biosafety regulations; Primary Containment for Biohazards and Bio safety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines - Government of India. Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture;

Module-IV:**(10 hours)**

Environmental release of GMOs; Overview of National Regulations and relevant International Agreements including Cartagena Protocol. Concept of Bioethics, Public concerns on Human genome research and transgenics- Genetic testing and screening, Ethics in clinical trials and GCP, ELSI & Human genome projects; Ethics in human cloning-a case study.

Books:

- [1] Stanley SA, Bioethics, Wisdom educational services
- [2] Sateesh MK, Bioethics and Biosafety, IK International Pvt. Ltd.