

### ELECTIVE – III

#### IPR, BIOSAFETY AND QUALITY CONTROL

Semester	Subject code	Category	Lecture		Theory		Practical		Credit
			Total hrs	Hrs/week	Total hrs	Hrs / week	Total hrs	Hrs/week	
III		Elective	75	5	75	5	0	0	3

#### COURSE OBJECTIVES

To enable the students to understand the importance of IPR, biosafety and quality control for research purposes

#### COURSE OUTCOMES

On the successful completion of the course, students will be able to understand the basic aspects of IPR, maintain the safety level and follow the guidelines and ethics while doing research.

CO Number	CO Statement	Knowledge Level (K1 – K4)
<b>CO1</b>	To understand the different forms of IPR, patent and how much important in the research field	<b>K2</b>
<b>CO2</b>	To analyse the biosafety levels according to the risk of research work and the guidelines to follow while released into the environment	<b>K4</b>
<b>CO3</b>	To remember the different safety committees which safe guide the researcher to work with rDNA	<b>K1</b>

<b>CO4</b>	To understand the ethical guidelines for conducting research using human and animals	<b>K2</b>
<b>CO5</b>	To remember the WHO Standards for food safety and its quality control	<b>K1</b>

#### **MAPPING WITH PROGRAMME OUTCOMES:**

<b>COS</b>	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>
<b>CO1</b>	M	M	M	M	M	M
<b>CO2</b>	M	M	M	M	M	M
<b>CO3</b>	M	M	M	M	M	M
<b>CO4</b>	M	M	M	M	M	M
<b>CO5</b>	M	M	M	M	M	M

**S- Strong;**

**M- Medium;**

**L- Low**

#### **Unit -I IPR and Patents**

**9 hrs**

IPR – definition – Different forms of IPR. WTO – Definition and WTO Agreements – GATT – Definition – Objectives. Economic impact of WTO– Benefits of WTO in relation to biotechnology. Patents – introduction – History of Indian patent system – Non patentable invention – Patent Application procedure in India. Infringement of patents – Patent Co-operation treaty – TRIP's - Other forms of IPR: copy right – Trade mark – designs.

#### **Unit- II Biosafety guidelines**

**9 hrs**

Bio safety – definitions – Bio safety levels – framework of Bio safety regulation in India; Biological safety Cabinets and their types. Primary containment for Biohazards. Environmental release of GMOs – Environmental risks – Cartagena protocol. Bio safety regulation for transgenic plants and animals. Regulations of Genetically modified organisms in India.

**Unit- III Bio safety****9 hrs**

Structure and functions of committees – Recombinant DNA Advisory Committee, Review committee on Genetic Manipulation, Institutional Bio safety Committee, Genetic Engineering Approval Committee, State Biotechnology Coordination committee, District Level Committee and Monitoring & Evaluation Committee – DBT guidance on Bio safety in conducting research in Biology/Biotechnology .

**Unit- IV Bioethics****9 hrs**

Bioethics – definition – Bioethics of IPR – Ethical criteria's in Biotechnology – Animal Ethics; Guidelines for use of lab animals in medical colleges – licensing of animal house – Human cloning – ethical issues – Ethical clearance norms for conducting studies on human subjects. Prevalence of ethical issues – Invitro fertilization and stem cell technology

**Unit- V: Quality control****9 hrs**

Quality control in food process technology – WHO standards – Quality control in dairy product technology – Quality control for potable water

**DISTRIBUTION OF MARKS:** Theory - 100% and Problems – Nil

**TEACHING METHODOLOGY:**

- ❖ **Lectures**
- ❖ **Power point presentation**
- ❖ **Charts**
- ❖ **Models**
- ❖ **Group discussion**
- ❖ **Group assignments**
- ❖ **Seminars**

**REFERENCE BOOKS:**

<b>S.No</b>	<b>Authors</b>	<b>Title</b>	<b>Publishers</b>	<b>Year Of Publication</b>
1.	Beauchamp & Leroy	Contemporary issues in Bioethics	Wordsworth Pub.Co. Belmont	1999
2.	Paul, RC	Situations in human rights in India	Efficient offset Printers.	2000
3.	Traylor, Tredsich & Koch	Bio safety	Michigan Sate university Pub U.S.A.	2002

**WEB REFERENCES:**

[www.ipr\\_helpdesk.org/](http://www.ipr_helpdesk.org/)

[www.patentoficce .nic.in/ipr/patentapatents. Html](http://www.patentoficce.nic.in/ipr/patentapatents.html)

[www.bangalorebio.com/Govtinfo/ipr.html](http://www.bangalorebio.com/Govtinfo/ipr.html)

**SYLLABUS DESIGNER:**

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