GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm

SEMESTER: II

Subject Name: Biotechnology and Regulatory aspects of Phytomedicines
Subject Code: MPM204T

Scope: This subject deals with the usefulness of biotechnology in phytomedicine development as well as regulatory aspects of herbal products

Objectives: Upon completion of this course the student should be able to

1. Discuss concepts of plant biotechnology and its applications
2. Describe various molecular biology methods useful in drug development
3. Discuss and analyse methods of plant genetic engineering, tissue culture techniques and processing techniques
4. Describe and implement Good Manufacturing practices for herbal products
5. Discuss and analyze various guidelines for quality control of phytomedicines

Sr No	Course Contents	Total Hrs
1	Introduction to Plant biotechnology: Historical perspectives, prospects for development of plant biotechnology as a source of medicinal agents. Applications in pharmacy and allied fields. Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray);	10
2	**Systems and methods of molecular biology:** Isolation and validation of targets; PCR, RT-PCR nucleic acid isolation; cloning vectors (some examples), enzymes used in molecular cloning methods (some examples); **Protein expression systems:** Gene expression in bacteria, yeast, insect and mammalian cells.	12
3	**Plant drug collection and cultivation with plant growth regulators:** Transgenic plants, and approaches for production of transgenic plants. genetic manipulations and plant genetic engineering. Cultivation technology for commercial production of some selected medicinal and aromatic plants. **Tissue culture techniques:** Micro-propagation of medicinal and aromatic plants, secondary metabolism in tissue culture, germplasm storage, methods of cell immobilization. **Biopharmaceuticals:** Concepts of upstream and downstream Processing techniques Biotechnology of propagation and production of antibiotic and non-antibiotic drugs from lower plants.	16

4	Regulatory aspects of Herbal Products and its registration as Food, Ayurveda (traditional medicine) and phytopharmaceuticals in India and various countries such as USA, Europe etc. Good Manufacturing Practice of Indian systems of medicine Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, working space, storage area, machinery and equipments, standard operating procedures, health and hygiene, documentation and records.	10
5	Guidelines for Good Agricultural Practices, Good Laboratory practice (GLP) for Ayurvedic and herbal drug materials. Good Clinical Practices for Phytomedicines/hebal drugs. National/Regional Pharmacopoeia, WHO Guidelines for Quality Control of Herbal Drugs, Regulations of Herbal Drugs in US, Europe and other countries Biodiversity act, Environment Assessment etc. and its importance in context to herbal products.	12

REFERENCES:

1. Phytomedicine, A treasure of pharmacologically Active Products from Plants, Rouf Ahmed Bhat et al, Elsevier, 2021
2. Plant Cell and Tissue Culture (Methods in Molecular Biology) Vol. 6 - Jeffrey W. Pollard and John M Walker, Humana press, 2014.
3. Plant cell culture: a practical approach by R. A. Dixon, Robert A. Gonzales, 2, illustrated, reprint, Oxford University Press, 1994
4. Plant Cell and Tissue Culture: A Laboratory Manual - J. Reinert and M.M. Yeoman, 1st Edition, Springer, 2012
5. Pharmaceutical Biotechnology by Concepts and Applications by Gary Walsh, John Wiley & Sons
6. Principles of Fermentation Technology by P F Stanbury, A. Whitaker, S. J. Hall. Butterworth-Heinemann
7. WHO guidelines on Quality Control of Herbal Products
8. Drugs and Cosmetics Act 1940 and rules thereunder
9. Guideline for herbal medicines by various regulatory agencies such as USFDA, EMA etc.