GUJARAT TECHNOLOGICAL UNIVERSITY

M. Pharm

SEMESTER: II

Subject Name: Biological Evaluation of phytomedicines
Subject Code: MPM203T

Scope: This subject deals with the pharmacological evaluation of phytomedicines. It covers preclinical and clinical aspects of drug evaluation along with safety and toxicological concepts.

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

1. Understand principles of drug evaluations
2. Select and design a proper *in vitro* and/or *in vivo* model for evaluation of phytomedicine for given pharmacological activity
3. Describe safety and toxicological aspects of herbal products
4. Understand various in silico methods for drug evaluation
5. Discuss and analyze various clinical trial protocol for phytomedicine.

Sr No	Course Contents	Total Hrs
1	Principles of drug evaluation: Methods of dose fixation and general data on laboratory animals. Importance and study of *in vitro* and *in vivo* methods of drug screening. Different therapeutic categories of botanical drugs: Pharmacological activities of these drugs and their correlation to therapeutic category.	12
2	Different *in vitro* and *in vivo* bioassays for evaluation of pharmacological activity of botanical/herbal drugs. Discussion of various models for evaluations of activity for anti-inflammatory, anti-diabetic, anti hyperlipidemic, anti-cancer, immunomodulatory, anti-microbial, anti-viral, cardiotonic activities, diuretic, hepatoprotective, kidney diseases, CNS diseases etc.	18
3	Safety and toxicological aspects and adverse reactions of herbal medicines. Herbal-drug and food-drug interactions, Interactions of herbal drugs and their derived compounds. An introduction to Computational models/ in silico activity, ligand preparation etc.	12
4	**Clinical trial protocol development:** Phases of clinical trial, responsibilities of investigators and sponsor. Comparison of clinical study data of pharmaceuticals versus herbal drugs. **Ethical principles:** Design and broad objectives of clinical trials for herbal drugs, type and laying of protocol for clinical trial. Parallel and	18

	cross over design of clinical trial, Placebo in clinical trials, sample size and objectives. Limitations of clinical trials of herbal drugs. Determinants of adverse drug reactions and post marketing surveillance data available for herbal drugs.	

REFERENCES:

1. Goodman & Gillman's, The Pharmacological Basis of Therapeutics, edited by Joel G. Hardman,
Lee E. Limbird, Consulting editor, Alfred Goodman Gilman
2. Herbal Medicine-Science Embraces Tradition- A New Insight into Ancient Ayurveda, editors- Narendra Singh and Marilena Gilca
3. Pharmacoepidemiology, edited by Brian L. Strom
4. Clinical Trial Manual from the Duke Clinical Research Institute by Margaret B.Lin & Kate Davis
5. Clinical Pharmacology by D.R. Laurence, P.N. Bunnet
6. Principle and Practice of Clinical Trial Medicine by, Richard Chin and Bruce Y. Lee
7. OECD guidelines, GMP and GLP as per guideline of AYUSH, Ministry of Health and Family Welfare, Govt. of India.
8. New Drugs and Clinical Trial Rules 2019 and its relevant updates