BTS 555 **PHARMACOLOGY AND DRUG DEVELOPMENT**
(SOFT CORE COURSE) **Hours: 40**

Course outcomes:

After successful completion of the course, students will be able to:

CO 1. Differentiate elements of pharmacology, pharmacokinetics and pharmacodynamics
CO 2. Understand various facets of drug development
CO 3. Comprehend principles and levels of toxicity, detection and safety
CO 4. Understand concepts of clinical trials and related regulations

Unit I (13 hrs)

Definition and scope of pharmacology. General principles of pharmacology - pharmacokinetics - membrane transport, absorption and distribution of drugs. Lipinski's rule for drug like molecule. Metabolism and excretion of drugs, kinetics of elimination, pharmacodynamics – mechanism of drug action, drug interactions, adverse drug interactions. Preclinical pharmacology; pre-clinical research (dose-response curve, maximum tolerated dose); CPCSEA guidelines, commonly used species of experimental animals. Basic principles of bioassays.

Unit II (13 hrs)

Drug development: Methods involved in the development of new drugs. Assay development. Receptor-drug interactions. High throughput screening (*in-vitro* and *in-vivo*) for pre-clinical pharmacokinetic and pharmacodynamic studies. Compartment models used in pharmacokinetics (oral and intravenous). Comparative fitting (once comp and two comp). Pharmacodynamic / pharmacokinetic correlation. Toxicology studies (NOEL, NOAEL). Drug toxicity tests: OECD guidelines, determination of LD50, acute, sub-acute and chronic toxicity studies. Irwin profile. Toxic risk assessment: Methods, monitoring, important and surveillance of risk assessment. Safety standards: Safety measure, safety regulation, protective practices and devices.

Unit III (13 hrs)

Clinical Trials – Introduction to good clinical practices, phases of Clinical Trials I-IV. Clinical Trial development: Study designs, protocol design and development; case report from design to development, Principles of data management, clinical trial management, pharmacovigilance. Regulatory authorities – FDA, EPA, EMEA, JPMA, TGA, DCGI. Quality standards: ISO. Organic medicinal product research and development. Drugs and cosmetics act, drug price control order, Application for new investigational new drug (IND), Application for new drug discovery (NDD) according to Indian control Authority and US FDA guidelines. Conducting bio-equivalence studies.

References

1. Human Physiology, Guyton
2. Essentials of Medical Pharmacology, Tripathi, K.D., Jaypee Bros Med Publ, New Delhi 2013
3. Pharmacology, Rang H.P., Dale, M.M., Ritter, J.M. et al, Elsevier Pub, 2012
4. Principles of Pharmacology, Munson, P.L., Breese, G.R., Mueller, R.A., Taylor & Francis, 1998
5. Modern Toxicology, Vol. I-III, Gupki P.K., Salunke, D. K. 1985, Metropolitan Publ, Delhi
6. Concepts of Toxicology, Omkar, 1995, Chand and Co., Jallandar

7. Ethical guidelines for Biomedical Research on Human participants, ICMR, Govt. of India, New Delhi 2006
8. Good Clinical Practices for Clinical Research in India, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India, 2013