

Subject Code: 1RI3000102	Subject Title: Essentials of Disciplinary Research Subject-1 Subject Sub-Title: Novel Drug Delivery System
Pre-requisite Subject	

Objectives of course:

To acquire adequate knowledge related to fundamental of controlled release and various controlled drug delivery systems. To gain comprehensive understanding related to different novel strategies, routes and carrier systems for drug delivery in order to achieve increased efficacy and reduced toxicity as well as the manufacturing and evaluation of certain novel types of drug delivery systems.

Learning outcomes:

The students will gain an insight of designing drug delivery systems and the formulation aspects of novel drug delivery systems, which may be more beneficial as compared to conventional drug delivery systems in terms of safety and efficacy. Thus, the students may play a crucial role in catering to the needs of the pharmaceutical industry in particular and the society at large.

Teaching Scheme (Credit Distribution)				Assessment Scheme (Weightage)	
Lecture	Tutorial	Practical	Credit	Hall Exam	Continuous Evaluation
4	--	--	4	60%	40%

Continuous evaluation is based on assignments/quiz/presentation/small projects as per the supervisor instructions.

Subject Content			
Unit	Topic	No. of Lecture	Weightage %
1	Theory of controlled release drug delivery systems : Physico-chemical, Biological and Pharmaceutical factors influencing design and development of oral solid control release dosage forms, kinetics & mechanism, general methods of design and evaluations of controlled release products		20
2	Advanced concepts in the design, development and production of various sustained release products, Colon targeted system, Targeted drug delivery system, Gastro retentive drug delivery system, Osmotic drug delivery systems, Intelligent drug delivery.		20
3	Mucoadhesive drug delivery systems: Buccal, stomach and vaginal drug delivery systems concepts, advantages and disadvantages. Nasal and pulmonary drug delivery systems and its applications.		10
4	Transdermal drug delivery systems: Theory, formulation, production and evaluation Implants and Inserts – Types, design and evaluation methods. Ophthalmic inserts: drug delivery kinetics, soluble ophthalmic drug inserts, ocusert, collagen shields, minidisc ocular therapeutic system		20

5	Microencapsulation and microspheres: Methods of encapsulation, kinetics of drug release from microcapsules, technology and applications. Supercritical fluid techniques.		10
6	Novel Emulsion systems: Microemulsion & Nanoemulsion, Self emulsifying drug delivery system (SEDDS), Self microemulsifying drug delivery system Basic techniques for development of liposomes, neosome, pharmacosomes, ethosomes, nanosuspension, nanoparticles and solid lipid nanoparticles etc.		20

List of References:

1. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6, Marcel Inc., N.Y.
2. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc., N.Y.
3. Joseph R. Robinson and Vincent H.L. Lee, "Controlled Drug Delivery", Drugs and Pharm. Sci. Series, Vol. 29, Marcel Dekker Inc., N.Y.
4. Vyas S.P. and Khar R.K., "Targeted and Controlled Drug Delivery", Published by CBS Publishers.
5. Jain N. K., "Progress in Control and Novel Drug Delivery", Published by CBS Publishers.
6. Ghosh T.K. and Pfizer W.R., "Drug Delivery to Oral Cavity", Molecules to Market. NY, USA: CRC Press.
7. Gupta R.B. and Kompella U.B., "Nanoparticle Technology in Drug Delivery", Marcel Dekker Inc., N.Y.
8. Guy R. and Hadgraft J., "Transdermal Drug Delivery", Marcel Dekker Inc., N.Y.
9. Mitra A.K., "Ophthalmic Drug Delivery System", Marcel Dekker Inc., N.Y.
10. Vincent M.L. and Robert G., "Bioadhesive Drug Delivery Systems", CRC Press.
11. Edith M., Donald E. Chickering, Claus-Michael L., "Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development", Drugs and Pharm. Sci. Series, Vol. 98, Marcel Dekker Inc., N.Y.
12. Russell O. Potts and Richard H. Guy, "Mechanisms of Transdermal Drug Delivery", Marcel Dekker Inc., N.Y.
13. Guru V. Betageri, Daniel L. Parson, Scott A. Jenkins, Daniel L. Parsons, "Liposome Drug Delivery Systems", Technomic Pub Co.
14. Xiaoling L. and Bhaskara R. Jasti, "Design Of Controlled Release Drug Delivery Systems", McGraw-Hill.
15. Chien Y.W., "Novel Drug Delivery Systems", 2nd ed., Marcel Dekker Inc., N.Y.
16. Simon Benita, "Microencapsulation: Methods and Industrial Applications", Second Edition, CRC Press.
17. Nixon J.N., "Microencapsulation", Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc., N.Y.
18. Gutcho M.I., "Microcapsules and Microencapsulation Techniques", Noyes Data Corporation, 1976.

Subject Code: 1RI3000103	Subject Title: Essentials of Disciplinary Research Subject-2 Subject Sub-Title: Experimental Drug Design & Intellectual Property Rights
Pre-requisite Subject	

Objectives of course: This course aims to guide students for achieving competence and proficiency in the use of experimental drug design as well as intellectual property rights and patent.

Learning outcomes:

At the end of the course, the students will be able:

- To understand the fundamental methodology & importance of experimental drug design.
- To understand IPR and Patents

Teaching Scheme (Credit Distribution)				Assessment Scheme (Weightage)	
Lecture	Tutorial	Practical	Credit	Hall Exam	Continuous Evaluation
2	--	--	2	60%	40%

Continuous evaluation is based on assignments/quiz/presentation/small projects as per the supervisor instructions.

Subject Contents			
Unit	Topic	No. of Lecture	Weightage %
1	Experimental Design: Terminology and definitions related to experimental design Study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques. Sampling Designs: Introduction, types of sample designs, steps, criteria of selection, characteristics, random sampling, drop outs. Advantage and disadvantage of conventional design over experimental design.		25%
2	Basic steps in experimental design. Screening Designs: Screening of factors, General properties for independent factor selected for experimental design. Fractional factorial design (FFD): Purpose advantage and disadvantage of fractional factorial design, Concept of Aliased Effects and Design Aliasing Structure and constructing FFD Analysis of fractional factorial design: Concept of Design Resolution for FFD Case study of factorial design Plackett–Burman designs: Purpose advantage and disadvantage and		35%

	construction of matrix , Comparison between placket-Burman and FFD design, Case study Full factorial design Optimization techniques and various method of optimization Introduction to contour plots Introduction of repose surface design: Classification Characteristic of design Matrix and analysis of design with case study Evolution of full and reduced mathematical models in experimental designs Central composite designs Taguchi and mixture design Application of experimental design in pharmacology for reduction of animal		
3	Patents: Patents definition, need for patenting, Types of Patents, Condition to be satisfied by an invention to be patentable, Introduction to patent search, The essential elements of patents, Guidelines for preparations of laboratory notebook, non obviousness in patents, Drafting of patent claims, Patent Infringement, Important patent related websites.		20%
4	Brief introduction to trademark protection and WTO patents, Introduction to "The Patents Act 1970" and "The Patents Rule 2003", with special emphasis on the forms to be submitted along with a patent application		20%

List of References:

1. Lewis G.A., Mathiea D., Phan-Tan-Luu Roger, "Pharmaceutical Experimental Design", Marcel Dekker Inc., N.Y.
2. Armstrong N. and James L.K.C., " Pharmaceutical Experimental Design and Interpretation", Taylor & Francis.
3. Cochran W.G. and Cox G.M., "Experimental Designs", Wiley, 1957.
4. Fisher R.A., " The Design of Experiments", 8th ed., Hafner, 1966
5. Vogt F. G., Kord A. S.. Development of Quality by Design Analytical Methods. J. Pharm. Sci.. 2010; 100(3): 797-812.
6. Patent laws , By P. Narayan. Eastern law house publications
7. [www. ipindia.nic.in](http://www.ipindia.nic.in),
8. www.uspto.gov
9. <https://www.epo.org>