INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICAL QUALITY ASSURANCE)**
SEMESTER	**1**
COURSE TITLE	**PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER**
COURSE CODE	**13MQ0104**
COURSE CREDITS	**4**

Objective:

1 This deal with technology transfer covers the activities associated with Drug Substance, Drug Product, and analytical tests and methods, required following candidate drug selection to completion of technology transfer from R&D to the first receiving site and technology transfer related to post-marketing changes in manufacturing places.

Course Outcomes: After completion of this course, student will be able to:

1 Upon completion of this course, the student should be able to
To understand the new product development process.

2 Upon completion of this course, the student should be able to
To understand the necessary information to transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D.
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3 Upon completion of this course, the student should be able to To elucidate necessary information to transfer the technology of existing products between various manufacturing places.

Pre-requisite of course:B.Pharm. Degree holder from an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 55 percent of the maximum marks (aggregate of 4 years of B.Pharm.).

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

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Contents : Unit	Topics	Contact Hours
1	**Unit-1** Principles of Drug discovery and development: Introduction, Clinical research process. Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Scale Up Post Approval Changes (SUPAC), and Bulk active chemical Post approval changes (BACPAC), Post-marketing surveillance, Product registration guidelines – CDSCO, USFDA.	12
2	**Unit-2** Pre-formulation studies: Introduction/ concept, organoleptic properties, purity, impurity profiles, particle size, shape, and surface area. , Solubility, Methods to improve the solubility of Drugs: Surfactants & its importance, co-solvency. Techniques for the study of Crystal properties and polymorphism. Pre-formulation protocol, Stability testing during product development.	12
3	**Unit-3** Pilot plant scale-up: Concept, Significance, design, layout of pilot plant scale-up study, operations, large scale manufacturing techniques (formula, equipment, process, stability, and quality control) of solids, liquids, semisolid and parenteral dosage forms. A new era of drug products: opportunities and challenges.	12
4	**Unit-4** Pharmaceutical packaging: Pharmaceutical dosage form and their packaging requirements, pharmaceutical packaging materials, medical device packaging, Enteral Packaging, Aseptic packaging systems, Container closure systems, Issues facing modern drug packaging, Selection and evaluation of Pharmaceutical packaging materials., Quality control test: Containers, closures, and secondary packing materials.	12
5	**Unit-5** Technology transfer: Development of technology by R&D, Technology transfer from R&D to production, Optimization, Production, Qualitative and quantitative technology models., Documentation in technology transfer: Development report, technology transfer plan, and Exhibit.	12
Total Hours		**60**

Textbook :

1 The process of new drug discovery and development, Charles G. Smith, James T, and O. Donnell, CRC Press, Group of Taylor and Francis., 2006

2 Tablets Vol. I, II, III , Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz,, Marcel Dekker Inc. New York., 1989

3 Textbook of Bio- Pharmaceutics and clinical Pharmacokinetics , Milo Gibaldi, Lea & Febriger, Philadelphia., 1991

Textbook :

4 Remington Pharmaceutical Science, Alfonso & Gennaro, Lippincot, Williams and Wilkins A Wolters Kluwer Company, 1995

5 Dissolution, Bioavailability and Bio-Equivalence , Abdou H.M, , Mack Publishing company, 1989

6 Pharmaceutical product development. , Vandana V. Patrevale. John I. Disouza. Maharukh T. Rustomji. , CRC Press, Group of Taylor and Francis., 2000

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
20.00	25.00	25.00	15.00	10.00	5.00

Instructional Method:

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

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