



Course Syllabus
Gyanmanjari Pharmacy College
Semester-1 (M.Pharm.)

Subject: Product Development and Technology Transfer (MPHQA11504)

Type of course: Major

Prerequisite: B. Pharmacy

Rationale: 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

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
CI	T	P		C	Theory Marks		Practical Marks		
			ESE		MSE	V	P	ALA	
4	-	-	4	75	10	--	--	50	150

Legends: CI-ClassRoom Instructions; T – Tutorial; P - Practical; C -- Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.



Course Content:

Chapter No.	Course content	Hrs	% Weightage
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	20
2.	Pre-formulation studies: Introduction/concept, organoleptic properties, purity, impurity profiles, particle size, shape and surface area. Solubility, Methods to improve 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	20
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. New era of drug products: opportunities and challenges.	12	20
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	20
5.	Technology transfer: Development of technology by R & D, Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitative technology models. Documentation in technology transfer: Development report, technology transfer plan and Exhibit.	12	20



Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	Faculty will assign small groups to simulate technology transfer from an R&D setting to a manufacturing environment. This includes preparing documentation and handling scale-up challenges and students upload on GMIU web portal.	15
2.	Faculty will provide topic to students in creating a mock regulatory dossier for a new product, understanding documentation needs across regions and students will upload on GMIU web Portal.	15
3.	Faculty will assign groups of students to create a checklist for regulatory compliance during technology transfer for a specific market (e.g., USFDA, EMA) and upload on GMIU web portal.	20
Total		50

Suggested Specification table with Marks (Theory):75

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	20%	45 %	20%	10%	05 %	-

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcome:

After learning the course, the students should be able to:	
CO1	Understand the new product development process.
CO2	Transfer technology from R&D to actual manufacturing by sorting out various information obtained during R&D
CO3	Elucidate necessary information to transfer technology of existing products between various manufacturing places.

Instructional Method:

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

From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

Reference Books:

- [1] The process of new drug discovery and development. I and II Edition (2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Group of Taylor and Francis.
- [2] Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of Industrial Pharmacy. Marcel Dekker Inc. New York.
- [3] Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Good manufacturing of pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishing house Mumbai.
- [4] Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B. Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.
- [5] Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by Milo Gibaldi, 3 rd Edn, Lea & Febriger, Philadelphia.
- [6] Pharmaceutical product development. Vandana V. Patrevala. John I. Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.
- [7] Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, Mack Publishing company, Eastern Pennsylvania.
- [8] Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19th Edn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters Kluwer Company, Philadelphia.
- [9] The Pharmaceutical Sciences; the Pharma Path way 'Pure and applied Pharmacy' by D. A Sawant, Pragathi Books Pvt. Ltd.
- [10] Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall. 1 st Edition(Reprint 2006). Taylor and Francis. London and New York.

