NIRMA UNIVERSITY
Institute of Pharmacy
(B. Pharm)
(Semester - VII)

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Course Code	**BP702T**
Course Title	**Industrial Pharmacy II -Theory**

Scope:
This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market

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

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms.
2. Understand the process of technology transfer from lab scale to commercial batch.
3. Know different Laws and Acts that regulate pharmaceutical industry.
4. Understand the approval process and regulatory requirements for drug products.

Course Learning Outcomes (CLO):
At the end of the course, students will be able to -

1. Define criteria for the pilot plant scale up and SUPAC guidelines for post approval changes.
2. Understand technology transfer process, parameters and documentation.
3. Describe regulatory requirements for drug approval process and licensing of pharmaceutical drugs.
4. Explain various concept used for quality management systems.
5. Correlate regulatory requirement for product approval in India and abroad.

Syllabus:

Teaching hours: **45**

Hours

UNIT I

10

Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology.

UNIT II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT – III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT – IV

8 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIV – V

7 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs

Tutorials

Teaching Hours: 15 Hours

Tutorials will be based on above syllabus.

Suggested Readings^: (Latest edition)

1. International Regulatory Affairs Updates, 2005. available at http://www.iraup.com/about.php
2. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition.
3. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.