INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**BACHELOR OF PHARMACY**
SEMESTER	**7**
COURSE TITLE	**INDUSTRIAL PHARMACY-II**
COURSE CODE	**13PH0702**
COURSE CREDITS	**4**

Objective:

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

Course Outcomes: After completion of this course, student will 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 the pharmaceutical industry.
4 Understand the approval process and regulatory requirements for drug products.

Pre-requisite of course: This course is designed to impart fundamental knowledge on pharmaceutical product development and translation from laboratory to market.

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
3	1	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Pilot plant scales up techniques** Pilot plant scales up techniques: General considerations – including the 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.	10

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Contents : Unit	Topics	Contact Hours
2	**Technology development and transfer** 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 equipment, 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.	10
3	**Regulatory affairs** 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.	10
4	**Quality management systems** 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	8
5	**Indian Regulatory Requirements** 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.	7
Total Hours		**45**

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	**Tutorials will be based on the above syllabus** Tutorial-1, Tutorial-2, Tutorial-3, Tutorial-4, Tutorial-5, Tutorial-6, Tutorial-7, Tutorial-8, Tutorial-9, Tutorial-10, Tutorial-11, Tutorial-12, Tutorial-13, Tutorial-14, Tutorial-15	15
Total Hours		**15**

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Textbook :

1 ROLE OF REGULATORY AFFAIRS IN A PHARMACEUTICAL INDUSTRY, Y. SRI HARSHA, V.SHARMILA REDDY, INTERNATIONAL JOURNAL OF PHARMACEUTICAL RESEARCH AND BIO-SCIENCE, 2017

References:

1 Regulatory Affairs from Wikipedia, the free encyclopaedia , Regulatory Affairs from Wikipedia, the free encyclopaedia , Wikipedia, Wikipedia, 2022

2 International Regulatory Affairs Updates,, International Regulatory Affairs Updates,, Jitendra Kumar Badjatya , Interantional journal of Drug Regulatory affairs, 2013

3 A Guide for Prescription Drugs, Medical Devices, and Biologics, A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J Pisano and David S. Mantus, CRC press, 2008

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**
10.00	20.00	25.00	25.00	10.00	10.00

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 black board 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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