Chitkara College of Pharmacy
Chitkara University, Rajpura, Punjab
Chandigarh–Patiala National Highway, Punjab – 140 401, India

Institute/School Name	Chitkara College of Pharmacy		
Department Name	Pharmacy		
Programme Name	B.Pharmacy		
Course Name	Industrial Pharmacy II	**Session**	Jul-Dec 25
Course Code	BP702T	**Semester/Batch**	VII/ 2022
L-T (Per Week)	3-1	**Course Credits**	4
Pre-requisite	Industrial Pharmacy I	**NHEQF Level**	6
Course Coordinator	Dr. Rajan Swami		
SDG	3, 4		

Objectives of the Course: Upon completion of the course, the student shall be able to know the process of pilot plant and scale up of pharmaceutical dosage forms; understand the process of technology transfer from lab scale to commercial batch; know different laws and acts that regulate pharmaceutical industry; understand the approval process and regulatory requirements for drug products.

Course Outcomes (COs)

Students should be able to:

	COs	**Program Outcomes (PO)**	**NHEQF Level Descriptor**	**No. of Lectures**
CO01	Grasp the essential aspects of pilot plant techniques, including their significance and the basic requirements involved.	PO1, PO3, PO4, PO9, PO11	Q1, Q2	**10**
CO02	Understand the pilot plant and scale up techniques for various dosage forms in pharmaceutical industry.	PO1, PO4, PO9, PO11	Q2	**10**
CO03	Comprehend the concept of technology transfer and its application in commercial batch production.	PO1,PO2, PO3	Q1,Q5	**10**
CO04	Obtain learning opportunities to understand the regulatory requirements for drug product approvals and marketing.	PO2,PO4,PO9	Q4	**5**
CO05	Acquire knowledge about total quality management, quality control, quality assurance and various certifications.	PO1, PO3, PO9, PO11	Q4	**5**
CO06	Learn about the working and official framework of various Indian regulatory commissions.	PO1, PO2, PO3, PO9,	Q2	**10**
Total Contact Hours				**50**

CO-PO Mapping

CO	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**	**PO7**	**PO8**	**PO9**	**PO10**	**PO11**	**Type of Assessment's**
CO01	3		3	2					2		2	Formative/Summative
CO02	3			2					3		3	Formative/Summative
CO03	3	3	2								2	Formative/Summative

CO04		3		2					2			Formative/Summative
CO05	3		3						3		3	Formative/Summative
CO06	3	2	2						2			Formative/Summative

3=High, 2=Medium, 1=Low

Recommended Books:

B01: Industrial Pharmacy II by Agarwal G, Ghangas J, Text book of Industrial Pharmacy II published by CBS Publishers and Distributors.

B02: Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs A Guide for Prescription Drugs, Medical Devices, and Biologics' Second Edition

Other readings and relevant websites:

Serial No	Link of Journals, Magazines, websites and Research Papers
1.	Indian Pharmacopoeia
2.	Pharmaceutical Technology Transfer. Abhishek Pandey, Vivek Singh Bhadauria. LAP Lambert Academic Publishing, India.
3.	Pharmaceutical Process Scale-Up. Michael Levin, Editor. 3rd edition. Informa Healthcare, New York City, 2011.

Lecture Plan

Lec no.	Topic	Book no, Ch no, page no.	TLM	ALM	Web References	Audio-video
1-2	Pilot plant scale up techniques: General considerations	B01, CH 1 Page no 1.1-1.15	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.iptsalipur.org/wp-content/uploads/2020/08/BP702T_IP_I.pdf	1-2
3-4	Pilot plant scale up considerations for solids	B01, CH 2 Page no 2.2-2.12	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.iptsalipur.org/wp-content/uploads/2020/08/BP702T_IP_I.pdf	3-4
5-6	Relevant documentation, SUPAC guidelines	B01, CH 3 Page no 3.2-3.8	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/supac-ir-immediate-release-solid-oral-dosage-forms-scale-and-post-approval-changes-chemistry	5-6
7	Introduction to platform technology, supac	B01, CH 3 Page no 3.9-3.11	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.slideshare.net/slideshow/platform-technology/237605446	7

8-9	Introduction to platform technology, Technology development and transfer	B01, CH 4 Page no 4.2-4.15	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.slideshare.net/slideshow/platform-technology/237605446	8-9
10-11	Technology development and transfer	B01, CH 5 Page no 5.1-5.13	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.pharmatutor.org/articles/overview-of-technology-transfer-in-pharmaceutical-industry#:~:text=In%20the%20pharmaceutical%20industry%2C%20%E2%80%9Ctechnology,technology%20available%20to%20commercial%20partner	10-11
12-13	Transfer from R & D to production (Process, packaging and cleaning)	B01, CH 6 Page no 6.1-6.7	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.pharmatutor.org/articles/overview-of-technology-transfer-in-pharmaceutical-industry#:~:text=In%20the%20pharmaceutical%20industry%2C%20%E2%80%9Ctechnology,technology%20available%20to%20commercial%20partner	12-13
14-15	Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation	B01, CH 7 Page no 7.1-7.6	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.slideshare.net/slideshow/granularity-of-tt-processpdf/253016257	14-15
16-17	Commercialization - practical aspects and problems (case studies), TT agencies in India APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI	B01, CH 8 Page no 8.1-8.6	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.slideshare.net/slideshow/granularity-of-tt-processpdf/253016250	16-17
18	TT related documentation - confidentiality agreement Licensing,	B01, CH 9 Page no 9.1-9.9	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www./granularity-of-tt-processpdf/263016257	18

	MoUs, legal issues					
19-20	Regulatory affairs: Introduction, Historical overview of Regulatory Affairs Regulatory authorities, Role of Regulatory affairs department.	B01, CH 10 Page no 10.1-10.9	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.jetir.org/papers/JETIR2106052.pdf	19-20
21-24	Responsibility of Regulatory Affairs Professionals Regulatory	B01, CH 11 Page no 11.1-11.12	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.jetir.org/papers/JETIR2106052.pdf	21-24
25-27	Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions Concept of Quality, Total Quality Management, Quality by Design (QbD)	B01, CH 12 Page no 12.1-12.11	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.slideshare.net/slideshow/what-are-the-applications-of-biostatistics-in-pharmacy/248317740	25-27
26	Data Presentation for FDA Submissions	B01, CH 13 Page no 13.1-13.8	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.iptsalipur.org/wp-content/uploads/2020/08/BP702T_IP_III.pdf	26
27-28	Concept of Quality, Total Quality Management, Quality by Design (QbD) Six Sigma concept	B01, CH 14 Page no 14.1-14.10	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.pharmatutor.org/articles/quality-by-design-qbd-in-pharmaceutical-industry-tools-perspectives-and-challenges	27-28
29-30	Out of Specifications (OOS), Change control NABL.	B01, CH 15 Page no 15.1-15.9	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/Industrial pharmacy.aspx	29-30

31	GLP	B01, CH 16 Page no 16.1-16.4	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/Pharmacy-induatrical pharmacy.aspx	31
32-36	Introduction to ISO 9000 series of quality systems standards ISO 14000	B01, CH 17 Page no 17.1-17.8	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/industrail pharmacy.aspx	32-36
37-38	Quality management systems: Quality management & Certifications Management of Clinical Studies Drug Metabolism and Toxicology General considerations of Investigational New Drug (IND) Application Clinical research / BE studies	B01, CH 17 Page no 17.9-17.12	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/heal/Industrial pharmacy.aspx	37-38
39-40	Clinical Research Protocol Indian Regulatory Requirements	B01, CH 17 Page no 17.13-17.16	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/Industrial pharmacy.aspx	39-40
41-42	Central Drug Standard Control Organization (CDSCO) State Licensing Authority: Organization	B01, CH 18 Page no 18.1-18.9	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/industrial pharacy. aspx	41-42
43-46	State Licensing Authority: Organization State Licensing Authority: Responsibilities	B01, CH 19 Page no 19.1-19.15	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health/Industrial pharmacy,.aspx	43-46
47-48	Regulatory requirements and approval procedures for New Drugs Regulatory requirements and approval	B01, CH 20 Page no 20.1-20.8	Lecture, Active learning, Discussion, Inductive teaching	Discussion, Questioning	https://www.news-medical.net/health industril pahrmacy..aspx	47-48

	procedures for New Drugs Certificate of					
49-50	Pharmaceutical Product (COPP) Certificate of Pharmaceutical Product (COPP)	B01, CH 21 Page no 21.1-21.6	Lecture, Active learning, Discussion, Inductive teaching	Discussion , Questioning	https://www.news-medical.net/health/Industrial pharmacy.aspx	49-50

Teacher in-charge Assistant Dean Dean