



BENGAL SCHOOL OF TECHNOLOGY

AUTONOMOUS

Estd.by Supreme Educational Development and Charitable Organization (SEDCO)

Recognised by UGC & included u/s 2(f) of UGC Act 1956

Approved by Pharmacy Council of India, New Delhi

Affiliated to: Maulana Abul Kalam Azad University of Technology (MAKAUT) &
West Bengal State Council of Technical and Vocational Education and Skill Development (WBSCT&VE&SD)

Accredited by NAAC with "A" Grade, NBA for B. Pharm & QCI

Lesson Plan

Class: B.Pharm, 7th Sem., 4th Year

Session: 2026-27 (Odd Sem)

Date of Commencement of Session: 30.07.2026

Subject Name: Industrial Pharmacy -II

Subject code: PT-716A

Faculty In charge: Mrs. Arunima Nag

Schedule of allotted class work (w.e.f)

Days	Monday	Tuesday	Wednesday	Thursday	Friday
Time/period Section A	-	10:40-11:40 a.m.	-	-	-
Section B	-	12:40-01:40 p.m.	-	-	-

Available Periods/week 2 Available periods in the total semester 15 Extra Classes

Guest Lectures planned if any with justification NA

Scope & Objective of the course: On completion this course students will have fundamental knowledge on pharmaceutical product development and translation from laboratory to market with objectives:

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

Reading materials:

A. Text Books

Sl. No.	Name of the Text Book(s)	Author	Edition	Publisher	Accession No.	Rack No
1	Industrial Pharmacy II	D.K. Tripathi	1 st	PharmaMed Press, Hyderabad	10842	R-7F

B. Reference Books

Sl. No.	Name of the Text Book(s)	Author	Edition	Publisher	Accession No.	Rack No
2	Industrial Pharmacy II	N.K.Jain	1 st	Vallabh Prakashan, Delhi	9871	R-6D

C. Journals / Website/Any other resources

Sl. No.	Name of the journal (s)/website/others	Source	Vol. no.	Month & Year
1	https://cdsco.gov.in	-	-	-

Daily Teaching Schedule for UNIT-III

Sl. No.	Date	Day	Title to be covered	Teaching Pedagogy / T.L.P.	Suggested Knowledge Resources
1	04.08.2026	Tuesday	Regulatory affairs: Introduction, Historical overview of Regulatory Affairs,	Offline (Smart Class & Black-Board)	A1,C1
2	11.08.2026	Tuesday	Regulatory authorities, Role of Regulatory affairs department,	Offline (Smart Class & Black-Board)	A1,B1,C1
3	18.08.2026	Tuesday	Responsibility of Regulatory Affairs Professionals	Offline (Smart Class & Black-Board)	A1,B1,C1
4	25.08.2026	Tuesday	Regulatory requirements for drug approval: Drug Development Teams,	Offline (Smart Class & Black-Board)	A1,B1
5	01.09.2026	Tuesday	Regulatory requirements for drug approval: Non-Clinical Drug Development, Pharmacology	Offline (Smart Class & Black-Board)	A1,B1
6	08.09.2026	Tuesday	Regulatory requirements for drug approval: Drug Metabolism and Toxicology	Offline (Smart Class & Black-Board)	A1,B1
7	15.09.2026	Tuesday	General considerations of Investigational New Drug (IND) Application	Offline (Smart Class & Black-Board)	A1,B1
8	22.09.2026	Tuesday	Investigator's Brochure (IB)	Offline (Smart Class & Black-Board)	A1,B1
9	29.09.2026	Tuesday	New Drug Application (NDA)	Offline (Smart Class & Black-Board)	A1,B1
10	06.10.2026	Tuesday	Clinical research / BE studies	Offline (Smart Class & Black-Board)	A1,B1
11	13.10.2026	Tuesday	Clinical Research Protocols	Offline (Smart Class & Black-Board)	A1,B1
12	27.10.2026	Tuesday	Data Presentation for FDA Submissions	Offline (Smart Class & Black-Board)	A1,B1
13	03.11.2026	Tuesday	Management of Clinical Studies.	Offline (Smart Class & Black-Board)	A1,B1
14	17.11.2026	Tuesday	Revision	Offline (Smart Class & Black-Board)	A1,B1
Grand total number of classes planned for the semester: 15					