1.1.2 The institution adheres to the academic calendar including for the conduct of CIE

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

B. Pharm. I YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork / Orientation programme	**28.11.2022**	
2	1st Spell of Instructions (including Induction programme)	28.11.2022	21.01.2023 (8 Weeks)
3	First Mid Term Examinations	23.01.2023	30.01.2023 (1 Week)
4	Submission of First Mid Term Exam Marks to the University on or before	04.02.2023	
5	2nd Spell of Instructions	31.01.2023	29.03.2023 (8 Weeks)
6	Second Mid Term Examinations	31.03.2023	08.04.2023 (1 Week)
7	Preparation Holidays and Practical Examinations	10.04.2023	15.04.2023 (1 Week)
8	Submission of Second Mid Term Exam Marks to the University on or before	15.04.2023	
9	End Semester Examinations	17.04.2023	29.04.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 93

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester classwork	**01.05.2023**	
2	1st Spell of Instructions (including Summer Vacation)	01.05.2023	08.07.2023 (10 Weeks)
3	**Summer Vacation**	15.05.2023	27.05.2023 (2 Weeks)
4	First Mid Term Examinations	10.07.2023	15.07.2023 (1 Week)
5	Submission of First Mid Term Exam Marks to the University on or before	22.07.2023	
6	2nd Spell of Instructions	18.07.2023	11.09.2023 (8 Weeks)
7	Second Mid Term Examinations	12.09.2023	16.09.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	19.09.2023	23.09.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	23.09.2023	
10	End Semester Examinations	25.09.2023	07.10.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 92

REGISTRAR

Principal
Vishnu Institute of Pharmaceutical Education & Research
Narsapur, Medak dist.-502313

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

B. Tech./B.Pharm. II YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork	**28.11.2022**	
2	1st Spell of Instructions	28.11.2022	21.01.2023 (8 Weeks)
3	First Mid Term Examinations	23.01.2023	30.01.2023 (1 Week)
4	Submission of First Mid Term Exam Marks to the University on or before	04.02.2023	
5	2nd Spell of Instructions	31.01.2023	29.03.2023 (8 Weeks)
6	Second Mid Term Examinations	31.03.2023	08.04.2023 (1 Week)
7	Preparation Holidays and Practical Examinations	10.04.2023	15.04.2023 (1 Week)
8	Submission of Second Mid Term Exam Marks to the University on or before	15.04.2023	
9	End Semester Examinations	17.04.2023	29.04.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 93

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester classwork	**01.05.2023**	
2	1st Spell of Instructions (including Summer Vacation)	01.05.2023	08.07.2023 (10 Weeks)
3	**Summer Vacation**	15.05.2023	27.05.2023 (2 Weeks)
4	First Mid Term Examinations	10.07.2023	15.07.2023 (1 Week)
5	Submission of First Mid Term Exam Marks to the University on or before	22.07.2023	
6	2nd Spell of Instructions	18.07.2023	11.09.2023 (8 Weeks)
7	Second Mid Term Examinations	12.09.2023	16.09.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	19.09.2023	23.09.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	23.09.2023	
10	End Semester Examinations	25.09.2023	07.10.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 92

24/10/22

REGISTRAR

Principal
Vishnu Institute of Pharmaceutical Education & Research
Narsapur, Medak dist.-502313

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

B. Tech./B. Pharm. III YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork	**09.09.2022**	
2	1st Spell of Instructions (including Dussehra Recess)	09.09.2022	10.11.2022 (9 Weeks)
3	Dussehra Recess	03.10.2022	08.10.2022 (1 Week)
4	First Mid Term Examinations	11.11.2022	17.11.2022 (1 Week)
5	Submission of First Mid Term Exam Marks to the University on or before	24.11.2022	
6	2nd Spell of Instructions	18.11.2022	12.01.2023 (8 Weeks)
7	Second Mid Term Examinations	16.01.2023	21.01.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	23.01.2023	28.01.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	30.01.2023	
10	End Semester Examinations	30.01.2023	11.02.2023 (2 Weeks)

Note: No. of Working/ instructional days: 92

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester classwork	**13.02.2023**	
2	1st Spell of Instructions	13.02.2023	08.04.2023 (8 Weeks)
3	First Mid Term Examinations	10.04.2023	15.04.2023 (1 Week)
4	Submission of First Mid Term Exam Marks to the University on or before	22.04.2023	
5	2nd Spell of Instructions (including Summer Vacation)	17.04.2023	24.06.2023 (10 Weeks)
6	**Summer Vacation**	15.05.2023	27.05.2023 (2 Weeks)
7	Second Mid Term Examinations	26.06.2023	01.07.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	03.07.2023	08.07.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	08.07.2023	
10	End Semester Examinations	10.07.2023	22.07.2023 (2 Weeks)

Note: No. of Working/ instructional days: 90

Principal
Vishnu Institute of Pharmaceutical Education & Research
Narsapur, Medak dist-502313

REGISTRAR

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

B. Tech./B. Pharm. IV YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork	**29.08.2022**	
2	1st Spell of Instructions (including Dussehra Recess)	29.08.2022	31.10.2022 (9 Weeks)
3	Dussehra Recess	03.10.2022	08.10.2022 (1 Week)
4	First Mid Term Examinations	01.11.2022	07.11.2022 (1 Week)
5	Submission of First Mid Term Exam Marks to the University on or before	12.11.2022	
6	2nd Spell of Instructions	09.11.2022	03.01.2023 (8 Weeks)
7	Second Mid Term Examinations	04.01.2023	10.01.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	11.01.2023	19.01.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	17.01.2023	
10	End Semester Examinations	*20.01.2023*	02.02.2023(2 Weeks)

Note: No. of Working/instructional days: 94

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester classwork	**03.02.2023**	
2	1st Spell of Instructions	03.02.2023	31.03.2023 (8 Weeks)
3	First Mid Term Examinations	01.04.2023	08.04.2023 (1 Week)
4	Submission of First Mid Term Exam Marks to the University on or before	15.04.2023	
5	2nd Spell of Instructions	10.04.2023	17.06.2023 (10 Weeks)
6	**Summer Vacation**	15.05.2023	27.05.2023 (2 Weeks)
7	Second Mid Term Examinations	19.06.2023	24.06.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	26.06.2023	01.07.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	01.07.2023	
10	End Semester Examinations	03.07.2023	15.07.2023 (2 Weeks)

Note: No. of Working/ instructional days: 91

REGISTRAR

Principal
Vishnu Institute of Pharmaceutical Education & Research
Bhimavaram, Vadak dist-534313

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

M.Tech./ M.Pharm. I YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork	**26.10.2022**	
2	1st Spell of Instructions	26.10.2022	20.12.2022 (8 Weeks)
3	First Mid Term Examinations	21.12.2022	28.12.2022 (1 Week)
4	Submission of First Mid Term Exam Marks to the University on or before	04.01.2023	
5	2nd Spell of Instructions	29.12.2022	25.02.2023 (8 Weeks)
6	Second Mid Term Examinations	27.02.2023	04.03.2023 (1 Week)
7	Preparation Holidays and Practical Examinations	06.03.2023	11.03.2023 (1 Week)
8	Submission of Second Mid Term Exam Marks to the University on or before	11.03.2023	
9	End Semester Examinations	13.03.2023	25.03.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 94

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester classwork	**27.03.2023**	
2	1st Spell of Instructions (including Summer Vacation)	27.03.2023	03.06.2023 (10 Weeks)
3	**Summer Vacation**	15.05.2023	27.05.2023 (2 Weeks)
4	First Mid Term Examinations	05.06.2023	10.06.2023 (1 Week)
5	Submission of First Mid Term Exam Marks to the University on or before	17.06.2023	
6	2nd Spell of Instructions	12.06.2023	08.08.2023 (8 Weeks)
7	Second Mid Term Examinations	09.08.2023	16.08.2023 (1 Week)
8	Preparation Holidays and Practical Examinations	17.08.2023	23.08.2023 (1 Week)
9	Submission of Second Mid Term Exam Marks to the University on or before	23.08.2023	
10	End Semester Examinations	24.08.2023	06.09.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 91

22/8/22
REGISTRAR

Principal
Vishnu Institute of Pharmaceutical Education & Research
Narsapur, Medak (Dist)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD
ACADEMIC CALENDAR 2022-23

M. Tech./ M. Pharm. II YEAR I & II SEMESTERS

I SEM

S. No	Description	Duration	
		From	To
1	Commencement of I Semester classwork		**21.10.2022**
2	1st Spell of Instructions	21.10.2022	15.12.2022 (8 Weeks)
3	Preparation of Project Work Proposals	21.10.2022	17.11.2022 (4 Weeks)
4	Project Work Review–I: (Project Submission & approval)	18.11.2022	24.11.2022 *(1 Week)*
5	Last date for submission of list of approved PRC-I students from the College to the University Examination branch.		26.11.2022
6	First Mid Term Examinations	16.12.2022	22.12.2022 (1 Week)
7	Submission of First Mid Term Exam Marks to the University on or before		30.12.2022
8	2nd Spell of Instructions	23.12.2022	16.02.2023 (8 Weeks)
9	Second Mid Term Examinations	17.02.2023	23.02.2023 (1 Week)
10	Preparation Holidays and Practical Examinations	24.02.2023	02.03.2023 (1 Week)
11	Submission of Second Mid Term Exam Marks to the University on or before		01.03.2023
12	End Semester Examinations	03.03.2023	16.03.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 92

II SEM

S. No	Description	Duration	
		From	To
1	Commencement of II Semester (Project Work Continuation) (25.11.2022 to 16.03.2023 – 16 weeks)		**17.03.2023**
2	Project Work Review -II (Phase-I)	17.03.2023	23.03.2023 (1 Week)
3	** Project Work Review -II (Phase-II)	11.04.2023	13.04.2023 (3 days)
4	Last date for submission of PRC-II marks		20.04.2023
5	Project Work Review -III (Phase -I) (24.03.2023 to 26.08.2023 – 22 Weeks)	28.08.2023	02.09.2023 (1 Week)
6	Last date for submission of Project Work Review-III (Phase-I) Marks		09.09.2023
7	* Date of eligibility of thesis submission		09.09.2023
8	Submission of Thesis and Project Viva –Voce Examination (PRC-III Phase-I)		--
9	** Project Work Review – III (Phase –II) (04.09.2023 to 02.12.2023 – 13 Weeks)	04.12.2023	06.12.2023 (3 days)
10	Last date for submission of Project Work Review –III (Phase-II) Marks		09.12.2023
11	Submission of Thesis and Project Viva –Voce Examination (Phase-II) follows		---

* After completion of 40 weeks from the date of approval of project work proposal and subject to approval of Project Work Review-III.

** Phase-II will be conducted only for unsuccessful students in Phase –I

Note: 1 The unsuccessful students in Project Work Review-II (Phase-II) shall appear for Project Work Review-II at the time of Project Work Review-III. These students shall reappear for Project Work Review-III in the next academic year at the time of Project Work Review -I only after completion of Project Work Review -II, and then Project Work Review -III follows.

2 The Project Viva-Voce External examination Marks must be submitted on the day of examination to the University.

REGISTRAR

7. MLTP & Academic dairy

- **MLTP**

VISHNU INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
Narsapur, Medak Dist-502313

MICRO LEVEL TEACHING PLAN

Academic year: 2022 / 23
Year/ Semester: IV/I
Name of the program: B. Pharmacy
Subject code: PS702
Name of the subject: INDUSTRIAL PHARMACY-II
Name of the faculty: Mrs.P.Durga Bhavani
Designation: Assistant. Professor

TEXT BOOKS:

1. Regulatory Affairs from Wikipedia, the free encyclopedia modified on 7th April available at http://en.wikipedia.org/wiki/Regulatory_Affairs.
2. International Regulatory Affairs Updates, 2005. Available at http://www.iraup.com/about.php
3. Douglas J Pisano and David S. Mantus. Text book of FDA Regulatory Affairs a Guide for Prescription Drugs, Medical Devices, and Biologics' 2nd Edition.
4. Regulatory Affairs brought by learning plus, inc. available at http.//www.cgmp.com/ra.htm.
5. Industrial Pharmacy by Roopa K Khar, S. P Vyas, Farhan J Ahmed, Gaurav K Jain, 4th Edition

S.No	Date	Name of the topic	Text Book/Reference Book	Instructional objective (Unit wise)	P.Os	Teaching aids BB/LCD GD/Demo
		UNIT-I				
1	29/08/2022	Introduction on pilot plant scale up	T1,T3,T5	Understanding of pilot plant design, scale up techniques & SUPAC guidelines	1,8	LCD
2	30/08/2022	General considerations - including significance of personnel requirements	T1,T4,T5		1,8,11	BB
3	01/09/2022	space requirements, raw materials	T1,T3,T5		1,11	LCD
4	02/09/2022	Pilot plant scale up considerations for Solids	T2,T3,T5		1,4	BB
5	03/09/2022	Pilot plant scale up considerations for Solids	T2,T3,T5		1, 8, 11	BB
6	05/09/2022	Pilot plant scale up considerations for oral Liquids	T1,T3,T5		1,4 , 6	BB

7	06/09/2022	Pilot plant scale up considerations for oral liquids	T1,T2,T4		1,2	BB
8	07/09/2022	Pilot plant scale up considerations for semi solids	T1,T2,T3		1, 8, 11	BB
9	13/09/2022	Relevant documentation of Pilot plant scale up	T1,T2,T3		1,5 , 6	LCD
10	14/09/2022	SUPAC guidelines	T1,T4,T5		1,8	LCD
11	15/09/2022	SUPAC guidelines	T1,T2,T4		1,8	LCD
12	16/09/2022	Introduction to Platform technology	T1,T4		1,6,9	BB
13	19/09/2022	REVISION	T2,T4		1,6,11	BB
UNIT -II						
15	20/09/2022	Introduction to Technology Transfer		Recognize the steps involved in technology transfer & the role of regulatory body and agencies in technology transfer.	1, 8, 11	BB
16	21/09/2022	WHO guidelines for Technology Transfer	T1,T4		1,7	LCD
17	22/09/2022	Technology transfer protocol	T1,T4		1, 11	BB
18	23/09/2022	Quality risk management,			1,2	BB
19	24/09/2022	Transfer from R & D to production	T1,T4		1, 11	BB
20	26/09/2022	Transfer from R & D to production	T1,T4		1,11	BB
21	27/09/2022	Granularity of TT Process	T1, T4		1, 6, 10	BB
22	29/09/2022	Documentation, Premises and equipments.	T1, T2,T3,T4		1,7, 11	LCD
23	30/09/2022	Qualification and validation	T1, T2,T3,T4		1, 5, 6	LCD
24	10/10/2022	Quality control: analytical method transfer	T1, T2,T3,T4		1,11	LCD
25	11/10/2022	TT (Technology Transfer) agencies in India	T1, T2,T3,T4		1,7	LCD
26	12/10/2022	Commercialization – practical aspects and problems	T1, T2,T3,T4		1, 11	LCD
27	13/10/2022	APCTD, NRDC	T1, T2,T3,T4		1, 11	LCD
28	14/10/2022	TIFAC, BCIL	T1, T2,T3,T4		1, 6	LCD
29	15/10/2022	TBSE / SIDBI	T1, T2,T3,T4		1, 11	LCD
30	17/10/2022	Technology of Transfer related documents confidentiality agreements,	T1, T2,T3,T4		1, 6	LCD
31	18/10/2022	Licensing MoUs, legal issues	T1,T4		1,4,11	LCD
32	19/10/2022	Licensing MoUs, legal issues	T1, T2,T3,T4		1, 11	LCD
33	21/10/2022	REVISION	T3,T4		1 ,6	BB
UNIT-III						
35	22/10/2022	Introduction to Regulatory Affairs	T1,T2,T3,T4	Will gain in-depth knowledge	1, 6	LCD
36	25/10/2022	Historical Overview of regulatory affairs	T1,T2,T3,T4		1, 6	LCD
37	26/10/2022	Regulatory authorities working in	T1,T2,T3,T4		1, 4, 6	LCD

		different countries of world		the role and scope of regulatory affairs in pharmaceutical industry		
38	27/10/2022	Role of regulatory affairs department	T1,T2,T3,T4		1,7	LCD
39	28/10/2022	Responsibilities of regulatory affair professionals	T1,T2,T3,T4		1,11	LCD
40	29/10/2022	Drug development teams	T1,T2,T3,T4		1,6,7	BB
41	31/10/2022	Non clinical drug development process	T1,T2,T3,T4		1,4,6	BB
42	01/11/2022 To 05/11/2022	I mid exams				
43	07/11/2022	Pharmacology study in non-clinical drug development	T1 ,T4		1,6	BB
44	08/11/2022	Pharmacokinetics study in non-clinical drug development process	T1,T2		1,6,7,9	BB
45	09/11/2022	Toxicology study in non -clinical drug development process	T1,T3		1,6,7,9	BB
46	11/11/2022	General considerations of IND (Investigational new drug) application	T1,T3		1,4,6	LCD
47	12/11/2022	General considerations of IB (Investigators brochure)	T1,T2		1,4,9	BB
48	14/11/2022	General considerations of NDA (New drug application)	T1,T4		1, 5	LCD
49	15/11/2022	Clinical research	T1.T3		2, 11	LCD
50	16/11/2022	Bioequivalence studies	T1,T2		2, 11	LCD
51	18/11/2022	Clinical research protocols	T1,T2,T3,T4		2, 11	LCD
52	19/11/2022	Biostatistics in pharmaceutical product development	T1,T2		1, 6,11	LCD
53	21/11/2022	Data presentation for FDA submission	T1 ,T4		1, 5	LCD
54	22/11/2022	Management of clinical studies	T1,T2,T3,T4		1,6	LCD
55	23/11/2022	Clinical research protocols	T1,T2,T3,T4		1,7	LCD
56	25/11/2022	REVISION	T1,T2,T3,T4		1, 5	LCD
		UNIT -IV				
58	26/11/2022	Quality management & Certifications	T1,T2,T3,T4	To know and apply the standards of ISO for quality assurance in developing	2, 3, 9	BB
59	28/11/2022	Concept of Quality	T1,T2,T3,T4		1, 8, 11	LCD
60	29/11/2022	Total Quality Management	T1,T2,T3,T4		1, 3, 6	BB
61	30/11/2022	Quality by design	T3,T4		2, 3, 9	LCD
62	01/12/2022	Six Sigma concept	T3,T4		2,3,9	BB
63	02/12/2022	Out of Specifications	T3,T4		1, 8, 11	LCD
64	03/12/2022	Change control	T3,T4		1, 3, 6	LCD

65	04/12/2022	Introduction to ISO 9000 series of quality systems standards	T3,T4	and delivering pharmaceutic al products	1, 8, 11	BB
66	05/12/2022	ISO 14000	T3,T4		1, 3, 6	BB
67	06/12/2022	NABL	T3,T4		1,10	BB
68	07/12/2022	GLP	T3,T4		1,10	BB
69	08/12/2022	Revision on quality by design	T3,T4		1,10	BB
		UNIT -V				
71	09/12/2022	Introduction on Regulatory Authorities	T1,T5	The organization and responsibilit ies of state licensing authority & The regulatory requirement s and approval procedures for new drugs in India.	1,4,9,11	BB
72	10/12/2022	Introduction to India regulatory system	T1,T5		1,3,9	BB
73	12/12/2022	Drug regulatory authority of India	T1,T5		2, 3, 9	LCD
74	13/12/2022	Central Drug Standard Control Organization(CDSCO)	T1,T5		1, 3, 6	LCD
75	14/12/2022	State Licensing Authority	T1,T5		1, 8, 11	LCD
76	22/12/2022	Organization, Responsibilities	T1,T5		1,4,7	B
77	23/12/2022	Drug controller general of India (DCGI)	T1,T5		1,3,8	BB
78	26/12/2022	Common Technical Document			1,6,9	BB
79	27/12/2022	Certificate of Pharmaceutical Product(COPP)	T1,T5		1, 11	LCD
80	28/12/2022	Regulatory requirements	T1,T2,T3		1, 8, 11	LCD
81	29/12/2022	Approval procedure for new drugs in India	T3,T4		1, 11	LCD
82	30/12/2022	National pharmaceutical pricing authority(NPPA)	T1,T2,T4		1,3,11	LCD
83	31/12/2022	Deficiencies and limitations of drug regulatory system	T1,T5		1,9,11	BB
84	02/01/2023	REVISION AND TEST ON UNIT-V	T1,T5		1,3,11	LCD
85	03/01/2023 TO 07/01/2023	II MID EXAMS	T1,T5		1,3,9	BB
86	09/01/2023	REVISION AND TEST ON UNIT-III	T1,T5		1,3,9,11	BB
87	10/10/2023	REVISION AND TEST ON UNIT-II	T1,T4,T5		1,4,9,11	BB

SUBJECT INCHARGE

PRINCIPAL

PRINCIPAL
Vishnu Institute of Pharma
Education & Resear
Narsapur, Medak Dist.-502

VISHNU
UNIVERSAL LEARNING

VISHNU INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
VISHNUPUR, NARSAPUR, MEDAK DT.

I Mid Subjective Examination NOV 2022

Year& Sem. : IV/ I
Subject& Code : INDUSTRIAL PHARMACY - II
Time : 2:00 PM to 3:30PM

Branch : B.Pharmacy
Date : 02/11/2022
Marks : 10

Q. No	Question Description	Marks	CO	PO	BL
	PART –A : Answer all				
1. a	What are the general considerations of pilot plant scale up studies?	1	1	1	1,2
b	Describe briefly about SUPAC guidelines.	1	1	1	1
c	Define the following terminologies 1) Change control 2) Drug master file	1	2	1	1
d	Enlist the prime responsibilities of RU (receiving unit) in process of analytical method transfer.	1	2	1	1
	PART- B:Answer either A or B				
2A	What is quality risk management? Explain briefly about quality risk management	3	2	1	1
2B	Explain in details about WHO guidelines for process of technology transfer	3	2	1	2
3A	Explain about pilot plant scale up considerations for solid dosage forms.	3	1	1	1
3B	Explain in detail about investigational new drug application	3	3	1	1,2

VISHNU INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
VISHNUPUR, NARSAPUR, MEDAK DT.

Code No: PS702 **Set No. 3**

IV B.Pharmacy - I Sem., I -Mid-Term Examinations, NOV , 2022

INDUSTRIAL PHARMACY - II

Objective Exam

Name: _____ **Hall Ticket No.** | | | | | | R | | | | |

Answer All Questions. All Questions Carry Equal Marks. Time: 20 Min. Marks: 10M.

I .Choose the correct alternative:

1. Which of the following is not a space requirement in general consideration of pilot plant?
   a)physical testing area b) standard equipment floor space c)storage area d) raw material [d]

2. NDA takes
   a)15 years b) 12 years c) 10years d) 5 years [C]

3. Key components of TQM are
   a) Consumer/Customer focus b) Continuous improvement
   c) Involvement of employee d) All of these [d]

4. Identification of critical elements in the process
   a) Design space b) GAP analysis c) IPQC d) acceptance criteria [b]

5. Pharmacovigilance is a part of
   a) ICH E1 guidelines b) ICH E3 guidelines
   c) ICH E2 guidelines d) ICH E2 (A-F) guidelines [d]

6. A measurable term under which test is considered as acceptable
   a) Bracketing b) commissioning c) acceptance criteria d) critical control point [c]

7. Common technical document (CTD) is developed by
   a).USFDA b) MHLW c) ICH d)TGA [c]

8. Key components of TQM are
   a) Consumer/Customer focus b) Continuous improvement
   c) Involvement of employee d) All of these [d]

9. Identification of critical elements in the process
   a) a) Design space b) GAP analysis c) IPQC d) acceptance criteria [b]

10. Pharmacovigilance is a part of
    a) ICH E1 guidelines b) ICH E3 guidelines
    c) ICH E2 guidelines d) ICH E2 (A-F) guidelines [d]

II Fill in the Blanks

1. _____an International regulatory authority for drug.
2. APCTT stands for _____.
3. Define, Measure, Analyze, Improve and Control includes in the concept of_____.
4. Kefauver – Harries Amendments to the FD&C act _____.
5. _____ is regulatory authority of India.
6. Medicine control council is regulatory agency of _____
7. Pilot COPP is issued by _____.
8. Process of increasing the batch size is called as _____.
9. Certification system for laboratory accreditation _____.
10. _____guidelines of ICH describes the quality management system.

VISHNU INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
Narsapur, Medak Dist. 502 313

COURSE FILE-C4113 (THEORY)

Name of the Course & Code	: INDUSTRIAL PHARMACY-II & PS702
Year & Semester	: IV Year I sem. B.Pharmacy
Ac. Yr.	: 2022-2023
Name of the faculty	: Ms.P.Durga Bhavani
Designation	: Assistant. Professor
Department	: Pharmaceutics

Subject in charge

Principal

PRINCIPAL
Vishnu Institute of Pharmaceutical
Education & Research
Narsapur, Medak Dist.-502 313, TS.

CONTENTS:

PRINCIPAL
Vishnu Institute of Pharmaceutical
Education & Research
Narsapur - 313. TS.

VISHNU INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH
Narsapur, Medak Dist. 502 313

COURSE FILE- 3116(PRACTICAL)

Name of the Course & Code	: Industrial Pharmacy (C3116)
Year & Semester	: III Year I sem. B.Pharmacy
Ac. Yr.	: 2022-2023
Name of the faculty	: Mrs .P.Durga Bhavani / Mr.T.Pavan kumar
Designation	: Asst. Professor / Asst. Professor
Department	: Pharmaceutics

Subject Incharge

HOD-Principal

Principal
Vishnu Institute of Pharmaceutical
Education & Research
Narsapur, Medak dist -502313

CONTENTS:

1. Lab Equipment list
2. Individual Lab time table
3. Registered Numbers of students
4. University prescribed experiments
5. MLTP & Academic Dairy
6. COs & Pos Mapping.
7. Experiments completion record
8. Continuous evaluation – Marks (Daily Assessment)
9. Lab Internal Examination – Question paper, Sample Answer scripts
10. Consolidated statement of Lab Internal Marks

Subject Incharge

HOD-Principal

Principal
Vishnu Institute of Pharmaceutical
Education & Research
Narsapur, Medak dist -502313

ACADEMIC YEAR 2022-2023

Name of the Faculty : P. Durga Bhavani

Designation : Assistant professor

JNTUH Faculty ID : 48150406 - 135026

Department : pharmaceutics (Theory / Laboratory)

Name of the Course : Industrial pharmacy - II

Course Code : 2

Number of Credit : 4

Year & Semester : IV / I

No. of Students Registered : 42 + 49 = 91

Month	Aug	Sep	Oct	Nov	Dec	Jan.
Subject Incharge						
HOD / Principal						

Course Outcomes (CO)

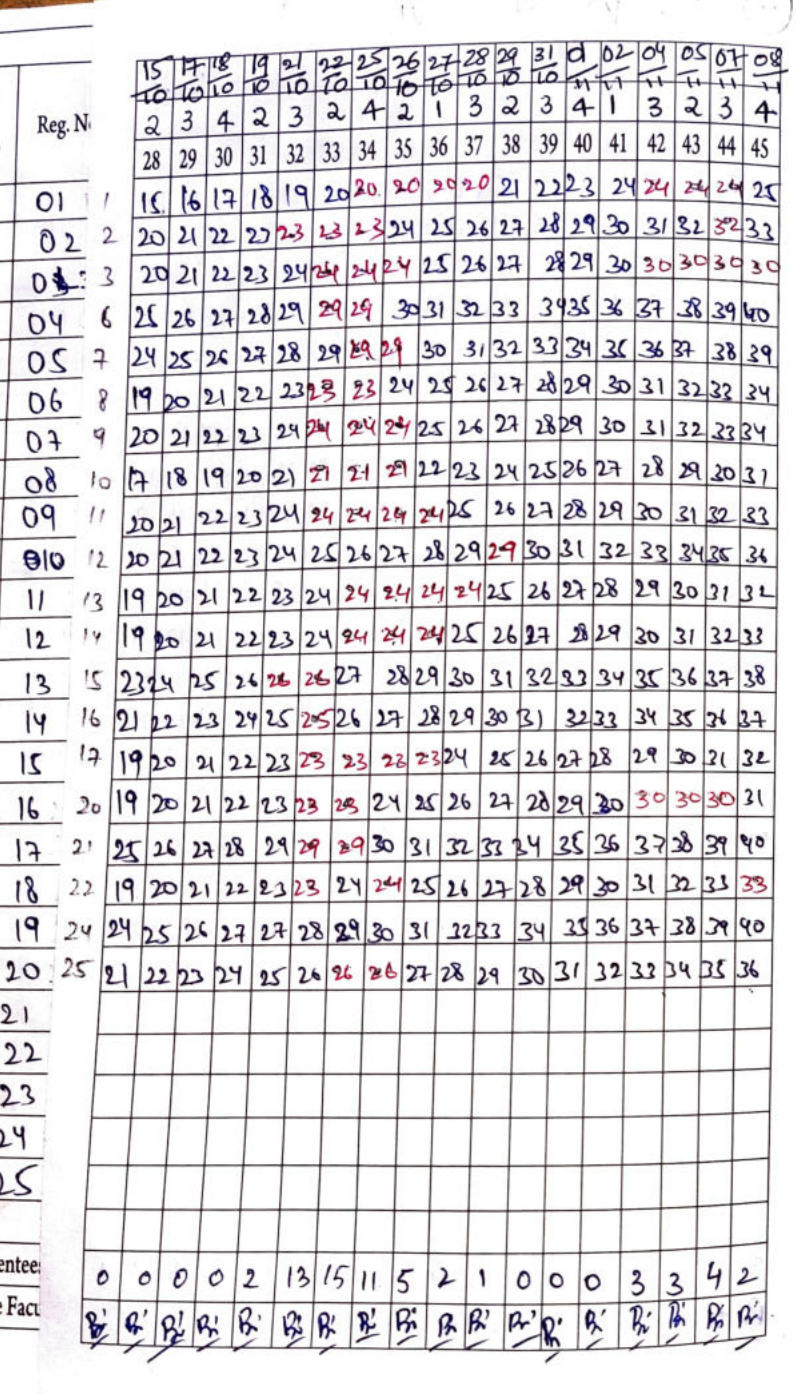
C411B.1.	Discuss the pilot plant and scale-up processes for pharmaceutical dosage forms as well as SUPAC guidelines.
C411B.2.	categorize the different aspects of technology transfer involved from research & development to manufacture
C411B.3.	comprehend & implement different responsibilities and regulatory requirements for drug approval.
C411B.4.	Communicate different laws and acts that regulate pharmaceutical industry and us.
C411B.5.	Explore the functions & responsibilities of regulatory agencies in drug approval
C411B.6.	Describe the structure and functions of the national & state licensing authorities

TIME TABLE

Day	Period	1	2	3	4		5	6	7
	Time	9:30AM to 10:15AM	10:15AM to 11:00AM	11:00AM to 11:55AM	11:55AM to 12:40PM				
Monday		~~B~~ IP-II		A IP-II		LUNCH			
Tuesday			(B) IP-II		(A) IP-II				
Wednesday		(A) IP-II		(B) IP-II					
Thursday									
Friday		(B) IP-II		(A) IP-II					
Saturday			(A) IP-II		(B) IP-II				

Sl. No	Reg. No.	Name	Date	29/8	30/8	1/9	2/9	3/9	5/9	06/09	07/09	13/09
			Period	3	4	2	3	2	3	4	1	4
			S. No.	1	2	3	4	5	6	7	8	9
1	01	R. Sathwika		1	A	1	A	1	1	1	2	2
2	02	CH. Uday		1	2	2	3	3	4	5	6	6
3	03	A. Divya Jyothi		1	1	2	3	4	5	6	7	7
4	04	Ayesha parveen		1	2	3	3	4	5	6	7	8
5	05	B. Kavya		1	1	2	3	3	4	5	6	7
6	06	B. Namratha		1	2	2	3	3	4	4	5	6
7	07	B. Lavanya		1	1	2	2	2	3	4	5	6
8	08	B. Karthik Reddy		1	1	2	2	2	2	2	3	4
9	09	B. Usha		1	2	2	2	2	3	4	5	6
10	010	B. Srimukhi		1	2	2	3	4	4	5	6	7
11	11	B. Shivatvika		1	1	2	2	3	4	5	6	7
12	12	B. Varsha		1	2	2	3	3	4	5	6	7
13	13	B. Bavya Sri		1	2	3	3	3	4	5	6	6
14	14	CH. Sathvika		1	2	2	3	3	4	5	6	7
15	15	C. Srivani		0	1	2	2	3	4	5	6	7
16	16	E. Dakshayani		1	2	3	3	4	4	5	6	7
17	17	E. Rupika		1	2	3	4	5	6	7	8	9
18	18	G. Mythri		1	1	2	2	3	3	4	5	6
19	19	G. Sanju Bhargavi		1	2	2	3	3	4	5	6	7
20	20	G. pooja		0	1	1	2	2	2	3	3	8
21	21											
22	22											
23	23											
24	24											
25	25											
26												
No. of absentees				2	8	10	9	12	6	3	1	4
Sign. of the Faculty				R.	R.	R.	R.	R.	R.	R.	R.	R.

14/09	15/09	16/09	19/09	20/09	21/09	23/09	23/09	24/09	26/09	27/09	29/09	30/09	10/10	11/10	12/10	13/10	14/10
1	2	2	3	4	1	2	3	2	3	4	1	3	3	4	1	2	3
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
2	3	3	3	3	3	4	5	6	7	8	9	10	11	12	12	13	14
6	7	7	7	7	7	8	9	10	11	12	13	14	15	16	17	18	19
7	8	8	8	8	9	10	11	12	13	14	15	16	17	17	18	18	19
8	9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
8	9	10	10	10	11	12	13	14	15	16	17	18	19	20	21	22	23
7	7	8	8	9	9	9	9	10	11	12	13	14	15	16	17	18	18
7	8	8	8	9	9	9	9	9	10	11	12	13	16	17	17	18	19
4	5	6	6	6	6	6	7	8	9	10	11	12	13	14	14	15	16
7	7	8	8	8	8	8	9	10	11	12	13	14	15	16	17	18	19
8	9	9	10	10	10	10	10	10	11	12	13	14	15	16	17	18	19
8	9	9	10	10	10	10	10	10	11	12	13	14	15	16	16	17	18
8	9	9	10	10	10	10	10	10	11	12	13	14	15	16	16	17	18
6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	20	21	22
8	8	8	8	8	8	9	10	11	12	13	14	15	16	17	18	19	20
8	8	8	8	8	8	8	9	10	11	12	13	14	15	16	17	17	18
8	8	8	8	8	8	8	9	10	11	12	13	14	15	16	16	17	18
10	11	12	13	13	14	14	15	16	17	18	19	20	21	22	22	23	24
6	6	6	6	6	7	8	9	10	11	12	13	14	15	15	16	17	18
8	9	10	10	11	11	12	13	14	15	16	17	18	19	20	21	22	23
9	9	9	9	9	9	10	11	12	13	14	15	16	17	18	19	19	20
8	6	13	14	15	14	10	5	4	0	0	0	0	0	2	8	3	1
R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.	R.



	03/12	04/12	05/12	06/12	07/12	08/12	09/12	10/12	12/12	13/12	14/12	22/12	23/12	26/12	27/12	28/12	29/12	30/12
	2	1	3	4	1	2	3	2	3	4	1	2	1	3	4	1	4	3
	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
1	40	41	42	43	43	44	45	46	47	48	49	50	51	54	52	53	53	54
2	51	54	52	53	54	54	55	56	57	58	59	60	61	62	63	63	64	65
3	47	48	48	49	50	51	52	53	54	55	56	57	58	58	59	60	61	62
6	59	60	61	62	63	63	64	65	66	67	68	68	69	70	71	72	73	74
7	54	55	56	57	58	59	60	60	61	62	63	64	65	66	66	67	68	69
8	49	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65
9	48	49	50	51	52	53	54	55	56	56	57	58	59	60	61	62	63	64
10	45	46	47	48	49	49	50	51	52	53	54	55	56	57	58	59	60	61
11	47	48	49	50	51	52	53	54	55	56	56	57	58	59	60	61	62	63
12	55	56	57	58	59	59	60	61	62	63	64	65	66	67	68	69	70	71
13	47	48	49	50	51	52	53	53	54	55	56	57	58	59	60	61	62	63
14	48	49	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64
15	52	53	54	55	56	56	57	58	59	60	61	62	63	64	65	66	67	68
16	55	56	57	58	59	70	71	72	73	74	75	76	77	78	79	80	81	82
17	48	48	49	50	51	52	53	54	55	55	56	57	58	59	60	61	62	63
20	48	49	50	51	51	52	52	53	54	55	56	57	58	59	60	61	62	63
21	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71
22	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65
24	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75
25	51	51	52	53	54	55	56	57	57	58	59	60	61	62	63	64	65	66
	3	3	2	0	2	5	1	2	1	2	1	1	0	2	1	1	1	0
	R_{25}	R_{24}	R_{22}	R_{21}	R_{20}	R_{17}	R_{16}	R_{15}	R_{14}	R_{13}	R_{12}	R_{11}	R_{10}	R_9	R_8	R_7	R_6	R_3

	31/12	02/01	03/01	04/01	05/01	06/01	07/01	09/01	10/01									
	2	3	4	1	2	3	2	3	4									
	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	
	55	56	57	58	59	59	59	60	61									
	66	67	68	69	70	71	72	73	74									
	63	64	65	66	67	68	69	70	71									
	75	76	77	77	78	79	80	81	82									
	70	71	72	73	74	75	76	77	78									
	66	67	68	69	69	70	71	72	73									
	68	66	69	68	69	70	71	72	72									
	62	63	63	64	65	66	67	68	69									
	64	65	66	69	68	68	69	70	71									
	72	72	73	74	74	74	75	76	77									
	63	64	65	66	67	68	69	70	71									
	65	66	67	68	69	69	70	71	72									
	69	70	71	71	72	72	72	73	74									
	82	83	84	85	86	87	88	89	90									
	63	64	65	66	67	68	69	70	71									
	64	65	66	67	67	68	69	70	71									
	72	73	74	74	75	76	77	78	79									
	65	65	66	66	67	68	68	69	70									
	76	77	78	78	79	80	81	82	83									
	67	68	69	70	71	71	72	73	74									
	4	2	1	5	3	6	3	0	1									
	R_{31}	R_{30}	R_{29}	R_{28}	R_{27}	R_{26}	R_{23}	R_{22}	R_{21}									

Sl. No	Reg. No.	Name	Date	29/8	30/8	1/9	2/9	3/9	5/9	6/9	07/09	13/09
			Period	3	4	2	3	2	3	4	1	4
			S.No.	1	2	3	4	5	6	7	8	9
27	26	G. Harshitha		1	2	3	4	5	6	7	8	9
28	27	G. Shiva prasad		1	1	1	1	2	2	3	4	5
29	28	H. Mahesh		1	2	3	4	5	6	7	8	8
30	29	J. Anil		0	0	0	1	2	3	4	5	5
31	30	J. Shivani		1	2	3	3	4	4	5	5	6
32	31	K. Sambashiva		0	1	1	1	2	3	4	5	5
33	33	K. Nithya Sri		0	1	2	3	4	4	4	5	6
34	34	K. Sreeja Reddy		1	1	2	2	3	3	4	5	5
35	35	K. Laya		0	1	1	2	3	4	5	6	7
36	36	K. Bhavana		1	1	2	2	3	3	4	4	4
37	37	K. Yashwanth Sai		0	0	1	2	3	4	5	6	6
38	38	K. Tharun Tej		1	1	1	1	1	2	3	4	5
39	39	K. Pranavi		0	1	1	1	1	2	3	4	5
40	40	K. Kumar		0	0	0	1	2	3	4	5	5
41	41	K. Srilatha		1	2	2	3	3	3	3	3	3
42	42	J. Loura vikona		0	0	0	1	2	3	4	5	5
43	44	M. Paramesh		0	0	1	1	1	2	3	4	4
44	45	M. Saroja		1	1	1	2	3	4	5	6	6
45	47	M. Anil kumar		0	0	1	1	1	2	3	4	5
46	48	M. Sravani		0	0	0	1	2	3	4	5	6
47	49	M. Chandrika		1	2	3	4	5	6	7	8	9
48	50	M. Vaishnavi		1	1	1	1	2	3	4	5	6
49												
50												
51												
52												
No. of absentees				11	13	12	10	5	6	2	3	11
Sign. of the Faculty				B'	B'	B'	B'	B'	B'	B'	B'	B'

14/09	15/09	16/09	19/09	20/09	21/09	23/09	25/09	26/09	27/09	30/9	20/09	10/10	11/10	12/10	13/10	14/10
1	2	2	3	4	1	2	3	2	3	4	1	3	3	4	1	2	3
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
5	5	6	6	6	6	7	7	8	9	10	11	12	13	13	14	15	16
8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	23	24
5	5	5	5	5	6	7	8	9	10	11	12	13	14	15	15	16	17
7	7	7	8	9	10	11	12	13	14	15	16	17	18	18	19	20	21
5	5	5	5	5	6	7	8	9	10	11	12	13	14	15	15	16	17
6	6	6	7	7	7	7	8	9	10	11	12	13	14	14	15	16	17
5	5	5	5	5	6	7	8	9	10	11	12	13	14	14	15	16	17
7	7	8	8	8	8	8	9	10	11	12	13	14	15	16	17	18	18
4	4	4	4	4	5	6	7	8	9	10	11	12	12	13	14	15	16
6	7	7	7	7	8	9	10	11	12	13	14	15	16	17	17	18	19
5	5	5	6	7	7	8	8	9	9	10	11	12	13	13	14	15	16
5	6	6	6	7	7	7	7	8	9	10	11	12	13	14	15	15	16
5	5	5	5	5	6	7	8	9	10	11	12	13	14	15	15	16	17
3	3	3	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
5	6	7	8	9	10	11	12	13	14	15	16	17	18	18	19	20	21
4	4	4	4	4	5	6	7	8	9	10	11	12	13	14	14	15	16
6	7	7	7	7	8	9	10	11	12	13	14	15	16	17	18	19	20
6	6	6	6	6	6	7	8	9	10	11	12	13	14	15	16	17	18
6	6	7	8	8	8	9	9	10	10	11	12	13	13	14	15	16	17
10	10	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
7	8	9	10	10	10	11	12	13	14	15	16	17	18	19	20	21	22
18	16	15	13	14	8	3	4	0	2	0	0	0	2	2	6	2	1
B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'

15/10	17/10	18/10	19/10	21/10	22/10	25/10	26/10	27/10	28/10	29/10	31/10	01/11	02/11	04/11	05/11	07/11	08/11
2	3	4	2	3	2	4	2	1	3	2		4	1	3	2	3	4
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
17	18	19	20	21	24	21	21	21	22	23	24	25	25	25	26	27	28
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
18	19	20	21	22	22	22	23	23	23	24	25	26	26	27	27	28	29
22	23	24	25	26	29	28	29	30	31	32	33	34	35	35	36	36	37
18	19	20	21	22	22	22	22	22	22	23	24	25	25	25	25	26	27
18	19	20	21	21	21	21	22	23	24	25	26	27	28	28	28	28	29
18	19	20	21	22	22	22	22	23	24	25	26	26	26	26	27	28	29
19	20	21	22	22	23	24	25	25	25	26	27	28	29	30	30	30	31
17	18	19	20	20	20	21	21	21	22	23	24	25	26	25	28	26	27
20	21	22	23	24	25	25	25	25	26	27	28	29	30	30	30	30	31
17	18	19	20	20	20	20	20	21	22	23	24	24	24	24	25	26	27
17	18	19	20	20	20	20	21	22	23	24	25	26	26	27	28	28	28
18	19	20	21	22	22	22	23	24	25	26	27	28	29	30	31	32	33
18	19	20	21	22	22	23	24	25	26	27	28	28	28	29	30	31	32
22	23	24	25	26	27	28	29	29	30	31	32	33	34	34	34	35	36
17	18	19	20	21	22	23	24	25	26	27	28	28	29	30	31	32	32
21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
19	20	21	22	23	23	23	23	24	25	26	27	28	28	29	30	31	31
18	19	20	21	22	23	24	25	26	27	28	29	29	30	30	31	32	33
26	27	28	29	29	29	30	31	32	33	34	35	36	36	37	37	38	39
23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
0	0	0	0	6	12	10	7	7	3	0	0	6	10	10	7	5	3
B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'

09/11	11/11	12/11	14/11	15/11	16/11	18/11	19/11	21/11	22/11	23/11	25/11	26/11	28/11	29/11	30/11	01/12	02/12
1	3	2	3	4	1	3	2	3	4	1	3	2	3	4	1	4	3
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61
29	30	31	32	33	34	34	34	34	35	36	37	38	40	41	42	43	44
43	44	45	46	47	48	49	50	51	51	51	52	53	54	55	56	57	58
30	31	32	33	34	35	35	35	36	37	38	39	40	41	42	43	44	45
38	39	40	41	42	42	43	44	45	45	46	47	48	49	50	51	52	53
28	29	30	31	32	33	33	34	35	36	36	36	37	38	39	40	41	42
30	31	32	33	34	35	36	36	36	36	37	38	39	40	41	42	42	44
30	31	32	33	34	35	36	36	37	37	37	38	39	40	41	42	43	44
32	33	34	35	36	37	38	38	38	38	39	40	41	42	43	44	45	46
28	29	30	31	32	33	33	34	34	35	36	37	38	39	40	41	42	43
32	33	34	35	36	37	37	37	38	39	40	41	42	43	44	45	46	47
28	29	30	31	32	33	34	34	35	36	36	37	38	39	40	41	42	43
29	30	31	32	33	34	35	36	37	37	38	39	39	40	41	42	43	44
34	35	36	37	38	39	39	40	40	41	42	43	44	45	46	47	48	49
33	34	35	36	37	38	39	39	40	41	42	42	43	44	45	46	47	48
37	38	39	40	41	42	43	44	45	45	45	46	47	48	49	50	51	52
33	34	35	36	37	38	38	39	39	39	40	41	42	43	44	45	46	47
39	40	41	42	43	44	44	45	45	46	46	47	48	49	50	51	52	53
32	33	34	35	36	37	38	38	39	39	39	40	41	42	43	44	45	46
34	35	36	37	38	39	40	40	41	42	43	44	45	45	45	46	47	48
40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57
41	42	43	44	45	46	47	48	49	50	51	51	52	53	54	55	55	57
0	0	0	0	0	1	9	9	7	9	7	3	1	1	1	0	0	0
B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'

	03/12	04/12	05/12	06/12	07/12	08/12	09/12	10/12	12/12	13/12	14/12	22/12	23/12	26/12	27/12	28/12	29/12	30/12
	2	1	3	4	1	2	3	2	3	4	1	2	1	3	4	1	4	3
	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
26	62	63	64	65	66	66	67	68	69	70	71	72	73	74	75	75	76	77
27	45	46	47	47	48	49	50	51	52	53	54	55	56	57	58	59	60	60
28	59	60	61	62	63	64	64	65	66	67	68	69	70	71	72	73	74	75
29	46	47	48	49	49	50	51	52	53	54	55	56	57	58	59	60	61	62
30	54	55	56	57	58	59	59	60	60	61	62	63	64	64	65	66	66	67
31	43	44	45	45	46	47	48	49	50	51	52	53	54	54	55	56	57	58
33	45	46	47	48	49	50	50	51	52	53	54	55	56	57	58	59	59	60
34	45	46	47	47	48	49	50	51	51	52	53	54	55	55	56	56	57	57
35	47	48	49	50	51	51	52	53	54	55	56	57	58	59	59	60	61	62
36	44	45	46	47	47	48	49	50	51	52	53	54	55	56	56	57	58	59
37	48	49	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	63
38	44	45	46	47	48	49	49	50	51	52	53	54	55	56	57	58	59	60
39	45	46	47	48	48	49	50	51	52	53	54	55	56	57	58	59	60	61
40	50	51	52	53	54	55	55	56	57	58	59	60	61	62	63	64	65	66
41	49	50	51	52	52	53	54	55	56	57	58	59	60	61	62	63	64	65
42	53	54	55	56	57	58	58	59	60	61	62	63	64	65	66	67	68	69
44	48	49	50	51	52	53	54	55	55	56	57	58	59	60	61	62	63	64
45	54	55	56	57	58	58	59	60	61	62	63	64	65	66	67	68	69	70
47	47	48	48	49	50	51	51	52	53	54	55	55	56	57	57	57	58	59
48	49	50	51	52	52	53	54	55	56	57	58	59	60	60	61	62	63	64
49	58	59	59	60	61	62	63	64	65	66	67	68	69	70	70	71	72	73
50	58	59	60	61	62	63	63	64	64	65	66	67	68	69	70	71	71	72
	0	0	3	3	5	3	8	0	4	0	0	1	0	4	4	3	3	3
	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1	B1

	31/12	02/01	03/01	04/01	05/01	06/01	07/01	08/01	10/01									
	2	3	4	1	2	3	2	3	4									
	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99
26	78	79	80	81	82	83	84	85	86									
27	61	62	63	64	65	66	67	68	69									
28	75	76	77	78	79	80	81	82	83									
29	63	64	64	65	66	67	68	69	70									
30	68	69	69	70	71	72	73	74	75									
31	59	60	61	62	63	64	65	66	67									
33	61	62	63	64	65	66	67	68	69									
34	58	59	60	61	62	63	64	65	66									
35	63	64	65	66	67	68	69	70	71									
36	60	61	62	63	64	65	66	67	68									
37	64	65	66	67	68	69	70	71	72									
38	61	62	62	63	64	65	66	67	68									
39	62	63	64	65	66	66	67	68	69									
40	67	68	68	69	70	71	72	73	74									
41	65	66	67	68	68	69	70	71	73									
42	69	70	71	72	73	74	75	76	77									
44	65	66	67	68	68	69	69	69	70									
45	71	71	72	73	74	75	76	77	78									
47	60	61	62	63	64	65	66	67	68									
48	65	66	67	68	69	70	71	72	73									
49	74	75	76	77	78	79	80	81	82									
50	73	74	75	76	77	78	79	80	81									
	2	1	4	0	2	1	1	1	0									
	B1	B1	B1	B1	B1	B1	B1	B1	B1									

Sl. No	Reg. No.	Name	Date	29/8	30/8	1/9	2/9	3/9	5/9	06/09	07/09	13/09
			Period	1	2	1	1	4	1	2	3	2
			S.No.	1	2	3	4	5	6	7	8	9
1	51	M. Rispa chelsi		1	2	3	4	5	6	7	8	9
2	52	M. Shaker ramani		1	2	3	4	5	6	7	8	9
3	53	M. Sai Keerthi		1	2	3	4	5	6	7	8	9
4	54	M. chandana		1	2	3	4	5	6	7	8	9
5	55	N. Likitha		1	2	3	4	5	6	7	8	9
6	56	N. Bhavani		1	2	3	4	5	6	7	8	8
7	57	N. Sai kiran		1	2	3	4	5	6	7	8	9
8	58	Neha		1	2	3	4	5	6	7	8	9
9	59	N. sneha		1	2	3	4	5	6	7	8	9
10	60	N. Nishanth		1	2	3	4	5	6	7	8	9
11	61	Noor sultana		1	2	3	4	5	6	7	8	9
12	62	P. sushma		1	2	3	4	5	6	7	8	9
13	63	P. Arun kumar		1	2	3	4	5	6	7	8	9
14	64	P. Nikhil rao		1	2	3	4	5	6	7	8	9
15	65	P. sowmya		1	2	3	4	5	6	7	8	9
16	67	P. sahana		1	2	3	4	5	6	7	8	9
17	68	P. Deevena kumari		1	2	3	4	5	6	7	8	8
18	69	P. Devendar		1	2	3	4	5	6	7	8	9
19	70	P. Deekshitha		1	2	3	4	5	6	7	8	9
20	71	P. Akhila kumari		1	2	3	4	5	6	7	8	9
21	72	P. Anusha		1	2	3	4	5	6	7	8	9
22	73	Sai sri. P		1	2	3	4	5	6	7	8	9
23	74	P. Rajya lakshmi		1	2	3	4	5	6	7	8	9
24	75	R. Abhinav		1	2	3	4	5	6	7	8	9
25												
26												
No. of absentees				0	0	0	0	0	0	0	0	2
Sign. of the Faculty				Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri

14/09	15/09	16/09	19/09	20/09	21/09	22/09	23/09	24/09	26/09	27/09	29/09	30/09	10/10	11/10	12/10	13/10	14/10
3	1	1	1	2	3	4	1	4	1	2	3	1	1	2	3	4	1
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	10	11	11	12	13	14	14	15	16	17	18	19	20	21	22	23	24
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	10	10	11	12	13	14	15	16	17	18	19	20	20	21	22	23	24
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	13	14	15	16	17	18	19	20	21	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	22	23	24	25	26
9	9	10	11	12	13	14	15	16	17	18	19	20	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
1	3	1	1	1	0	0	1	0	0	0	0	0	2	0	0	0	0
Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri	Ri

03/12	04/12	05/12	06/12	07/12	08/12	09/12	10/12	12/12	13/12	14/12	22/12	23/12	26/12	27/12	28/12	29/12	30/12
4	1	1	2	3	4	1	4	1	2	3	4	1	1	2	3	4	1
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
62	63	64	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
61	62	63	64	65	66	67	68	69	70	71	76	77	78	79	80	81	82
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81
0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	B'	A'	A'	B'	B'	B'	B'

31/12	02/01	03/01	04/01	05/01	06/01	07/01	09/01	10/01
4	1	2	3	4	1	4	1	2
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
81	82	83	84	85	86	87	88	89
82	83	84	85	86	87	88	89	90
79	80	81	82	83	84	85	86	87
81	82	83	84	85	86	87	88	89
82	83	84	85	86	87	88	89	90
83	84	85	86	87	88	89	90	91
81	82	83	84	85	86	87	88	89
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
81	82	83	84	85	86	87	88	89
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
79	80	81	82	83	84	85	86	87
82	83	84	85	86	87	88	89	90
80	81	82	83	84	85	86	87	88
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
81	82	83	84	85	86	87	88	89
82	83	84	85	86	87	88	89	90
82	83	84	85	86	87	88	89	90
0	0	0	0	0	0	0	0	0
B'	B'	B'	B'	B'	B'	B'	B'	B'

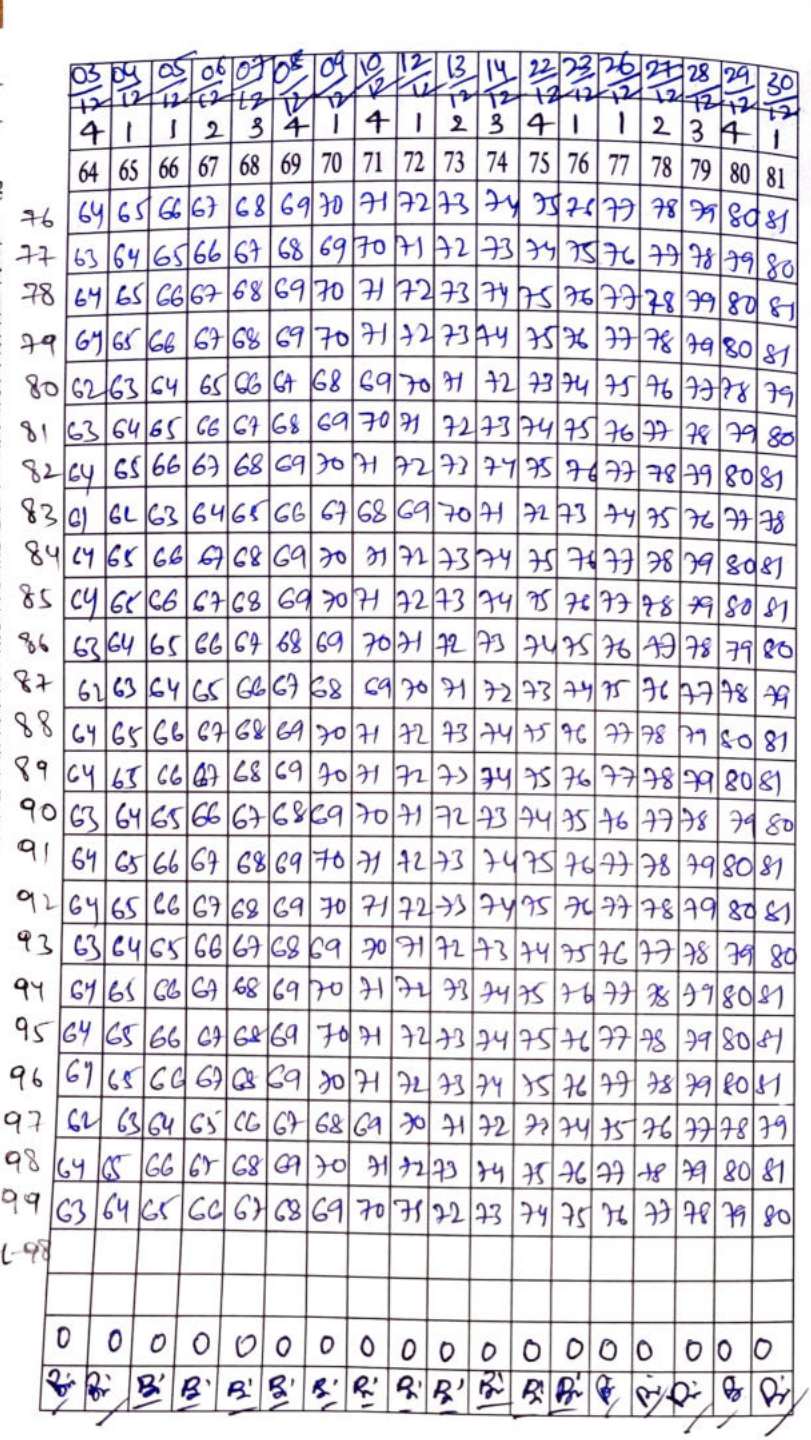
Sl. No	Reg. No.	Name	Date	29/8	30/8	1/9	2/9	3/9	5/9	06/09	07/09	13/09
			Period	1	2	1	1	4	1	2	3	2
			S.No.	1	2	3	4	5	6	7	8	9
27	76	R. Akhila		1	2	3	4	5	6	7	8	9
28	77	R. Akshitha		1	2	3	4	5	6	7	8	9
29	78	R. Geetha Priya		1	2	3	4	5	6	7	8	9
30	79	R. Akhila		1	2	3	4	5	6	7	8	9
31	80	R. Sai Arjun		1	2	3	4	5	6	7	8	9
32	81	R. Pradeep		1	2	3	4	5	6	7	8	9
33	82	R. Nandini		1	2	3	4	5	6	7	8	9
34	83	R. Aishwarya		1	2	3	4	5	6	7	8	9
35	84	S. Akshitha		1	2	3	4	5	6	7	8	9
36	85	S. Tejaswi		1	2	3	4	5	6	7	8	9
37	86	S. Tejaswi		1	2	3	4	5	6	7	8	9
38	87	S. Mahitha Vani		1	2	3	4	5	6	7	8	9
39	88	Shaik Mustafa		1	2	3	4	5	6	7	8	9
40	89	Shakeera		1	2	3	4	5	6	7	8	9
41	90	S. Harikanth		1	2	3	4	5	6	7	8	9
42	91	S. Sai Krishna		1	2	3	4	5	6	7	8	9
43	92	S. Gayathri		1	2	3	4	5	6	7	8	9
44	93	M.V. Srihari lakshm		1	2	3	4	5	6	7	8	9
45	94	S. Saina Sar		1	2	3	4	5	6	7	8	9
46	95	S. Fasi Ahmed		1	2	3	4	5	6	7	8	9
47	96	T. Thirumala		1	2	3	4	5	6	7	8	9
48	97	T. Srija		1	2	3	4	5	6	7	8	9
49	98	V. Ramya Sree		1	2	3	4	5	6	7	8	9
50	99	Parinitha		1	2	3	4	5	6	7	8	9
51	7L-98	C. Priyanka		1	2	3	4	5	6	7	8	9
52												
No. of absentees				0	0	0	0	0	0	0	0	0
Sign. of the Faculty												

15/09	16/09	19/09	20/09	21/09	22/09	23/09	26/09	26/09	27/09	29/09	30/09	10/10	11/10	12/10	13/10	14/10
3	1	1	1	2	3	4	1	4	1	2	3	1	1	2	3	4	1
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	24	25	26
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
9	9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	26
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
4	4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

IV (8)

05/10	17/10	18/10	19/10	21/10	22/10	25/10	26/10	27/10	28/10	29/10	31/10	01/11	02/11	04/11	05/11	07/11	08/11
4	1	2	3	1	4	2	3	1	1	4	1	2	3	1	4	1	2
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	39	40	41	42	43	44
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	39	40	41	42	43	44
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0

09/11	11/11	12/11	14/11	15/11	16/11	18/11	19/11	21/11	22/11	23/11	25/11	26/11	28/11	29/11	30/11	01/12	02/12
3	1	4	1	2	3	1	4	1	2	3	1	4	1	2	3	1	1
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
45	46	48	49	50	50	51	52	53	54	55	56	57	58	59	60	61	62
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61
45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	50	51	52	53	54	55	56	57	58	59	60	61	62
44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61
46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63
46	47	48	49	50	50	51	52	53	54	55	56	57	58	59	60	61	62
0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0



RECORD OF CLASS WORK

Date	Period	Topics Covered
		unit - I
29/8/22	3	Introduction on pilot plant scale up
30/8/22	4	General considerations - including significance of personnel requirements
01/09/22	2	Space requirements, raw materials
2/9/22	3	pilot plant scale up consideration for solids
3/9/22	2	pilot plant scale up considerations for solids
5/9/22	3	Pilot plant scale up considerations for oral liquids
6/9/22	4	pilot plant scale up consideration for oral liquids
7/9/22	1	Pilot plant scale up considerations for semi-solids
13/9/22	4	Relevant documentation of pilot plant scale up
14/9/22	1	SUPAC guidelines
15/9/22	2	SUPAC guidelines
16/9/22	2	Introduction to platform technology
19/9/22	3	REVISION
		unit - II
20/9/22	4	Introduction to technology transfer
21/9/22	1	WHO guidelines for tabnology transfer
22/9/22	2	Technology transfer protocol
23/9/22	3	Quality risk management

HOD / Principal Sign

Teacher Sign

RECORD OF CLASS WORK

Date	Period	Topics Covered
24/9/22	2	Transfer from R&D to production
26/9/22	3	Transfer from R&D to Production
27/9/22	4	Granularity of TT Process
29/9/22	1	Documentation, premises & equipments
30/9/22	3	Qualification & validation
10/10/22	3	Quality control: Analytical method transfer
11/10/22	4	TT (Technology transfer) agencies in India
12/10/22	1	Commercialization - Partical aspects & problems
13/10/22	2	APCTD, NRDC
14/10/22	3	TIFAC, BCIL
15/10/22	2	TBSE/SIDBI
17/10/22	3	Technology of transfer related documents confidentiality agreements.
18/10/22	4	Licensing MOUs legal issues
19/10/22	2	Licensing MOUs legal issues
21/10/22	3	REVISION
		unit - III
22/10/22	2	Introduction to regulatory affair
25/10/22	4	Historical Overview of regulatory affairs
26/10/22	2	Regulatory authorities working in different countries of world
27/10/22	1	Role of regulatory affairs department
28/10/22	3	Responsibilities of regulatory affairs Professionals

HOD / Principal Sign

Teacher Sign

RECORD OF CLASS WORK

Date	Period	Topics Covered
29/10/22	2	Drug development team.
31/10/22	3	Non clinical drug development process
1/11/22 - 5/11/22	4	I Mid exams
7/11/22	3	Pharmacology study in non-clinical drug development
8/11/22	4	pharmacokinetics study in non-clinical drug development process
9/11/22	1	Toxicology study in non-clinical drug development process
11/11/22	3	General considerations of IND application
12/11/22	2	General considerations of IB
14/11/22	3	General consideration of NDA
15/11/22	4	clinical research
16/11/22	1	Bioequivalence studies
18/11/22	3	clinical research protocols
19/11/22	2	Biostatistics in pharmaceutical product development
21/11/22	3	Data presentation for FDA submission
22/11/22	4	Management of clinical studies
23/11/22	1	clinical research protocols
25/11/22	3	REVISION
		unit - IV
26/11/22	2	Quality management & certifications
28/11/22	3	Concept of Quality

HOD / Principal Sign

Teacher Sign

RECORD OF CLASS WORK

Date	Period	Topics Covered
29/11/22	4	Total quality Management
30/11/22	1	Quality by design
1/12/22	4	six sigma Concept
2/12/22	3	Out of specifications
3/12/22	2	Change Control
4/12/22	1	Introduction to ISO9000 series of quality systems standards
5/12/22	3	ISO 14000
6/12/22	4	NABL
7/12/22	1	GLP
8/12/22	2	Revision on quality by design
		unit - V
9/12/22	3	Introduction on regulatory authorities
10/12/22	2	Introduction to India regulatory syster
12/12/22	3	Drug regulatory authority of India
13/12/22	4	Central Drug Standard control organisation
14/12/22	1	State Licensing Authority
22/12/22	2	Organisation, Responsibilities,
23/12/22	1	Drug controller general of India (DCGI)
26/12/22	3	common technical Document
27/12/22	4	certificate of pharmaceutical product
29/12/22	1	Approval procedure for new drugs in India
30/12/22	4	Regulatory requirements

HOD / Principal Sign

Teacher Sign

RECORD OF CLASS WORK

Date	Period	Topics Covered
30/12/22	3	National pharmaceutical pricing authority (NPPA)
31/12/22	2	Deficiencies and limitations of drug regulatory system
2/1/23	3	Revision & test on unit - V
3/1/23 - 7/1/23		II Mid exams
9/1/23	3	Revision & test on unit - III
10/1/23	4	Revision & test on unit - II

HOD / Principal Sign

Teacher Sign