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

NAAC Criteria I Cycle 3

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

B. Pharm. I YEAR I & II SEMESTERS

LSEM

S. No	Description	Duration	
		From	То
1	Commencement of I Semester classwork / Orientation programme		28.11.2022
2	1 st 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	2 nd 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

C No	Description	Duration		
S. No		From	То	
1	Commencement of II Semester classwork		01.05.2023	
2	1 st 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	2 nd 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

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

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

1 SEM

S. No	Description	Duration	
		From	To
]	Commencement of I Semester classwork	28.11.2022	
2	1 st 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 (1 week)	
5	2 nd 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	
)	End Semester Examinations	17.04.2023	29.04.2023 (2 Weeks)

Note: No. of Working / Instructional Days: 93

H SEM

S. No	Description	Duration	
		From	То
1	Commencement of II Semester classwork		01.05.2023
2	1 st 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 (1 Week)	
6	2 nd Spell of Instructions	18.07.2023	11.09.2023 (8 Weeks)
7	Second Mid Term Examinations	12.09.2023	16.09.2023 (8 Weeks)
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

Wishnu Institute of Pharmaceutical

Education & Research

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD <u>ACADEMIC CALENDAR 2022-23</u>

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

I SEM

S. No	Description	Duration	
		From	То
1	Commencement of I Semester classwork		09.09.2022
2	1 st 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	2 nd 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	То
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		
5	2 nd 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

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD <u>ACADEMIC CALENDAR</u> 2022-23

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

I SEM

S. No	Description	Duration		
131 140		From	То	
1	Commencement of I Semester classwork		29.08.2022	
2	1 st 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	2 nd 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	
5.110		From	То
1	Commencement of II Semester classwork		03.02.2023
2	1 st 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	2 nd 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

Vishnu Institute of Phermaceutical
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Phermaceutical
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Phermaceutical

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

ACADEMIC CALENDAR 2022-23

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

I SEM

S. No	Description Commencement of J Semester classwork	Duration	
D. 140		From	То
1			26.10.2022
2	1 st 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	2 nd 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	
136 140		From	То
1	Commencement of II Semester classwork		27.03.2023
2	1 st 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	2 nd 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

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JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD ACADEMIC CALENDAR 2022-23

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

1 SEM

S. No	Description	Duration	
D5 140		From	То
1	Commencement of I Semester classwork		21.10.2022
2	1 st 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	2 nd 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

U 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)	V 2 10 7 (20 C) 200	
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 -1

Note: | 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.



7. MLTP & Academic dairy

> MLTP

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

MICRO LEVEL TEACHING PLAN

Academic year: 2022 / 23

Name of the program: B. Pharmacy

Year/ Semester: IV/I

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/Refere nce Book	Instructional objective (Unit wise)	P.Os	Teaching aids BB/LCD GD/Dem o
		UNIT-I	I	2.		
1	29/08/2022	Introduction on pilot plant scale up	T1,T3,T5		1,8	LCD
2	30/08/2022	General considerations - including significance of personnel requirements	T1,T4,T5	Understandin g of	1,8,11	BB
3	01/09/2022	space requirements, raw materials	T1,T3,T5	pilot plant	1,11	LCD
4	02/09/2022	Pilot plant scale up considerations for Solids	T2,T3,T5	design, scale up techniques	1,4	BB
5	03/09/2022	Pilot plant scale up considerations for Solids	T2,T3,T5	& SUPAC guidelines	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	LCI
10	14/09/2022	SUPAC guidelines	T1,T4,T5	1	1,8	LCI
11	15/09/2022	SUPAC guidelines	T1,T2,T4	1	1,8	LCI
12	16/09/2022	Introduction to Platform technology	T1,T4	1	1,6,9	BE
13	19/09/2022	REVISION	T2,T4	-	1,6,11	BE
		UNIT -			-,-,-	
15	20/09/2022	Introduction to Technology Transfer			1, 8, 11	BI
16	21/09/2022	WHO guidelines for Technology Transfer	T1,T4		1,7	LC
17	22/09/2022	Technology transfer protocol	T1,T4	1	1, 11	BE
18	23/09/2022	Quality risk management,	1.,.,		1,2	BE
19	24/09/2022	Transfer from R & D to production	T1,T4	1	1, 11	BE
20	26/09/2022	Transfer from R & D to production	T1,T4	1	1,11	B
21	27/09/2022	Granularity of TT Process	T1, T4	Recognize the	1, 6, 10	В
22	29/09/2022	Documentation, Premises and equipments.	T1, T2,T3,T4	steps involved in technology	1,7, 11	LC
23	30/09/2022	Qualification and validation	T1, T2,T3,T4	transfer & the role of	1, 5, 6	LC
24	10/10/2022	Quality control: analytical method transfer	T1, T2,T3,T4	regulatory body and	1,11	LC
25	11/10/2022	TT (Technology Transfer) agencies in India	T1, T2,T3,T4	agencies in technology	1,7	LC
26	12/10/2022	Commercialization – practical aspects and problems	T1, T2,T3,T4	transfer.	1, 11	LC
27	13/10/2022	APCTD, NRDC	T1, T2,T3,T4		1, 11	LC
28	14/10/2022	TIFAC, BCIL	T1, T2,T3,T4		1, 6	LC
29	15/10/2022	TBSE / SIDBI	T1, T2,T3,T4		1, 11	LC
30	17/10/2022	Technology of Transfer related documents confidentiality agreements,	T1, T2,T3,T4		1, 6	LC
31	18/10/2022	Licensing MoUs, legal issues	T1,T4	1	1 4 11	7.0
32	19/10/2022	Licensing MoUs, legal issues	T1, T2,T3,T4		1,4,11	LC LC
33	21/10/2022	REVISION	T3,T4		1	
		UNIT-I			1,6	BI
35	22/10/2022	Introduction to Regulatory Affairs	T1,T2,T3,T4		1.	Y 01
36	25/10/2022	Historical Overview of regulatory affairs	T1,T2,T3,T4	Will gain in- depth	1, 6	LCI LCI
37	26/10/2022	Regulatory authorities working in	T1 T2 T2 T	knowledge		
7/	20/10/2022	regulatory authorities working in	T1,T2,T3,T4	wreage	1, 4, 6	LCI

20	25	different countries of world		the role and		
38	27/10/2022	Role of regulatory affairs department	T1,T2,T3,T4	scope of regulatory	1,7	LCD
39	28/10/2022	Responsibilities of regulatory affair professionals	T1,T2,T3,T4	affairs in	1,11	LCD
40	29/10/2022	Drug development teams	T1,T2,T3,T4	pharmaceutic al industry	1,6,7	BB
41	31/10/2022	Non clinical drug development process	T1,T2,T3,T4		1,4,6	BB
004-000	01/11/2022 To	I mid exams				
42	05/11/2022	N -		(2)		
43	07/11/2022	Pharmacology study in non-clinical drug development	T1 ,T4		1,6	ВВ
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	2 BC.	1,4,6	LCD
47	12/11/2022	General considerations of IB (Investigators brochure)	T1,T2		1,4,9	BB
	14/11/2022	General considerations of NDA	T1,T4	_×	1, 5	LCD
48		(New drug application)				
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	147	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
		TINKE	TXZ			
	26/11/2022	UNIT - Quality management &	T1,T2,T3,T4	T	220	DD
58		Certifications			2, 3, 9	BB
59	28/11/2022	Concept of Quality	T1,T2,T3,T4	To know and	1, 8,	LCD
60	29/11/2022	Total Quality Management	T1,T2,T3,T4	apply the	1, 3, 6	BB
	30/11/2022	Quality by design	T3,T4	standards of	2, 3, 9	LCD
61	01/12/2022	Six Sigma concept	T3,T4	ISO for	2,3,9	BB
62	02/12/2022	Out of Specifications	T3,T4	quality	1, 8,	LCD
63	- 175		· ·	assurance in	11	
00	03/12/2022	Change control	T3,T4	developing	1, 3, 6	LCD

	04/12/2022	Introduction to ISO 9000 series of	T3,T4	and delivering	1, 8,	BB
65		quality systems standards		pharmaceutic	11	
66	05/12/2022	ISO 14000	T3,T4	al products	1, 3, 6	BB
67	06/12/2022	NABL	T3,T4		1,10	BB
68	07/12/2022	GLP	T3,T4	1	1,10	BB
69	08/12/2022	Revision on quality by design	T3,T4	1	1,10	BB
		UNIT -V	-			
	09/12/2022	Introduction on Regulatory Authorities	T1,T5		1,4,9,11	BB
71		Transfer on Trogulatory Transferres	11,15	The		
/ 1	10/12/2022	Introduction to India regulatory system	T1,T5	organization	1,3,9	BB
72	10/12/2022	introduction to maja regulatory system	11,13	and	1,5,5	22
72	12/12/2022	Design recognists are such suits and Latin	T1 T6	responsibilit	2, 3, 9	LCD
	12/12/2022	Drug regulatory authority of India	T1,T5	ies of state licensing	2, 3, 9	LCD
73	12/12/2022	G + 1B G + 1 G + 1		authority &	1 2 6	LCD
	13/12/2022	Central Drug Standard Control	T1,T5	The	1, 3, 6	LCD
74	14/12/2022	Organization(CDSCO)	m. m.	regulatory	1 0 11	LCD
75	14/12/2022	State Licensing Authority	T1,T5	requirement	1, 8, 11	LCD F
76	22/12/2022	Organization, Responsibilities	T1,T5	s and	1,4,7	
	23/12/2022	Drug controller general of India	T1,T5	approval procedures	1,3,8	BB
77	26/12/2022	(DCGI)		for new	1.60	BB
78	26/12/2022	Common Technical Document	T1 T5	drugs in	1,6,9	
70	27/12/2022	Certificate of Pharmaceutical Product(COPP)	T1,T5	India.	1, 11	LCD
79	28/12/2022	Regulatory requirements	T1,T2,T3	 	1, 8, 11	LCD
80	29/12/2022	Approval procedure for new drugs in	T3,T4	」	1, 11	LCD
0.1	29/12/2022	India	13,14		1, 11	LCD
81	30/12/2022	National pharmaceutical pricing	T1,T2,T4	 	1,3,11	LCD
02	30/12/2022	authority(NPPA)	11,12,14		1,5,11	LCD
82	31/12/2022	Deficiencies and limitations of drug	T1,T5	1 -	1,9,11	BB
83	31/12/2022	regulatory system	11,10		1,2,11	<i>DD</i>
0.3	02/01/2023	REVISION AND TEST ON UNIT-	T1,T5	1	1,3,11	LCD
84	02/01/2023	V	,		1,5,11	LOD
04	03/01/2023	II MID EXAMS	T1,T5	1 -	1,3,9	ВВ
	TO				-,-,-	22
85	07/01/2023					
	09/01/2023	REVISION AND TEST ON UNIT-	T1,T5		1,3,9,11	BB
86		III				
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 & Researt
Narsapur, Medak Dist.-5021



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

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

Marks : 10

Time : 2:00 PM to 3:30PM

Q. No	Question Description	Marks	со	PO	BL
	PART -A: Answer all		-		
1. a	What are the general consideratios of pilot plant scale up studies?	1	1	1	1,2
	Describe briefly about SUPAC guidelines.	1	1	1	1
С	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

[d,]

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

Non	Objective Exam				
Nan	Hall Ticket No. R				
Aus	r All Questions. All Questions Carry Equal Marks. Time: 20 Min. Marks: 10M.				_
	se the correct alternative:				
1.	Thich of the following is not a space requirement in general consideration of pilot plant? physical testing area b) standard equipment floor space c)storage area d) raw material	[6	l l]	
2.	DA takes a)15 years b) 12 years c) 10 years d) 5 years	[(]	
3.	ey components of TQM are				
	a) Consumer/Customer focus b) Continuous improvement		١		
	c) Involvement of employee d) All of these]	3]	
4.	lentification of critical elements in the process				
	a) Design space b) GAP analysis c) IPQC d) acceptance criteria	[0]	
5.	harmacovigilance is a part of				
	ICH E1 guidelines b) ICH E3 guidelines				
	ICH E2 guidelines d) ICH E2 (A-F) guidelines	[0			
6.	measurable term under which test is considered as acceptable	[(
	Bracketing b) commissioning c) acceptance criteria d) critical control point	[(<u>_</u> ,]	
7.	mmon technical document (CTD) is developed by				
	.USFDA b) MHLW c) ICH d)TGA	[(_	J	
8.	ey components of TQM are				
	a) Consumer/Customer focus b) Continuous improvement		1		
	c) Involvement of employee d) All of these	l	d	J	
9.	entification of critical elements in the process				
	a) a) Design space b) GAP analysis c) IPQC d) acceptance criteria	[6]	
10	narmacovigilance is a part of				
10	ICH E1 guidelines b) ICH E3 guidelines				
	ICH E2 guidelines d) ICH E2 (A-F) guidelines	ſ	A	. 1	ĺ

II Fill in the Blanks

1.	1	- Peartin	an In	ternational i	egulato	ry authority	for drug.			
2.	APCTT 8	stands for			-	:: * :				
3.	Define, of	Measure,	Analyzc,	Improve	and	Control	includes	in	the	concept
4.	Kefauver	- Harries Ai	mendments to	o the FD&C	act			_·		
5.			is regulator	y authority o	f India.					
6	Medicine	control cour	ncil is regulat	ory agency	of					
		PP is issued t								
8.	Process of	of increasing	the batch size	e is called as						
9.	Certificat	tion system for	or laboratory	accreditatio	n					
10.		350	guidel	ines of ICH	describ	es the quali	ty managem	ent sy	stem.	(



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 to charge

Principal PRINCIPAL

Shou Institute of Pharmaceutical
Education & Research

Narsapur, Medak Dist.-502 313, TS.

CONTENTS:

- 1. Vision & Mission of the Institute & Department
- 2. Program Educational Objectives, Program Outcomes & course outcomes
- 3. JNTU Academic calendar & List of holidays
- 4. Registered No of students
- 5. Individual time table
- 6. Syllabus including Text books and Reference books
- 7. MLTP & Academic dairy
- 8. Mapping of Program Outcomes and Course Outcomes
- 9. Content Beyond syllabus
- 10. Mapping of Contents beyond syllabus with Program Outcomes
- 11. Assignment Questions
- 12. Unit wise Questions (subjective, MCQs and Fill in the blanks)
- 13. Assessment Methodology
- 14. I&II Mid Question paper/sub/obj/key. Highest & Lowest Answer scripts
- 15. I&II Sessional marks & Consolidated Attendance (Theory & lab)
- 16. Identification of weak students
- 17. Remedial classes Time table
- 18. Lecture Notes
- 19. Course Assessment
- 20. Analysis of students performance in the course (Result Analysis individual)

PRINCIPAL

Wishnu Institute of Pharmaceutical

Education of Pasearch

Narrageutical

10 313. 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.

: 2029-2027

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

Designation

: P. Dwga Bhavani : Assistant protenon

INTUH Faculty ID

: 48150406-135026

Department

: pharmaceubics

Name of the Course

: Industrial pharmay - II

Course Code

Number of Credit

Year & Semester

· [x]]

No. of Students Registered:

42+49 = 91

Month	BUA	sep	oct	Nov	Dec	Jan
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HOD / Principal			1			A

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RECORD OF CLASS WORK

Date	Period	Topics Covered
		unit-1
29/8/22	3	Introduction on pilot plant scale up
30 8 22	4	General considerations - including
	•	rightflance of personnel sequisements-
01 09 22	2_	space requirements, now materials
2 19/22	3	pilot plant scale up considerations for solids
319/22	2	pilot plant scale up considerations for volids
5 9 22	3	Prot plant scale up considerations for
		and liquide
69/22	4	Pilot plant scale up consideration for
		oral liquide
7/9/22	1	Pilot plant rode up considerations for
		remi-solide
13 9 22	4	Relevant documentation of pulot plant
		scale up
14/9/22	1	SUPAC quidelines
11/9/22	2	SUPAC quidelines
10/9/22	2	Introduction to platform technology
19/9/22	3	REVISION
		unit-11
20/9/22	4	Introduction to technology transfer
21/9/22	1	WHO guidelines for to motogy transfer
2/9/22	2 (Technology transfer protocol
13/9/22	3	Quality acre management
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RECORD OF CLASS WORK

Date	Period	Topics Covered
29 9 22	2,	Transfer from Pf D to production
26 9 22	8	Transfer from P4D to Production
27 9/22	4	Granulassby of TT Process
29/9/22	1	Do cymentation, premiser & equipments
30/9/22	3	Qualification & validation
10/10/22	3	Quality control: Analytical me that transfer
11/10/22	4	TT (folyplogy framely) agencies in India
12/10/22	1	Commercialization-protical aspects of problems
13/10/20	2	APCTD, NRDC
14/10/22	3	TIFAC, BCIL
10/20/20	2	TBSE/SIDBI
17/10/22	3	Technology of transfer related documents
	, y	confidentiality agreements.
18/10/22	牛	Licensing Modellegal issue
19/10/22	2	Licensing Mouselegal assus
21/10/22	3	REVISION
۸.		unit - III
22 10 22	2	Introduction to regulatory offairs
25/10/20	4	Historical overview of regulatory affair
26/10/22	2	Regulatory authorities wasking in
		different countries of world
27/10/22	1	Role of regulatory affairs department
28/10/20	3)	Responsibilities of regulatory affair
		professionale

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RECORD OF CLASS WORK

2 3 4 3 4-	Daug development team: Non clinical daug development process I Mid exam: tharmacology study in non-clinical daug development phormatolistics study in non-clinical daug development process Toxicology study in non-clinical
4 3 4-	Non clinical daug development process I Mid exams Pharmacology study in non-clinical daug development pharmatolinatics study in non-clinical daug development process Toxitology study in non-clinical
3 4-	phormatokinetice study in non-clinical day development process. Toxicology study in non-clinical
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1	phormatokinetice study in non-clinical day development process. Toxicology study in non-clinical
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	Toxiliology study in non-clinical
3	
3	daug development process
	General considerations of IND application
2	General considerations of 1B
	General consideration of NDA
	clinical research
	Broequevalence staties
	clinical research protocols
	Biostatistics un pharmaceuteal product development
_	Data presentation for FDA Submussion
103	Management of clerical studies
4	clinical regrearch protocols
3	RENITION PROTOCO
	unat -IV
7	Quality management fatherations
3	concept of quality
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RECORD OF CLASS WORK

Date	Period	Topics Covered
19/11/22	4	Total quality Management
30/11/20	1	Quality by design
1/2/20	4	Six sigma Concept
2/12/24	3	of specifications
3/18/28	2	Change Control
4/11/22	1	antroduction to 150,9000 review of
		quality yetems standards
5 12/28	3	150 14000
6/12/22	4	NABL
7/12/28	- 1	GLP
8/12/28	2	Revision on quality by design
		emit -V
9/12/22	3	In sparction on gegulatory authoration
10/12/20	2,	Potroduction to Endia regulation water
12/22	3	Dang regulatory authority of india
13/12/22	+	Contral Daug Handard control organistis
14/12/20	1	State licensing Authority
Minter	2	Organization, Responsibilities,
23/12/22	- 1	Drug controller general of Sidea (Deg!
26 12/22	3	common technolal Document
87/mm	4	certificate of pharmaoutical product
29 12 22		Approval procedure for new daugs in
122	1/4	Shoka Regulatory requirements
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RECORD OF CLASS WORK

Date	Period	Topics Covered
30 12/2	3	Notional phormaneutical spacing
	(Area Control of the	authority (NPPA)
81 12/2	2	Deficiencia and limitations of
- 1(144)		drug regulatory rystem
01.1.	3	
S/1/25		Revision fet on unit-V
1/1/23	•	I Mad crams
9 1 23		Revision of test on unit -111
विशिध	4	Revision + test on unit - 11
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