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RAJJU SHROFF ROFEL UNIVERSITY, VAPI

A STEP AHEAD TOWARDS A SUCCESSFUL CAREER.

Program	Master of Pharmacy (M.Pharm)	Semester - 2
Type of Course	-	
Prerequisite		
Course Objective	-	
Effective From A.Y.	2023-24	

Teaching Scheme (Contact Hours)				Examination Scheme				
	Tutorial	Lab	Credit	Theory Marks		Practical Marks		Total
Lecture				External Marks (T)	Internal Marks (T)	External Marks (P)	Internal Marks (P)	Marks
-	-	12	6	-	-	100	50	150

SEE - Semester End Examination, CIA - Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.)

Cou	rse Content	T - Teaching Hour	s W - Weig	ghtage	
Sr.	Topics		Т	W	
1	Organic contaminants residue analysis by HPLC				
2	Estimation of M	letallic contaminants by Flame photometer	4	2	
3	Identification o	f antibiotic residue by TLC	6	4	
4	Estimation of H	ydrogen Sulphide in Air	4	2	
5	Estimation of C	hlorine in Work Environment	6	2	
6	Sampling and a	nalysis of SO2 using Colorimetric method	4	2	
7	Qualification of Compression M	following Pharma equipment a. Autoclave b. Hot air oven c. Powder Mixer (Dry) d. Tablet lachine	30	25	
8	Validation of ar	analytical method for a drug	20	10	
9	Validation of a	processing area	6	4	
10	Qualification of	at least two analytical instruments	20	10	
11	Cleaning valida	tion of one equipment	8	4	
12	Qualification of Disintegration	Pharmaceutical Testing Equipment (Dissolution testing apparatus, Friability Apparatus, Fester)	20	10	
13	Check list for B	ulk Pharmaceutical Chemicals vendors	6	3	



Course Content

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T - Teaching Hours | W - Weightage

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Sr.	Topics		T	W
14	Check list for ta	ableting production	6	3
15	Check list for s	terile production area	6	3
16	Check list for W	/ater for injection	6	3
17	Design of plant	layout: Sterile and non-sterile	10	3
18	Case study on a	application of QbD	6	3
19	Case study on a	application of PAT	6	3
		Total	18 0	100

Suggested Distribution Of Theory Marks Using Bloom's Taxonomy					
Level	Analyze	Evaluate			
Weightage	60	40			

NOTE : This specification table shall be treated as a general guideline for the students and the teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Cour	se Outcomes			
At the end of this course, students will be able to:				
C01	Ability to perform Qualification of Instruments and validation of analyical methods			
C02	Understanding of Cleaning validation, preparation of checklist and case studies			