

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester I

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRA101T	Good Regulatory Practices	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA102T	Documentation and Regulatory Writing	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA103T	Clinical Research Regulations	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA105P	Regulatory Affairs Practical I	-	12	-	6	-	6.0	-	1.00	-
6	MRA106S	Seminar/Assignment-I	-	7	-	4	-	-	-	1.00	-
Total			16	19	-	26	-	-	-	-	-
			35								

L: Lectures, P/T: Practicals/Tutorial, C: Credits

LPW/PW: Laboratory / Project Work

SEE: Semester End Examination

CE: Continuous Evaluation

Nirma University
Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester II

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/ PW	T	C	Duration		Component Weightage		
							SEE	LPW/ PW	CE	LPW/ PW	SEE
1	MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA202T	Regulatory Aspects of Herbal & Biologicals	4	-	-	4	3.0	-	0.60	-	0.40
3	MRA203T	Regulatory Aspects of Medical Devices	4	-	-	4	3.0	-	0.60	-	0.40
4	MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	-	-	4	3.0	-	0.60	-	0.40
5	MRA205P	Regulatory Affairs Practical II	-	12	-	6	-	6.0	-	1.00	-
6	MRA206S	Seminar/Assignment-II	-	7	-	4	-	-	-	1.00	-
Total			16	19	-	26	-	-	-	-	-
			35								

L: Lectures, P/T: Practicals/Tutorial, C: Credits
 LPW/PW: Laboratory / Project Work
 SEE: Semester End Examination
 CE: Continuous Evaluation

Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester - III

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/PW	T	C	Duration		Component Weightage		
							SEE	LPW/PW	CE	LPW/PW	SEE
1	MRM301T	Research Methodology and Biostatistics*	4	-	-	4	3.0	-	0.60	-	0.40
2	MRA302T	Journal Club	1	-	-	1	-	-	1.0	-	-
3	MRA303T	Discussion/Presentation (Proposal Presentation)	2	-	-	2	-	-	1.0	-	-
4	MRA304P	Research Work*	-	28	-	14	-	1.0	-	1.0	-
		Total	7	28		21					

* Non University Examination (NUE)

L: Lectures, P/T: Practicals/Tutorial, C: Credits

LPW: Laboratory / Project Work

SEE: Semester End Examination

CE: Continuous Evaluation

w.e.f. academic year 2018-2019 and onward

Nirma University

Institute of Pharmacy

Teaching & Examination Scheme of (M. Pharm. - Regulatory Affairs)

Semester - IV

Sr. No.	Course Code	Course Title	Teaching Scheme				Examination Scheme				
			L	LPW/ PW	T	C	Duration		Component Weightage		
							SEE	LPW/ PW	CE	LPW/ PW	SEE
1	MRA401T	Journal Club	1	-	-	1	-	-	1.0	-	-
2	MRA402P	Research work and Colloquium	-	31	-	16	-	1.0		1.0	-
3	MRA403T	Discussion/Final Presentation (Proposal Presentation)	3	-	-	3	-	-	1.0	-	-
Total			4	31		20					

L: Lectures, P/T: Practicals/Tutorial, C: Credits

LPW: Laboratory / Project Work

SEE: Semester End Examination

CE: Continuous Evaluation

w.e.f. Academic Year 2018-2019 and onwards