

# GUJARAT TECHNOLOGICAL UNIVERSITY

## Pharmaceutical Regulatory Affairs

### Semester I

Subject code	Subject name	Teaching Scheme (Hours)			Credits	Theory Marks		Practical Marks		Total Marks
		Theory	Tutorial	Practical		ESE(E)	PA (M)	ESE(V)	PA (I)	
MRA101T	Good Regulatory Practices	4	0	0	4	75	25	0	0	100
MRA102T	Documentation and Regulatory Writing	4	0	0	4	75	25	0	0	100
MRA103T	Clinical Research Regulations	4	0	0	4	75	25	0	0	100
MRA104T	Regulations and Legislation for Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals In India and Intellectual Property Rights	4	0	0	4	75	25	0	0	100
MRA105P	Regulatory Affairs Practical I	0	0	12	6	0	0	100	50	150
MSA106P	Seminar/Assignment	0	0	8	4	0	0	0	100	100
	<b>Total</b>	16	0	20	26					

### Semester II

Subject code	Subject name	Teaching Scheme (Hours)			Credits	Theory Marks		Practical Marks		Total Marks
		Theory	Tutorial	Practical		ESE(E)	PA (M)	ESE(V)	PA (I)	
MRA201T	Regulatory Aspects of Drugs & Cosmetics	4	0	0	4	75	25	0	0	100
MRA202T	Regulatory Aspects of Herbal & Biologicals	4	0	0	4	75	25	0	0	100
MRA203T	Regulatory Aspects of Medical Devices	4	0	0	4	75	25	0	0	100
MRA204T	Regulatory Aspects of Food & Nutraceuticals	4	0	0	4	75	25	0	0	100
MRA205P	Regulatory Affairs Practical II	0	0	12	6	0	0	100	50	150
MSA206P	Seminar/Assignment	0	0	8	4	0	0	0	100	100
	<b>Total</b>	16	0	20	26					

Semester III										
Subject code	Subject name	Teaching Scheme (Hours)			Credits	Theory Marks		Practical Marks		Total Marks
		Theory	Tutorial	Practical		ESE(E)	PA (M)	ESE(V)	PA (I)	
MRM301T	Research Methodology and Biostatistics*	4	0	0	4	75	25	0	0	100
	Journal club	1	0	0	1	-	-	-	-	25
	Discussion / Presentation (Proposal Presentation)	2	0	0	2	-	-	-	-	50
	Research Work	0	0	28	14	0	0	350	0	350
	<b>Total</b>	7	0	28	21					

\* Non University Exam

Semester IV										
Subject code	Subject name	Teaching Scheme (Hours)			Credits	Theory Marks		Practical Marks		Total Marks
		Theory	Tutorial	Practical		ESE(E)	PA (M)	ESE(V)	PA (I)	
	Journal club	1	0	0	1	-	-	-	-	25
	Research Work	0	0	32	16	0	0	400	0	400
	Discussion / Presentation (Final Presentation)	3	0	0	3	-	-	-	-	75
	<b>Total</b>	7	0	28	20					