GUJARAT TECHNOLOGICAL UNIVERSITY
PLASTIC TECHNOLOGY
B. E. SEMESTER: VII

Subject Name: **Medical Plastics**
Subject Code: **172303**

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	University Exam (E)		Mid Sem Exam (Theory) (M)	Practical (Internal)
				Theory	Practical		
3	0	2	5	70	30	30	20

Sr. No	Course Content	Total Hrs.
1.	**Introduction:** Medical Device Definition, Types of Devices, Materials Used in Medical Devices, Medical Devices—Material Selection Process, Physical and Mechanical Criteria, Thermal Criteria, Electrical Criteria, Chemical Resistance, Sterilization Capability, Biocompatibility & Long Term Durability.	04
2.	**Regulation for Medical Devices and Application to Plastics Suppliers History and Overview** History and Introduction, Regulations, FDA Master Files, ISO 13485 (European and Global Standard), European Union Medical Device Directive, India, Japan & China.	02
3.	**Materials Used in Medical Devices** Introduction, Metals, Ceramics and Glass, Plastics, Why Plastics?, Types of Plastics Thermoplastics, Thermosets, Elastomers, Homopolymers and Copolymers & Polymer Blends and Alloys.	02
4.	**Material Requirements far Plastics used in Medical Devices** Introduction, Material Characterization, Sterilization, Chemical Resistance, Biocompatibility, USP Class VI, ISO 10993, Shelf Life and Aging & Joining and Welding.	04
5.	**Polymer Additives Used to Enhance Material Properties for Medical Device Applications** Introduction, Types of Additives, Things to Consider When Using Additives, Plasticizers, Wear-Resistant and Lubricious Additives, Pigments, Laser Marking, Radiopaque Additives, Antimicrobials, Conductive Fillers, Nanoadditives & Stabilizers.	06

6.	**Commodity Thermoplastics: Polyvinyl Chloride, Polyolefin's, and Polystyrene** Introduction Properties, Chemical Resistance, Sterilization, Biocompatibility, Joining and Welding & application of following materials – PVC, PE, PP, COC & PS.	06
7.	**Engineering Thermoplastics** Introduction Properties, Chemical Resistance, Sterilization, Biocompatibility, Joining and Welding & application of following materials – Acrylics, PC, Polyurethanes, Polyacetals, Polyesters, Copolyesters & Polyamides.	06
8.	**High-Temperature Engineering Thermoplastics: Polysulfones, Polyimides, Polysulfides, Polyketones, LCP and Fluoropolymers** Introduction Properties, Chemical Resistance, Sterilization, Biocompatibility, Joining and Welding & application of following materials – PSUs, Polyimides, Polyamide-Imides (PAIs), Polyphenylene Sulfide(PPS), PEEK, LCP & Fluoropolymers.	06
9.	**Other Polymers: Styrenics, Silicones, Thermoplastic Elastomers, Biopolymers, and Thermosets** Introduction Properties, Chemical Resistance, Sterilization, Biocompatibility, Joining and Welding & application of following materials – Styrenics, Silicones, TPEs, Biopolymers & Thermosets.	06

Text Book:

1. Plastics in Medical Devices: Properties, Requirements and Applications By Vinny R. Sastri.

Reference Books:

1. The Complete Book On Medical Plastics by Niir Board Of Consultants & Engineers
2. Plastics Engineering by Crawford