

Laboratory	GLR Laboratories Private Limited, 444, Gokulam Street, Mathur, Chennai, Tamil Nadu		
Accreditation Standard	ISO/IEC 17025: 2005		
Discipline	Biological Testing	Issue Date	05.08.2015
Certificate Number	T-2614	Valid Until	04.08.2017
Last Amended on	09.11.2015	Page	1 of 3

S. No.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
I.	DRUGS AND PHARMACEUTICALS			
A.	Surgical Dressings & Medical accessories			
1.	Medical Devices Urological Devices: Catheters, Stents, Wires, Bags, Filters, Tubes	Pyrogen	USP 38 (2015) ISO 10993-11: 2006	Qualitative (Pass/Fail)
		Abnormal Toxicity	USP 38 (2015)	Qualitative (Pass/Fail)
2.	Cardiovascular Devices: Catheters, Stents, Bags, Electrodes, Wires	Acute Systemic Toxicity	ISO 10993-11: 2006	Meets the requirements of ISO 10993 (Part 11)
3.	Orthopedic Devices: Joints, Blocks, Screws, Pins, Rods, Tubes, Coatings		USP 38 (2015)	Meets the requirements of USP 38
4.	Ocular Devices: IOL, Implements, Eye Drops, Containers Surgical Implements: Blades, Needles, Surgical Implements, Electrodes, Sutures, Mesh; Staplers	Skin Irritation Test	ISO 10993-10: 2010; (GLR Validated SOP – TOX-015); Schedule Y, Drug and Cosmetics Amd. 2 rules, 2005	Qualitative (Irritant/Non-Irritant)

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5.	Respiratory Devices: Tubes, Catheters, Bags, Gastrointestinal Devices: Tubes, Catheters, Bags, Scopes	Intracutaneous Irritation Test	ISO 10993-10: 2010; USP 38 (2015)	Qualitative (Irritant/Non-Irritant)
6.	Pediatrics: Tubes, Catheters, Electrodes, Incubator	Skin Sensitization Test	ISO 10993-10: 2010; (GLR Validated SOP-TOX-011, TOX-040, TOX-041. TOX-042 and TOX-043); Schedule Y, Drug and Cosmetics Amd. 2 rules, 2005	Qualitative (Sensitizer /Non-Sensitizer)
7.	Neurological: Implements, Electrodes, Wires, Needles, Tubes, Catheters Gynaecological: Equipments, Tubes, Catheters, Scopes, Rings, Loops	Eye Irritation Test	ISO 10993-10: 2010; (GLR Validated GLR SOP -TOX-027); Schedule Y, Drug and Cosmetics Amd. 2 rules, 2005.	Qualitative (Irritant/Non-Irritant)
8.	Hematological Devices And IV Sets: Filters, Blood Collections Sets, Bags, IV Sets, Needles, Syringes Wound Care Products	Hemolysis	ISO 10993-4: 2002, ISO 3826-1: 2013	Qualitative (Hemolytic/Non-hemolytic)

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9.	Personal Care Products: Gloves, IUD, Contraceptives, Lubricants, Incubators	Cytotoxicity	ISO 10993-5: 2009	Qualitative (Cytotoxic /Non-cytotoxic)
10.	Raw Ingredients: Collagen, Plastics, Metals, Polymers	Bacterial Reverse Mutation (Ames) Test	ISO 10993-3: 2014	Qualitative (Mutagenic/ Non-mutagenic)

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