

• END TO END • BIOCOMPATIBILITY TESTING

For All Medical Devices

Category and ISO No.	Study Type	TAT for Draft Report
Cytotoxicity Tests (ISO10993-5)	Elution Method (MTT/NRU)	3-5 weeks
	Direct Cell Contact Method	3-5 weeks
	Agar Diffusion Method	3-5 weeks
Sensitization Tests (ISO10993-10)	Guinea Pig Maximization Test (GPMT)	6-8 weeks
	Buehler Sensitization Test	6-8 weeks
	Local Lymph Node Assay (LLNA)	6-8 weeks
Irritation Test-ISO 10993-23	Intracutaneous Reactivity Test	3-5 weeks
	Skin Irritation Test (in Vivo and in Vitro Assays)	3-5 weeks
	Ocular Irritation Test (in Vivo and in Vitro Assays)	3-5 weeks
	Bladder Irritation Test	3-5 weeks
	Vaginal Irritation Test	3-5 weeks
	Rectal Irritation Test	3-5 weeks
	Penile Irritation Test	3-5 weeks
Systemic Toxicity Testing (ISO 10993-11)	Acute Systemic Toxicity Test	3-5 weeks
	Material Mediated Pyrogenicity Testing	3-5 weeks
	Subacute/Subchronic (28 days) Systemic Toxicity Test	12-14weeks
	Subacute/Subchronic (90 days) Systemic Toxicity Test	20-22 weeks
	Chronic Systemic Toxicity Test (180 days)	30-32 weeks

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Implantation Test ISO 10993, Part 6 - Intramuscular	Intramuscular (1 week) Implantation Test	3 -4 weeks
	Intramuscular (2 week's) Implantation Test	4-6 weeks
	Intramuscular (4 week's) Implantation Test	8-10 weeks
	Intramuscular (8 week's) Implantation Test	14-16 weeks
	Intramuscular (12 week's) Implantation Test	16-18 weeks
	Intramuscular (13 week's) Implantation Test	18-20 weeks
Implantation Test ISO 10993, Part 6 - Subcutaneous	Subcutaneous (1 week) Implantation Test	4-6 weeks
	Subcutaneous (2 week's) Implantation Test	6-8 weeks
	Subcutaneous (4 week's) Implantation Test	8-10 weeks
	Subcutaneous (12 week's) Implantation Test	16-18 weeks
	Subcutaneous (26 week's) Implantation Test	30-32 weeks
	Subcutaneous (52 week's) Implantation Test	56-60 weeks
Implantation Test ISO 10993, Part 6 - Bone	Bone (4 week's) Implantation Test	8-10 weeks
	Bone (8 week's) Implantation Test	14-16 weeks
	Bone (12 week's) Implantation Test	16-18 weeks
	Bone (13 week's) Implantation Test	18-20 weeks

Category TAT for Study Type and ISO No. **Draft Report** Hemo a. Haemolysis Test 2-3 weeks compatibility (Direct Contact & Extract Method) **Tests** b. Complement Activation Test 3-4 weeks (ISO 10993-4) c. Coagulation Test 2-3 weeks d. Platelet Activation Test 2-3 weeks Genotoxicity Bacterial Reverse Mutation Test 6-8 weeks Tests In Vitro Mammalian Chromosomal 12 weeks (ISO10993-3) Aberration Test in CHO Cells In Vitro Mammalian Cell Gene 12 weeks Mutation Test Using the Thymidine Kinase Gene In Vitro Mammalian Chromosomal 12 weeks Aberration Test in Human Peripheral Blood Lymphocytes In Vitro Mammalian Cell 12 weeks Micronucleus Test In Vivo Micronucleus Test 12 weeks In Vivo Chromosomal Aberration 6-8 weeks

















audited by the USFDA GLP studies submitted as part of an IND







AAALAC accredited animal house facility in India





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