

Laboratory **Bionees India Private Limited, Devarahosahally, Sompura Hobli, Nelamangala Taluk, Bangalore Rural District, Karnataka**

Accreditation Standard **ISO/IEC 17025: 2005**

Certificate Number **TC-6647**

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Validity **15.02.2019 to 14.02.2021**

Last Amended on --

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
<u>BIOLOGICAL TESTING</u>				
I. DRUGS AND PHARMACEUTICALS				
1.	Microbial Limit Test	Total Viable Bacterial Count	IP 2018	Upto 50000 CFU/g
		Yeast and Mold Count	IP 2018	Upto 30000 CFU/g
		E-coli	IP 2018	Absent / Present /g
II. MEDICAL ACCESSORIES AND SURGICAL PRODUCTS				
1.	Toxicology Electrodes, External prostheses, Fixation tapes, Compression bandages, Probes of monitors of various types like ECG, blood pressure, Wound dressing materials, Contact lenses, Urinary catheters, Intravaginal and intra-intestinal devices, Endotracheal tubes, Bronchoscopes Dental prostheses Orthodontic devices, Dressings or healing devices, Occlusive patches for ulcers, burns and granulation tissue,	Cytotoxicity Test: Elution method Agar overlay assay Direct contact assay NRU Cytotoxicity MTT Cytotoxicity	ISO 10993-5 ISO 10993-12	Qualitative
		Acute Systemic Toxicity Test	ISO 10993-11	Qualitative
		Irritation Test	ISO 10993-10	Qualitative
		Genotoxicity Test: Bacterial reverse mutation test <i>In vitro</i> mammalian chromosome aberration test <i>In vitro</i> mammalian-micronucleus test Mouse Lymphoma gene assay	ISO 10993-3 ISO 10993-33 ISO 10993-12	Qualitative
		Hemocompatibility Test	ISO 10993-4	Qualitative
		Skin Sensitization test	ISO 10993-10	Qualitative
		Material Mediated Pyrogenicity in Rabbits	ISO 10993-11	Qualitative

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	Solution administration sets, extension sets, transfer sets and blood administration sets, Laparoscopes, Arthroscopes, draining systems, Dental cements, Dental filling materials, Skin staples, Intravascular catheters , Temporary pacemaker electrodes, Oxygenators, Extracorporal oxygenator tubing and accessories, Dialysers, dialysis tubing and accessories, Haemoadsorbents and immunoabsorbents, Orthopaedic pins, plates, replacement joints, Bone prostheses, Bone cements, Intra-osseous devices, Pacemakers, Drug supply devices, Neuromuscular sensors and simulators, Replacement tendons, Breast implants, Artificial larynxes, Subperiosteal implants, Ligation clips and intra-uterine devices, Pacemaker electrodes,			

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Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Artificial arteriovenous fistulae, Heart valves, vascular grafts, Internal drug-delivery catheters and ventricular assist devices, Stunts , Corneal Storage Media, Gels, Ophthalmic solutions, Scalpels, Gloves, Cochlear Implant, Condoms IUD and HIUD, Haemostat, Bioresorbable cardiac stent system, Bioresorbable Bare Metal cardiac stent system, Barrier Cream, Hernia Mesh, Respules, Rubber cork, Sutures, Needles,			

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<u>CHEMICAL TESTING</u>				
1.	DRUGS AND PHARMACEUTICALS			
1.	Tablets/Capsules	General Test		
		Uniformity of Weight	IP 2018	0.05 g to 1.0 g
		Dissolution	IP 2018	50 % to 125%
		Disintegration Test	IP 2018	1 min to 60 min
2.	Oral Suspensions	Weight	IP 2018	0.5 g/ml to 1.5 g/ml
		pH	IP 2018	1.6 to 12
3.	Drug Substance (Active Pharmaceutical Ingredients)	General Test		
		Description	IP 2018	Qualitative
		Solubility	IP 2018	Qualitative
		Limit Test for Iron	IP 2018	Qualitative
		Limit Test for Chloride	IP-2018	Qualitative
		Determination of Sulphated Ash	IP 2018	0.01% w/w to 5% w/w
		Determination of Water Content	IP 2018	0.01 % w/w to 20% w/w
		General Test		
		Determination of Ash	IP 2018	0.01 % w/w to 20% w/w
Loss on Drying	IP 2018	0.01 % w/w to 20% w/w		