

Laboratory **Liveon Biolabs Pvt. Ltd., # 46 & 47, KIADB Industrial Area, Phase-II, Antharasanahalli, Tumakuru, Karnataka**

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

Certificate Number **TC-6794 (In lieu of T-4318)**

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Validity **15.12.2018 to 14.12.2020**

Last Amended on --

"In view of the transition for ISO/IEC 17025:2017, the validity of this accreditation certificate will cease on 30.11.2020"

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.	TOXICOLOGY			
1.	Pharmaceutical Formulations Human Chorionic Gonadotropin (HCG) Pharmaceutical formulations as per Monograph	Abnormal Toxicity Test	IP 2018, Clause 2.2.1	Qualitative
2.	Medical devices (Including Disposable Catheters, Perfusion Sets Bags, Cardiac Stents, Wound suture and closure products, Drug Eluting Stents, Fixation tapes, Compression Bandages, Probes of Monitors of Various types like ECG, blood Pressure, Wound Dressing Materials, Contact lenses,	Bacterial Reverse Mutation	ISO 10993-3	Qualitative
		In Vitro Chromosomal Aberration Test in Human Peripheral Blood Lymphocytes	ISO 10993-3	Qualitative
		In Vitro -CHO Cell lines/In Vivo Chromosomal Aberration	ISO 10993-3	Qualitative
		In Vitro -CHO Cell lines/In Vivo Micronucleus Test	ISO 10993-3	Qualitative
		In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene	ISO 10993-3	Qualitative
		Acute systemic toxicity	ISO 10993-11	Qualitative
		In Vivo pyrogenicity	ISO 10993-11	Qualitative
		Skin irritation tests in rabbits	ISO 10993-10	Qualitative

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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
	Urinary catheters, Intra Ocular Lenses, , Blood I.V. Cannula, Bone Cements, heart valves, Scalp Vein Set, Internal Prosthetic Replacements, Peritoneal dialysis sets) Biomaterials [Polymers like Nylon, Polyvinyl Chloride, Metals, Polyethylene (linear), Polystyrene, Fluorocarbon Resins, Polypropylene, Polyurethane, Resins, Polyesters] Note: Tests indicated in column 3 are common for medical devices and biomaterials, Sutures, Stents, Low Density Polyethylene Granules (LDPE)	Local effects after implantation	ISO 10993-6	Qualitative
		Interactions with blood	ISO 10993-4	Qualitative
		In vitro cytotoxicity test	ISO 10993-5	Qualitative
		Skin sensitization in guinea pigs	ISO 10993-10	Qualitative
3.	Medical devices (Including	Bacterial Reverse Mutation	ISO 10993-13	Qualitative
		In Vitro Chromosomal		Qualitative

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	Disposable Catheters, Perfusion Sets Bags, Cardiac Stents, Wound suture and closure products, Drug Eluting Stents, Fixation tapes, Compression Bandages, Probes of Monitors of Various types like ECG, blood Pressure, Wound Dressing Materials, Contact lenses, Urinary catheters, Intra Ocular Lenses, , Blood I.V. Cannula, Bone Cements, heart valves, Scalp Vein Set, Internal Prosthetic Replacements, Peritoneal dialysis sets) Biomaterials [Polymers like Nylon, Polyvinyl Chloride, Metals, Polyethylene	Aberration Test in Human Peripheral Blood Lymphocytes		Qualitative
		In Vitro -CHO Cell lines/In Vivo Chromosomal Aberration		
		In Vitro -CHO Cell lines/In Vivo Micronucleus Test		
		In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene		
		Acute systemic toxicity	ISO 10993-11	Qualitative
		In Vivo pyrogenicity		Qualitative
		Skin irritation tests in rabbits	ISO 10993-10	Qualitative
		Local effects after implantation	ISO 10993-6	Qualitative
		Interactions with blood	ISO 10993-4	Qualitative
		In vitro cytotoxicity test	ISO 10993-5	Qualitative
		Skin sensitization in guinea pigs	ISO 10993-10	Qualitative

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	(linear), Polystyrene, Fluorocarbon Resins, Polypropylene, Polyurethane, Resins, Polyesters] Note: Tests indicated in column 3 are common for medical devices and biomaterials, Sutures, Stents, Low Density Polyethylene Granules (LDPE)			
II.	VETERINARY TESTING			
1.	Hematology for Rats	Red Blood cell Counts	LBPL-INS-002	(7 to 10) X 10 ⁶ / μL
		White Blood cell counts		(6 to17) X 10 ³ /μL
		Platelets count		(500 to1300) X 10 ³ /μL
		Hemoglobin		11 g/dL to 18 g/dL
		Hematocrit (HCT)		36 (%) to 48 (%)
	Hematology for Mice	Red Blood cell Counts	LBPL-INS-002	(7 to12.5) X 10 ⁶ / μL
		White Blood cell counts		(6 to15) X 10 ³ /μL
		Hemoglobin		10.2 g/dL to 16.6 g/dL
		Hematocrit (HCT)		39 (%) to 49 (%)
	Hematology for Rabbit	Red Blood cell Counts	LBPL-INS-002	(4.5 to 8.5) X 10 ⁶ / μL
		White Blood cell counts		(4 to13) X 10 ³ /μL
		Platelets count		(180 to750) X 10 ³ /μL
		Hemoglobin		9.4 g/dL to 17.5 g/dL
		Hematocrit (HCT)		31 (%) to 50 (%)

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