



CERTIFICATE OF ACCREDITATION

This is to attest that

CRYSTAL BIOLOGICAL SOLUTIONS

DGLOBAL BUILDING, SR. NO. 311/5, PLOT NO. 60,61, SAI PARK LANE NO 5, SHEWALWADI ROAD, URULI
DEVACHI
PUNE, MH, 412308, REPUBLIC OF INDIA

Testing Laboratory TL-1015

has met the requirements of AC89, *IAS Accreditation Criteria for Testing Laboratories*, and has demonstrated compliance with ISO/IEC Standard 17025:2017, *General requirements for the competence of testing and calibration laboratories*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date January 12, 2024



A handwritten signature in black ink, reading 'Raj Nathan'.

President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

CRYSTAL BIOLOGICAL SOLUTIONS

Contact Name Nitin More

Contact Phone +91-9975821511

Accredited to ISO/IEC 17025:2017

Effective Date January 12, 2024

ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within risk management process
ISO 10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity. (OECD 471, <i>Bacterial Reverse Mutation Test</i> , OECD 473, <i>In vitro Mammalian Chromosome Aberration Test</i> , OECD 476, <i>In vitro Mammalian Cell Gene Mutation Test</i>) Sample Preparation in accordance with ISO 10993-12.
ISO 10993-4	Biological evaluation of medical devices Part 4: Selection of Tests for interaction with blood. (Thrombosis Tests, Hemolysis, Hematology, coagulation test, platelet test, complement system test). Sample Preparation in accordance with ISO 10993-12.
ISO 10993-5	Biological evaluation of medical devices Part 5: Tests for <i>in vitro</i> cytotoxicity. Sample Preparation in accordance with ISO 10993-12.
ISO 10993-6	Biological evaluation of medical devices Part 6: Tests for Local effects after implantation. (Subcutaneous, Intramuscular, bone implantation and brain implantation). Sample Preparation in accordance with ISO 10993-12.
ISO 10993-10	Biological evaluation of medical devices Part 10: Tests for skin sensitization (Guinea Pig maximization test (GPMT), Close patch test in guinea pig). Sample Preparation in accordance with ISO 10993-12.
ISO 10993-11	Biological evaluation of medical devices Part 11: Tests for systemic toxicity (Test for acute systemic toxicity, test for subacute systemic toxicity, test for sub-chronic systemic toxicity and test for chronic systemic toxicity). Sample Preparation in accordance with ISO 10993-12.
ISO 10993-23	Biological evaluation of medical devices Part 23: Tests for irritation (Animal Irritation Test, Animal Intracutaneous (intradermal) reactivity test, Ocular irritation test, Oral mucosa irritation test, Penile irritation test, Rectal irritation test and Vaginal irritation test). Sample Preparation in accordance with ISO 10993-12.
ISO 10993-33	Biological evaluation of medical devices Part 33: Guidance on test to evaluate genotoxicity – Supplement to ISO 10993-3. Sample Preparation in accordance with ISO 10993-12.
USP 151/ ISO 10993-11 Annex F	Systemic Toxicity - Material Mediated Pyrogenicity.
USP Chapter 87	Biological reactivity tests, <i>In Vitro</i> (Direct contact test and elution test)

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USP Chapter 88	Biological reactivity tests, <i>In Vivo</i> (Systemic Injection Test, Intracutaneous Test and Implantation Test)
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