ADVERTISING FEATURE

Internationally Accredited testing services for medical devices, biomaterials and IVDs

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The development of medical devices and in vitro diagnostics (IVDs) aims at ensuring patient safety. Hence their safety and efficacy evaluation is critical. These medical devices are made of different kinds of materials like polymers, metals, ceramics, alloys, biodegradable materials, fabric etc., which, when coming in contact with skin, tissue, blood or bone, may cause adverse reactions that endanger human life. These materials and the devices made up of these materials are to be compatible with tissue or blood. If not compatible, the body may reject the material causing adverse reactions. Regulatory authorities like CDSCO in India, US FDA, Therapeutics and Goods Administration in Australia., the Pharmaceutical and Medical Devices Agency in Japan and others enforce strict regulatory compliance to ensure safety and mitigate risks to the end users of medical devices and IVDs.

The medical device testing involves the proportional mixing of knowledge from various disciplines like material science, chemistry, physical sciences, mechanics, biochemistry, toxicology, histopathology, microbiology, veterinary science, engineering etc. The implementation of the quality system based on ISO 17025 takes care of all the procedures right from the review and acceptance of test request till the issue of report. The testing services has been instrumental in testing and evaluation of various category of products during the two decades of its service and many of the Indian manufacturers have availed our services.

So medical device testing could be called as a “must availed service”.

The testing requirement for medical devices & biomaterials was an unmet need in India during early 2000, and SCTIMST, with the mandate to promote the Medical Device Industry in India and develop and translate medical technologies, decided to fill this gap. Identification and implementation of this unmet need was favoured by the fact that the Institute already had alliances with Medical Devices Industry. Also, the products developed by the Institute had to pass through preclinical testing on/before the Technology transfer, ensuring an experience which spear-headed this venture.

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Citation: Sandhya CG, Balram S (2023) Internationally acredited testing services for medical devices, biomaterials and IVDs from a research institution of national importance, Opn. Med. Sci. Technol. Health, 2023; 1(2): e23018

Keywords: medical devices, testing services, industry, standards

Received: June 26, 2023

Accepted: July 10, 2023

Published: July 31, 2023

Data Availability Statement: All relevant data are within the manuscript.

Funding: The authors received no specific funding for this work.

Competing interests: Non declared.

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Two Decades of Testing Services

The 'structured' and 'systematic' operations thus gave an impetus to implement a **Quality Management System** in place which would evolve procedures for the functioning of the service system. Thus the Quality Management System for testing services confirming to the international standard **ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories"** was implemented in 2003. The Quality Management System had to be accredited by an Accreditation agency which is well acceptable by the Regulatory Authorities and the Accreditation of Testing Services was thus done by **Le Comite Francais d'Acreditation (COFRAC)** of France.

Calibration services (mechanical and thermal calibration) are accredited by National Accreditation Board for Testing & Calibration Laboratories (**NABL**)

Physico-chemical testing (Residual EO, Compositional Analysis of materials using TGA, Determination of Transition Temperature & Enthalpies of fusion and crystallization of materials using DSC) is accredited by National Accreditation Board for Testing & Calibration Laboratories (**NABL**).

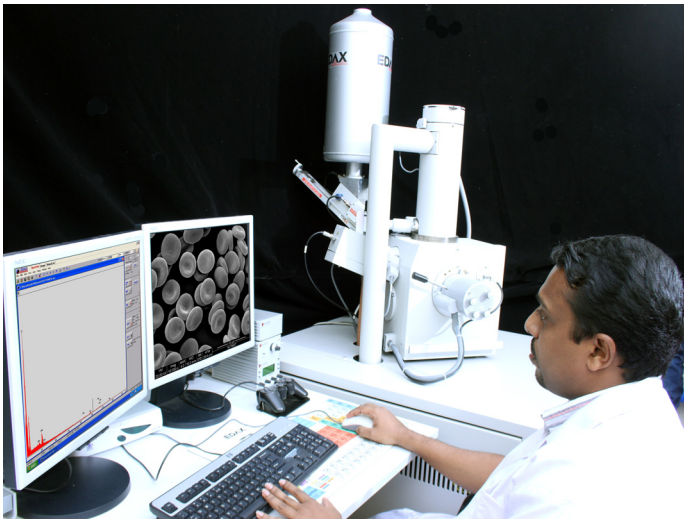
From 2019 the Institute is a Certified medical device testing laboratory under **CDSCO.**

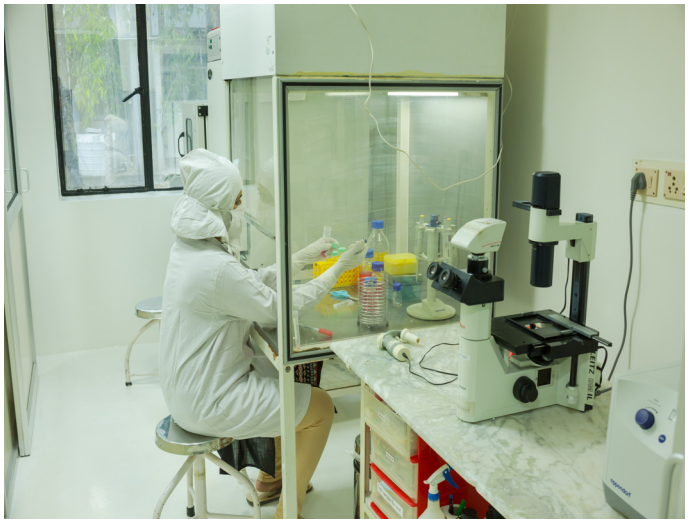
Infrastructure for Testing Services

BMT wing has unmatched sophisticated infrastructure for medical devices and biomaterial research / testing in the country

State of Art Equipment

Imaging - Scanning Electron Microscope (SEM)/ SEM/EDS, Transmission Electron Microscope (TEM), Laser Scanning Confocal Microscope, Micro CT
Material characterization – FT Raman spectroscopy, FTIR spectroscopy, UV- Vis

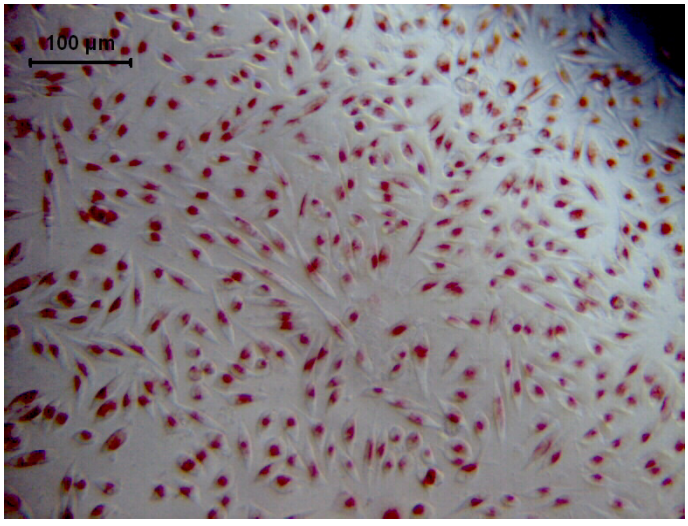




spectroscopy, High Performance Liquid Chromatography(HPLC), Thermal Analyzer, Dynamic Mechanical Analyser, UTM, Vickers microhardness tester, profilometer, Gel Permeation Chromatography, Gas Chromatography

Facilities

In house Calibration Cell: with Reference materials maintained for ensuring traceability of measurement to national / international standards.
Histopathology: facility is equipped for gross and histological evaluation of tissue response to a material for assessment of biocompatibility and necropsy studies in pre-clinical evaluation of medical devices. The facility has sophisticated equipments like smart tissue processor, robotic cover slipper & auto stainer, rotary microtome, saw microtome, tissue embedder, image analysis/microscopes and undertakes paraffin/resin embedding.
Animal Surgery Theatre: A unique facility for the preclinical safety or functional evaluation of medical devices with CPCSEA registered large animal house to house and breed pig, sheep, calf, goat, dog etc . Fully equipped surgical OT for large animal surgeries including open heart surgery, cardiac catheterization, interventional radiology, transthoracic and TE echocardiography, AD Instruments Powerlab 4/30 for acquiring physiological pressure and electrical events, clinical laboratory for blood gas analysis, coagulation analysis, serum biochemistry and hematology, sterilizers (steam/ETO/ chemical) etc.
Small Animal facility: Under the supervision of a veterinary doctor, ensures humane care, management and supply of small laboratory animals of quality for accredited testing and scientific research activities as per ISO 10993- Part-II. As per CPCSEA guidelines, there are separate facilities for breeding and nursery.
Microbial Technology: The facility maintains a Controlled environment, a class 10,000 facility for the performance of sterility test. The facility also has full-fledged microbiology, virology and tissue culture laboratories meeting the requirements of testing laboratories as per ISO 17025 and offering other microbiological evaluations for medical devices and biomaterials and IVDs.
Thrombosis research: The facility is equipped to carry out the evaluation of material - blood interactions. The facility is involved in the evaluation of blood compatibility through thrombosis, coagulation, platelets and platelet function, hematology and immunology.



Tissue Culture: The facility maintains mammalian cell culture facility to meet the requirements of ISO standards. The laboratory offers *in vitro* cytotoxicity testing of biomaterials.

Toxicology: A state-of-art unique facility for preclinical toxicity evaluation of medical devices and biomaterials. The facility is equipped with small animal surgery theatre, full-fledged facility for conducting GLP studies for biocompatibility, material toxicity, nanomaterial toxicity, pyrogenicity, genotoxicity, short, long-term toxicity studies, carcinogenicity, teratogenicity and chronic toxicity studies.

Standards for Medical Devices Testing

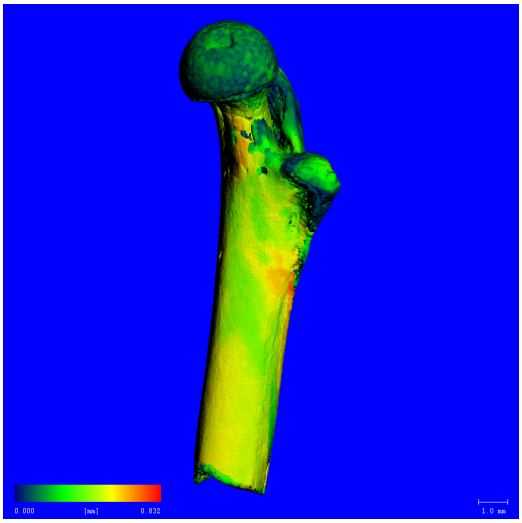
The tests are carried out through established procedures, based on Indian / international standards and is accredited for the same by national and international bodies. The prominent standards used in medical device testing are based on the International Organization for Standardization (ISO), American Society for Testing and Materials (ASTM), American National Standards Institute (ANSI), United States Pharmacopoeia Convention (USP), etc.

Services Offered for Physicochemical Characterisation at SCTIMST

Imaging
Scanning electron microscopy
Transmission electron microscopy
Micro CT
Fluorescence microscopy
Stereo microscopy
Confocal Raman
Atomic Force microscopy
Live animal imaging
Chromatography
Gas chromatography – Qualitative, Quantitative, Residual Ethylene Oxide
Gel Permeation chromatography
High Performance Liquid chromatography
Spectroscopy
FTIR spectroscopy
UV visible spectroscopy
Micro Raman Spectroscopy
X- ray diffraction spectroscopy
Trace element analysis (ICP-OES)
Thermal analysis
Differential Scanning Calorimetery (DSC)
Differential Thermal Analysis(DTA)
Thermogravimetric Analysis (TGA)
Mechanical testing – tensile, compressive, shear, 3 point bending, Dynamic Mechanical analysis
Profilometry – line/surface scanning
Tests for PPE and fabrics Tensile strength and elongation at break, tear strength, synthetic blood penetration test, water vapour transmission rate

Services Offered for Biological Testing at SCTIMST

Cell culture
In vitro cytotoxicity – direct contact, indirect contact, MTT assay (ISO 10993- 5)
Cell adhesion
Toxicology
Acute systemic toxicity (ISO 10993-10)
Irritation – intracutaneous, animal skin, penile, vaginal (ISO 10993-23)
Sensitization – maximization, closed patch (ISO 10993-10)
Hemoltyic property (ASTM – 756)
Implantation – subcutaneous, muscle, bone (ISO 10993-6)
Genotoxicity – in vivo (ISO 10993-3)
Hemocompatibility
Hemolysis - Plasma Hb, % Hemolysis
Platelet function – collagen /ADP
Platelet activation by flow cytometry
Platelet secretion – ELISA
Coagulation
Complement activation
Histopathology
Gross and histopathological evaluation (ISO 10993-6)
Gross & histopathology evaluation – soft and hard tissue
Necropsy, grossing & tissue sampling, tissue processing, block making, microtomy, HE staining, special staining, qualitative microscopy
Immunohistochemistry
Microbiology
Sterility testing (USP 71)
Genotoxicity – *in vitro* (ISO 10993-3)
Bioburden analysis (ISO 11737 PART 1)
Bacterial adhesion studies
Spore viability testing
Antimicrobial activity
Air monitoring
Microbiological analysis of water



Tailored Testing Services

There are various other requirements by the medical device companies which are to be customised based on the specific test requirements. Such customised tests include:

- Medical device functional safety and performance in large animal models
- Preclinical small animal evaluation to prove the efficacy of a medical device/ biomaterial
- Acute and chronic toxicity studies
- In vivo genotoxicity studies
- Gross and histopathological evaluation
- Drug release studies
- Antimicrobial evaluations
- Studies on antimicrobial coatings
- Toxicokinetic studies
- Accelerated ageing studies
- Microscopy imaging and quantification
- Histomorphological analysis
- Blood bag evaluations
- In vitro cell adhesion studies
- Cytocompatibility evaluations
- In vitro osteogenesis evaluation of biomaterials
- Validation of ETO sterilisation systems
- Cellular uptake studies
- In vitro hepatotoxicity studies

For any further information or assistance on testing and evaluation of medical devices requirements at SCTIMST, you may also contact us at:

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