



ADVERTISING FEATURE

SCTIMST - Your partner for testing and biological evaluation of medical devices & biomaterials

Testing and Biological evaluation of the medical devices based on international standards is gaining importance for meeting regulatory requirements in the country. The Biomedical Technology Wing (BMT) of Sree Chitra Tirunal Institute for Medical Sciences & Technology has over the years established a strong testing and evaluation capability and has been a pioneer in offering an accredited testing service to the medical device industry and academia. Medical device industry across the country have availed the testing services of the Institute and it has helped them to get regulatory approvals from Central Drugs Standard Control Organization (CDSCO), US Food & Administration (USFDA), European Union (EU), Conformité Européenne Mark (CE Mark) certification etc. for their products.

The Quality Management System (QMS) for testing services conform to the international standard ISO/IEC 17025: "General requirements for the competence of testing and calibration laboratories".

Physicochemical Characterisation

- ♣ Imaging - SEM, TEM, Stereomicroscopy, Fluorescence Microscopy, Live Animal Imaging
- ♣ Spectroscopy - FTIR, Confocal Microscopy, X-ray Diffraction Spectroscopy, UV-Vis
- ♣ Micro Raman Spectroscopy, Confocal Raman Microscopy
- ♣ Trace element analysis (ICP-OES), Residual EO Analysis
- ♣ Profilometry – line/surface scanning, Tests for PPE and fabrics
- ♣ Thermal analysis - DSC, TGA, DTA
- ♣ Mechanical testing-Tensile, Compressive, shear, 3 point bending, DMA

Biocompatibility Testing

About twenty biological tests which includes biocompatibility testing also are accredited by Le Comité Français d'Accréditation (COFRAC) of France

In vitro Cytotoxicity - Direct & indirect contact, Test on extract (ISO 10993-5); Acute Systemic Toxicity (ISO 10993-10); Irritation - Intracutaneous, Animal Skin, Penile, Vaginal (ISO 10993-23); Sensitization - Maximization, Closed Patch (ISO 10993-10); Hemolytic property (ASTM 756); Implantation - Subcutaneous, Muscle, Bone (ISO 10993-6), Genotoxicity Test (ISO 10993-3), *In vitro* hemocompatibility (ISO 10993-4), Sterility Testing, Bioburden Analysis, Antimicrobial Studies, Bacterial Adhesion, Culture Identification, Cell Adhesion Studies.

Calibration Services

Calibration services are accredited by National Accreditation Board for Testing & Calibration Laboratories (NABL) in the following fields,

Mechanical, Thermal and Electro-Technical Calibration

Study Mode Evaluation

Evaluations that are not regular and is tailor made to the customer, usually follow a study mode which will be carried out under the responsibility of study Director/s

- ♣ *In vivo biofunctional evaluation of devices in large animal models*
- ♣ *Microbiological evaluation*
- ♣ *IC50 and in vitro glucose uptake study, Hepatotoxicity studies, ALP Studies*
- ♣ *Acute toxicity studies*
- ♣ *Gross and histopathological evaluation*
- ♣ *Efficacy study on small animals*
- ♣ *In vivo efficacy studies in small animals*

Please visit www.sctimst.ac.in/tcs for all information on the testing activities such as Test Request forms, Procedure, submitting samples, Test charges and mode of payment can be accessed from the Institute website using the link

One may also contact CSC on email csc@sctimst.ac.in or phone 0471-2520307

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

TEAM CSC

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