Our Core Team

Dr. U S N Murty, FRES, MNASc
Director, NIPER-G

Dr. Murty is the driving force and asset of the nation for Pharmaceutical research. He has been instrumental in setting up the MDTF. Prior to NIPER, he was a Chief Scientist at CSIR-IICT.

Dr. Radhakrishnanand P
Centre Head

Former Director of US Pharmacopeia - India with 23+ years of experience in validating & standardizing methods as per USFDA, USP. He has rich experience in analytical testing, QA-QC, GLP, GMP

Dr. Saurabh Kumar
Quality Manager

Alumnus of Biomedical Section, CSIR-NPL, New Delhi. He has rich 10+ years of experience in fabrication of bio-materials, lithography, bio-sensors. Previously associated with IISc-CeNSE, KAUST and DTU.

Dr. Uday Kiran Roopavath
Deputy Quality Manager

Alumnus of BME department, IIT-Hyderabad and Division of Surgery and Interventional science, UCL, UK. He has 4+ years of experience in Medical Devices industry. He is the cofounder of M/s Medoja Bio Pvt. Ltd.

Mr. Mayur Krishna Das
Calibration Engineer

He is an alumnus of Gauhati University. His expertise includes electronics & electrical testing and calibration as per ISO/IEC/IS.

Medical Devices Testing and Calibration Facility at NIPER-Guwahati was established in 2022 for testing and calibration of medical devices by ensuring the quality, safety, and compliance as per MDR-2017, ISO 17025:2017, and ISO 13485:2016 .

VISION

To be a department of excellence in **promoting high-standard testing** of medical devices through the dissemination of knowledge for the ultimate benefit of the Indian society and industry.

MISSION

- ❑ To carry out testing for medical devices as per international standards. – **Tested once at NIPER-G, accepted globally**.
- ❑ To be an interdisciplinary source of professional manpower in the field of Medical Devices and associated sectors.
- ❑ To support MSMEs, start-ups to get their products tested as per global standards and unlock the global markets with quality confidence.

NIPER GUWAHATI

Department of Pharmaceuticals
Ministry of Chemicals and Fertilizers
Government of India

CC-3932

Medical Devices Testing and Calibration Facility (MDTF), NIPER-G

(An NABL Accredited Laboratory)

Unlocking global doors for
Testing and calibration of medical devices

First Ever NABL-Accredited Facility on Medical Devices Calibration among all NIPERs

Accustomed with ISO 17025:2017
MDR-2017 and ISO 13485:2016

NER's only dedicated govt. facility for Medical Devices Testing and Calibration

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About NIPER-Guwahati

National Institute of Pharmaceutical Education and Research (NIPER) Guwahati is the first and only national-level institute in pharmaceutical sciences located at NER, with a proclaimed objective of becoming a centre of excellence for advanced studies and research in pharmaceutical sciences. The Government of India has declared NIPER as 'Institute of National Importance'. It is an autonomous body set up under the aegis of Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India. The lush green campus amidst NER's mesmerizing hills is rich with state of art facilities and experts in pharmaceutical & Medical Devices research. The Institute is conceived to provide leadership in pharmaceutical sciences and related areas not only within the country, but also to the countries in South East Asia, South Asia and Africa. NIPER is a member of Association of Indian Universities and Association of Commonwealth Universities. NIPER-G houses 10 dedicated Centres of Excellence funded by DoP, DST, DoNER, DBT, NITI Ayog, MoHFW, MeiTY Tribal Affairs, Min of commerce etc.,

Medical Devices Testing and Calibration facility (MDTF) Mechanical Section

Mechanical section houses *Universal testing machine* (5kN & 250N) with various grips/fixtures suitable for mechanical testing of syringes, needles, bandages, catheters, sutures, surgical gloves and other MDs.

The following are core testing done at MDTF,

- Syringe glide force, breakaway force as per ISO 11040-4/EN ISO 11499, Annex E
- Leakage test for sterile hypodermic syringe as per ISO 7886- 1 & 2
- Penetration force for hypodermic needles as per ISO 11040-4, Annex F
- 3 point bending test for hypodermic needle as per ISO 7864
- Peel-off force/ adhesive force for bandages as per ASTM D330
- Tensile property in catheter as per ISO 10555-1
- Tensile properties of plastic as per ASTM D638
- Tensile and break-off testing for surgical suture
- Tensile and endurance testing for surgical gloves as per ISO 11193-1&2

Future facilities being established

- **DMA** - Dynamic Mechanical Analyzer
- **Fatigue Analyzer**
- **Infusion pump/Syringe pump Analyzer**
- **Gas flow analyzer**
- **Vital signs Simulator**
- **Electrosurgical Analyzer**
- **Photo Therapy Analyzer**
- **Incubator Analyzer**
- **Fetal Simulator**
- **Dialysis Reference meter**
- **Earth Resistance tester**

Medical Devices Testing and Calibration facility (MDTF) Electronics Section

The Electronics section houses Defibrillator Analyzer, Pacemaker Analyzer, ECG Simulator, Electrical Safety Analyzer, LUX meter suitable for testing Medical Electronic Devices(MEDs) as per IEC 60601 and its parts in accordance with corresponding IS and NABL guidelines.

The testing facility is both in-house and onsite.

MDTF has NABL Accreditation for calibration of 20 parameters of Defibrillator, ECG and External pacemaker.

The following are core testing done at MDTF,

- Electrical Safety, Energy, Charging time test, Synchronization test, Heart rate and ECG simulation for **Defibrillators** as per IEC 60601-1, IEC60601-2 and IEC 61010-2040.
- Electrical Safety, Pacer amplitude, Pacer rate accuracy tests for **External pacemakers**
- Electrical Safety, Heart rate, ECG amplitude for **ECG units**

Non NABL accredited Testing parameters:

- Electrical Safety of **Patient Monitors, Blood Gas analyser, Electronic/Mechanical bed, Semi auto analyser, Irradiance meter, EEG, Hematology Analyser and OT table.**
- Light intensity test for **OT light**, **Transilluminator light source**
- Electrical Safety *(Leakage test, Ground test, Continuity test, Product Testing)* for **OT Bed, Hematology Analyzer, EEG, Irradiance Meter, Semi Auto Analyzer, Electro-surgical Unit** and other MEDs as per IEC 60601-1