



# Globally Reputed CRO for Medical Device Testing



Ultimate solution...

FDCA LICENCE NO. GTL/37/31

ISO 17025, OECD-GLP, AAALAC & USFDA Registered Testing Lab

# About Us

Accuprec is a Global service provider for various types of Regulatory testing services as well as Research based services required for **Medical devices**. Currently we are working as an extended partner for more than 300+ Medical Devices companies globally. Further, we do provide Regulatory testing services as well as Research based services required for 650+ **Pharmaceutical, Chemicals, Phytochemicals, Herbal Formulations and Food** manufacturers globally.

At Accuprec, we provide Regulatory Testing & Research based solutions in 13 different vertical for Medical Devices through our state-of-the-art 85,000 Sq.ft. facility built up in 5 acre campus and with help of 200+ technical team members.

## MISSION

To provide quality testing services with **ACCURACY and PRECISION** to offer its clients a seamless experience in ensuring quality of their products. We aim to become the "**Ultimate Solution provider**" for our clients.



**Shri Mulubhai Kandoriya**  
(MD)



**Dr. Rina Gokani**  
(Director & CSO)

To become the most-preferred Quality testing service provider for our clients, making the clients feel Accuprec as their "**Extended Partner**".

## VISION

## AIM

To become Catalyst for our client's growth by means of Conversion from "**Research to Revenue**".



**Dr. Manish A. Rachhh**  
(Director & CEO)



**Mr. Mayur Kandoriya**  
(Director & CMO)

## MOTTO

"Uncompromised Quality and Prompt Service"

## Accreditations



GTL/37/31



GLP/23074404/  
39015/B



1709/PO/RcBi/  
S/13/CPCSEA



BN19768/18855



TC-6124  
ISO 17025:2017



GATL/03



TU/IV-RD/  
4417/2021



TL/MD/2021/  
00002



87-409-4551



GCTL/3



GLP/C-203/2023



001972



SrNo1/06/2023



FEI No.:  
3017085815

## 1) Physico-Chemical Testing of Raw Material & Finished Medical Devices

- Chemical Characterization Study (ISO 10993-18)
- Chemical testing of Nylon Resin used in Packaging of Food material and in Medical Devices (21 CFR 177.1500)
- Chemical testing of Polymers used in Packaging of food material and in Medical Devices (21 CFR 177)
- Cleaning Validation Testing (Particulate Matter) (USP <788>)
- Cleaning Validation Testing (TOC, TPH, Residual chemicals, Inorganic matters) (ISO 19227)
- Extractable, Leachable and Biological Risk Assessment study (ISO 10993-18, ISO 10993-17 & ISO 10993-1)
- Migration Study (EN 1186)
- Physico-Chemical Testing of Intraocular Lens (IOL) (ISO 11979-5:2020)
- Physico-Chemical Testing of Soft Contact lens (ISO 11981 & ISO 11986)
- Residual EO & ECH Testing (ISO 10993-7)
- Residual Phthalate Testing (ASTM D7823-18)
- TSE/BSE Testing for Animal origin raw material (WHO Guideline) (By ELISA method)



## 2) Biocompatibility Testing of Medical Devices (As per ISO 10993-1:2018)

- In-vitro Cytotoxicity Testing (ISO 10993-5)
- Skin Sensitization Testing (ISO 10993-10)
- Irritation or Intracutaneous Reactivity Test (ISO 10993-23)
- Acute Systemic Toxicity Test (ISO 10093-11)
- Material Mediated Pyrogen Test (ISO 10093-11)
- Sub-Acute Systemic Toxicity Test (ISO 10993-11)
- Sub-Chronic Toxicity Test (ISO 10993-11)
- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM / SC / Intraocular / Intra-biliary / Intra-arterial) (ISO 10993-6)
- Genotoxicity Tests (ISO 10993-3 & ISO 10993-33)
- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15)
- Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
- In-vitro Skin Sensitization Test (ISO 10993-10)
- Mucosal Membrane Irritation Test (Oral, Ocular, Penile, Vaginal & Rectal) (ISO 10993-11)



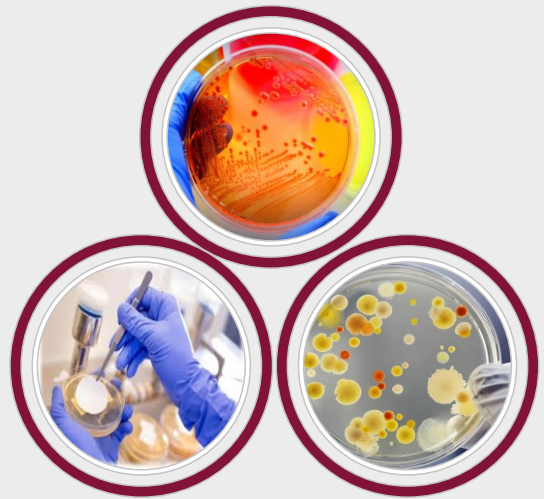
## 3) Biological Testing of Raw Material of Plastic, Rubber, Silicone, Polymers, etc. (As per IP / BP / EP / JP / USP)

- In-vitro Cytotoxicity Testing
- In-vivo Intracutaneous Testing
- In-vivo Acute Systemic Toxicity Testing
- Implantation Testing
- Material medicated Pyrogen Testing
- Abnormal Toxicity Testing



## 4) Microbiological Testing Services

- Bioburden Testing & Its Validation (ISO 11737-1)
- Sterility Testing & its Validation (ISO 11737-2)
- Bacterial Endotoxin Testing & its Validation (USP <85> & USP <161>)
- Sterility Assurance Level Testing (EN 556-1, ANSI/AAMI ST67)
- Microbiological Barrier Testing (ASTM F1608)
- Preservative Efficacy Testing (PET) (BP/USP)
- Antimicrobial Efficacy Testing of Devices (ISO, ASTM & EN)
- Environmental Monitoring Services (ISO, ICH & WHO)



## 5) Packaging Testing

- Packaging Integrity Testing & Validation Testing (ISO 11607-1 & ISO 11607-2)
- Performance Testing of Medical Grade Paper & Tyvek Pouch
- Sterilant Penetration Test (ISO 17665-1 & ISO 17665-2, AAMI/ANSI/ISO 11135-1)
- Drying Time Validation (ISO 17665-1 & ISO 17665-2, AAMI/ANSI/ISO 11135-1)
- Indicator Performance Testing for Steam, EO and Gamma Sterilization (AAMI/ANSI/ISO 11140-1)
- Chemical Indicator Color Stability Testing (ANSI/AAMI/ST44, ANSI/AAMI ST60 & ISO 11138-7)

## 6) Stability Testing Services

- All zones Stability Testing available
- Accelerated Stability Study (ASTM F1980, ASTM D7160)
- Real Time Stability Study (ASTM F1980, ASTM D7160)
- Transport Stability Testing / Shipment System Performance Testing (ASTM D4169 & ISTA)



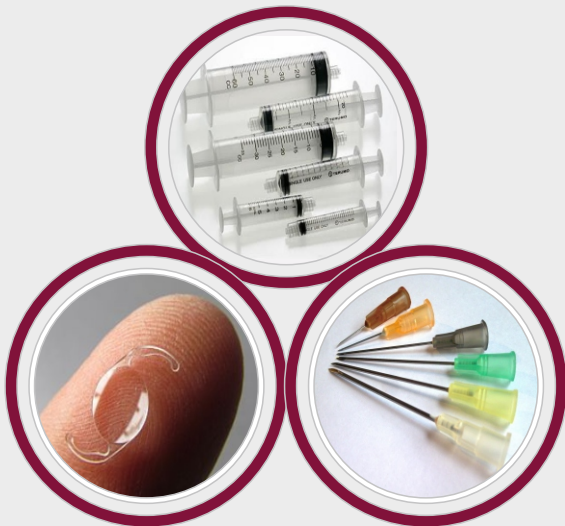
## 7) Mask, PPE, Gloves & Textile Testing

- Surgical Face Mask (IS 16289, EN 14683 & ASTM F2100)
- N95/FFP Face Mask (ASTM F2100, EN 149 & NIOSH)
- PPE kit (IS 16546 / ISO 16603)
- Nitrile and Latex Gloves (EN ISO 374-1)
- Medical Gloves for Single Use (EN 455 Part 1 to 4)
- Nitrile Examination Gloves (ASTM D6319)
- Rubber Examination Gloves (ASTM D3578)
- Nitrile Examination Gloves (EN 21420)
- Surgical Drapes & Gowns (EN 13795-1)
- Surgical Gown (AAMI Level I to IV & AATCC standards)
- Nonwoven Fabrics testing (ISO & ASTM)



## 8) Performance Testing of Medical Devices

- Hypodermic Syringe (ISO 7886-1, ISO 7886-3, ISO 7864, ASTM F3212)
- Sterile single use syringe for Insulin (ISO 8537)
- Stainless Steel needle tubing (ISO 9626, IS 10654)
- Single use Hypodermic needles (ISO 23908)
- IV - set (IS 12655)
- BT set (IS 9824)
- Glass fiber reinforced plastics (IS 12709)
- Intrauterine contraceptive devices (IS/ISO 7439)
- Condoms (IS/ISO 4047, ISO 25841)
- Tubal Rings (IS 13009)
- Sutures (USP/BP)
- Catheter (ISO 10555)
- Blood Bags (IS 9824-3)
- Intraocular lens (ISO 11979-5, ISO 11979-6)
- Orthopedic Implants (IS 5347-1 to 6)
- Ablation devices (ISO 14117)
- Gauze Swab (B.P.)



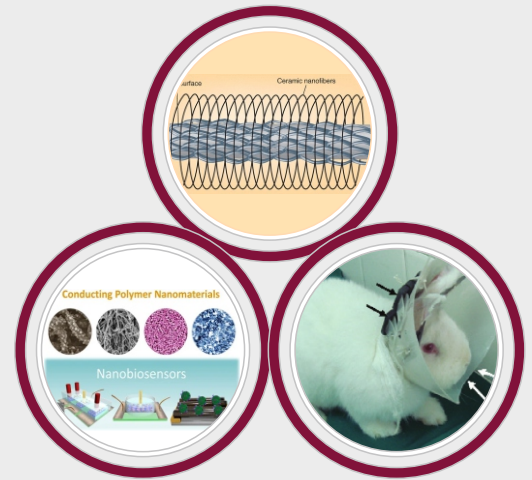
## 9) Performance Testing of Rapid In-Vitro Diagnostic Kits

- HCG diagnostic kit
- Malarial diagnostic kit
- Blood Glucose monitoring kit
- HIV diagnostic kit
- Dengue diagnostic kit (IgM ELISA)
- Syphilis diagnostic kit



## 10) Research & Development Services

- Development of In-vitro model to prove efficiency of Medical Devices
- Development of In-vivo model to prove efficiency of Medical Devices
- Development of Chemical sensors for Rapid diagnosis purpose
- Development of Nano-bio-sensors for Rapid diagnosis purpose
- Design and Development of Innovative Medical Devices as per the client's requirement
- Development of Innovative Coating technology for Drug coated Medical Devices.



## 11) Clinical Study

- Clinical Evaluation Report (CER) as per the requirement of EU MDR 2017
- Clinical trial of Medical Device as per ICMR, CDSCO, EU MDR and ICH-GCP guidelines

## 12) Regulatory Dossier Preparation Services

- Preparation of Medical Device Dossier for EU (Europe) market
- Preparation of Common Submission Dossier Template (CSDT) for ASEAN region
- Dossier preparation for 510k for USA market



## 13) IPR Management Services

- Patent Search, Drafting & Filing
- Trademark Search & Filing Services
- Industrial Design Search & Filing
- Copyright Filing Services
- PCT Application Drafting & Filing
- Patent Prosecution
- IP Valuation & its Management
- Technology transfer & License agreements

# Board of Advisors



**Mr. Padmin Buch**  
Project & IPR Domain Expert,  
Former MD GITCO



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Management Association



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Former Chairman In-Charge (IPAB);  
Former Joint Controller of Patents & Designs DNV GL Notified Body (Norway), Delhi



**Dr. Atul Anand**  
Lead Auditor,

## Out Reach of Accuprec

**Sāyujya 2023 – Celebrating Accuprec's 11th Anniversary of Accuprec, Ahmedabad**

- Sāyujya 2023 – Celebrating Accuprec's Milestones, Delhi**
- Bio Asia 2018 (Hyderabad, Feb. 2018)**
- IPHEX 2018 (New Delhi, May 2018)**
- World IPR 2023, Ahmedabad**
- 15th IMDI Exhibition 2018 (Ahmedabad, Oct. 2018)**
- Innovative Approaches in Laboratory Animal Research Conference 2023 @ICMR-NARFBR, Hyderabad**
- CPHI 2018 (New Delhi, Dec. 2018)**
- National Children's Science Congress-2023, Science City, Ahmedabad**
- 8th world Ayurvedic congress 2018 (Ahmedabad, Dec. 2018)**
- Agilent Executive Technical-Summit 2023, Germany**
- CPHI, 2019 (New Delhi, Dec. 2019)**
- Science Conclave, Ahmedabad 2022**
- Meditech & Healthcare Expo (Dec. 2020)**
- Centre-State Science Conclave 2022, Science City, Ahmedabad**
- STP-I (Oct. 2021)**
- Pharma & Lab Expo 2022, HeliPad Exhibition Centre, Gandhinagar**
- Innovations and Developments in Medical Plastics / Devices 2022 Hyderabad**
- Global AYUSH Investment & Innovation Summit 2022**
- Medical 2022 Hyderabad**



*Accurate Testing, Precise Reporting*



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