



Globally Reputed CRO for Medical Device Testing



ACCUPREC[®]
RESEARCH LABS PVT. LTD.

Ultimate solution...

FDCA LICENCE NO. GTL/37/31

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 250+ Medical Devices companies globally. Further, we do provide Regulatory testing services as well as Research based services required for 750+ **Pharmaceutical(Human/Veterinary), Agrochemicals, 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 acres 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 at becoming the "**Ultimate Solution**" for our clients.



Shri Mulubhai Kandoriya (MD)



Dr. Rina H. Gokani (Director & CSO)

VISION

To become the most-preferred Quality testing service provider for its clients with services making the clients feel Accuprec as their "**Extended Enterprise**".

AIM

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



Dr. Manish A. Rachchh
(Director & CEO)



Mr. Mayur Kandoriya
(Director & CMO)

MOTTO

"Uncompromised Quality and Prompt Service"

Accreditations



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)
- Particulate Matter, VOC & Leachable test for Ventilator & related blood gas pathway products (ISO 18562)
- 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)
- Toxicological Risk Assessment
- 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)



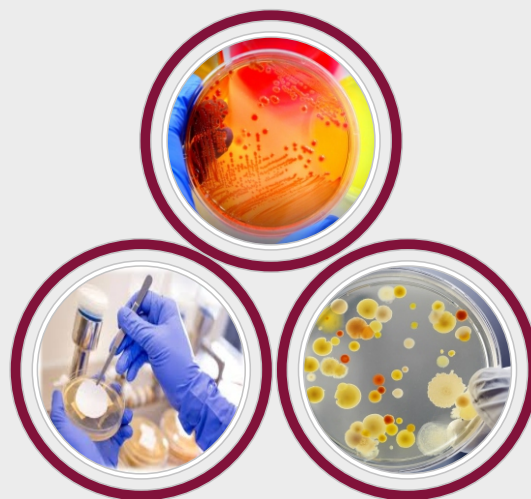
3) Biological Testing of Raw Material of Plastic, Rubber, Silicone, Polymers, etc.(As per IP / BP / EP / JP / USP)

- In-vitro Cytotoxicity Testing
- In-vivo Intracutaneous Testing
- In-vivo Acute Systemic Toxicity Testing
- Implantation Testing
- Material mediated 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 Simulation Testing / Shipment System Performance Testing (ASTM D4169)



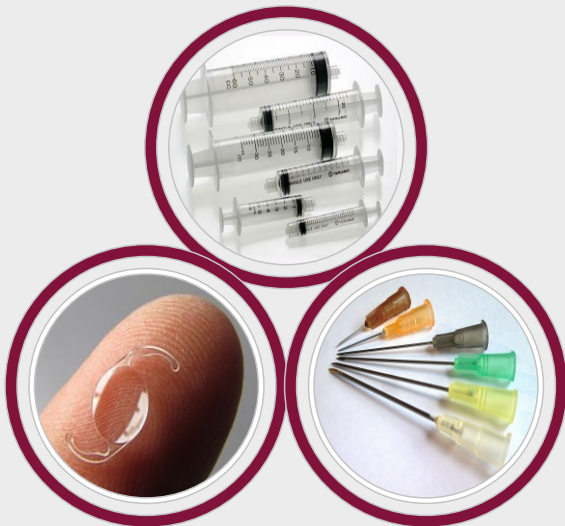
7) Mask, PPE, Gloves & Textile Testing

- 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.)



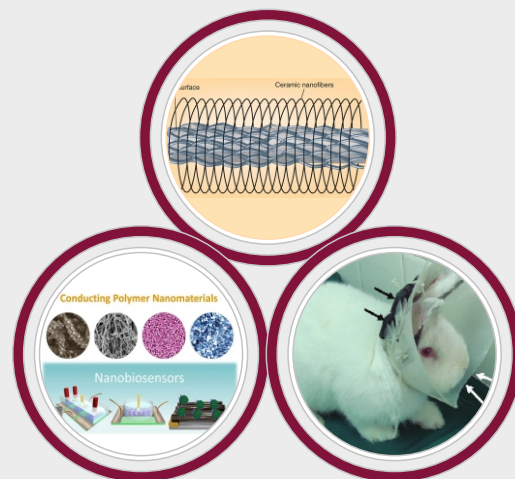
9) Performance Testing of Rapid In-Vitro Diagnostic Kits

- 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

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Out Reach of Accuprec





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