



ACCUPREC
RESEARCH LABS PVT. LTD.

Ultimate solution...

FDCA LICENCE NO. GTL/37/31

Medical Device Testing Services



FDCA Licence No.: GTL/37/31



FDCA Licence No.: GTL/37/31



Reg. No. 1309/PQ/R/25/1/CPCSEA



(Certificate No. 2017-HK-0010)



(Certificate No. TC - 6124)



(Certificate No. 201710-01)

Accuprec Research Labs Pvt. Ltd.

Biocompatibility Study of Medical Devices

[As per ISO 10993 & USFDA Guidelines]

- Cytotoxicity Study
- Sensitization Study
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity Study (Acute)
- Genotoxicity
- Implantation Study
- Systemic Toxicity Study (Sub - Chronic)
- Systemic Toxicity Study (Chronic)
- Hemocompatibility Study
- Pyrogen Testing
- Degradation & Toxicokinetic Study
- Carcinogenicity test
- Reproductive / Developmental toxicity



Stability Testing Services

- All Zones Stability Testing are available
- Determination of Shelf life of Medical Device & Disposables
- Stability Testing
(As per ISO 10993 & ASTM Guideline)



Sterility Testing Services

- Sterility Testing of Medical Devices
(As per ISO 11737-2)
- Bioburden Testing (As per ISO 11737-1)



Extractable & Leachable Study

- Extractable & Leachable study (As per ISO 10993-18 and USP Guidelines)
- Migration Study
- Food Contact Material (FCM) Testing (EN 1935/2004)
- Bio-degradability Testing (ISO 17556-2012 & ASTM D 5988-12)
- Cleaning Validation (As per USP & EN standard)
- Packaging Validation (As per USP & EN standard)



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



Regulatory Dossier Preparation Services

- Preparation of medical device dossier for EU (Europe) market
- Preparation of Common submission dossier Template (CSDT) for ASEAN region.
- Clinical evaluation report preparation of medical devices as per MEDDEV2.7/1 rev.4, 2016 guideline.
- Dossier preparation for India and USA market.





We Will Be Happy To Provide You Below Mentioned Research & Testing Services

- Analytical testing of Pharmaceuticals & Cosmetics
- Biotechnological Services
- Microbiological Services
- Bio-Compatibility Studies of Medical Devices
(As per ISO 10993, MHRA & USFDA Guideline)
- Formulation & Development Services
- Dyes & Pigment Testing Services
- Herbal Formulation Development
- Stability Testing Services
- Preclinical & Toxicology Services
- Regulatory Dossier Preparation
- IP Management Services
- Clinical Services
- Phytochemical Services
- Food Testing Services



Ultimate solution...

FDCA LICENCE NO. GTL/37/31

Canada Office:

Sudbury, ON, Canada

E-mail: info.canada@accuprec.com

North America Office:

Pittsburgh, PA, USA

E-mail: info.usa@accuprec.com

Regi. Address :

Opp. Zydus Pharmed, Changodar-Bavla Highway,
Near Matoda Patia, Post: Matoda,
Dist: Ahmedabad - 382213, Gujarat, India
(M) 9099616769 / 9909919545 / 9099981023
E-mail: info@accuprec.com

Scan QR Code
for More Details

