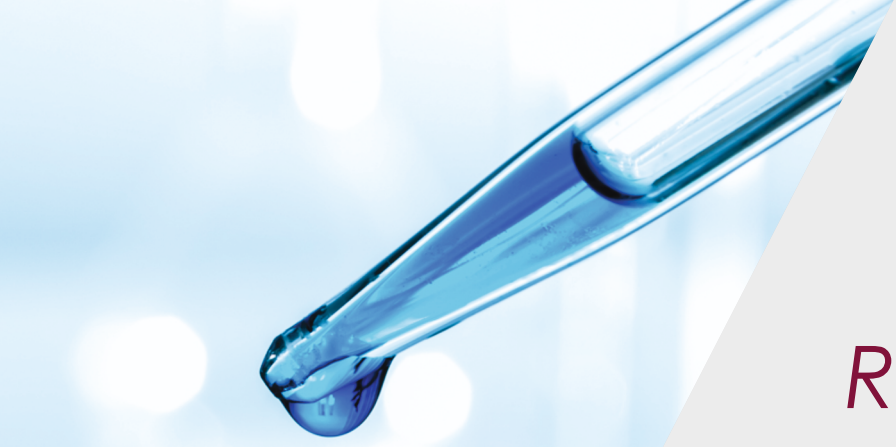


RESEARCH
REDEFINE

ACCUPREC®
RESEARCH LABS PVT. LTD.
Ultimate solution...

FDCA LICENCE NO. GTL/37/31

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

About Us

Accuprec is a service provider for various types of Regulatory testing services as well as Research based services required for **Pharmaceuticals, Chemicals, Phytochemicals, Herbal Formulations, Food and Medical devices**. Currently we are working as an extended partner for more than 1000+ Pharmaceuticals & API companies in India as well as out side of India.

At Accuprec, we provide Regulatory Testing & Research based solutions in 14 different verticals for Pharmaceuticals & Chemicals 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)

VISION

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

AIM

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

Dr. Manish A. Rachchh
(Director & CEO)

Mr. Mayur Kandoriya
(Director & CMO)

MOTTO

"Uncompromised quality and prompt service"

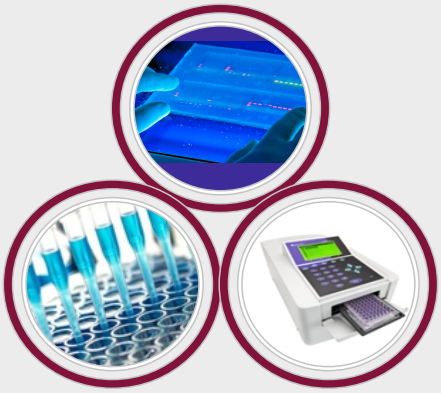
Accreditations

GTL/37/31 | GLP/23074404/39015/B | 1709/PO/RcBi/S/13/CPCSEA | BN19768/18855 | TC-14775 ISO 17025:2017 | GATL/03 | TU/IV/-RD/4417/2024

TL/MD/2021/000002 | 87-409-4551 | GCTL/3 | GLP/C-203/2023 | 001972 | SrNo1/06/2023 | FEI No.: 3017085815 | LRMD/LRS/OSL-7176516

1) Analytical Testing of Pharmaceuticals, Cosmetics, Medical Devices & Agrochemicals

- Analytical Testing of Pharmaceuticals & Cosmetics
- API characterization and analysis Analytical method development
- Bio-Analytical Method Development and Validation
- Comparative Dissolution Study
- Excipient compatibility Study
- Extractable and Leachable Study (As per USP)
- Impurity Isolation and Characterization
- Method Validation as per ICH and USP guidelines
- Nitrosamine impurities viz. NDMA, NDEA, NEIPA, NDIPA, NDBA & NMBA testing & validation using LCMS/MS method and GC-MS/MS (USFDA method)
- NDSRIs testing and Validation as per EMA & USFDA
- Iron Carbohydrate Complex Characterization

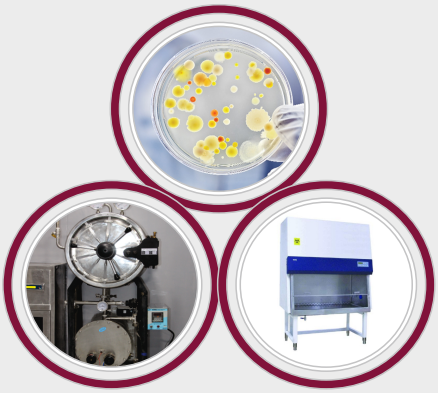


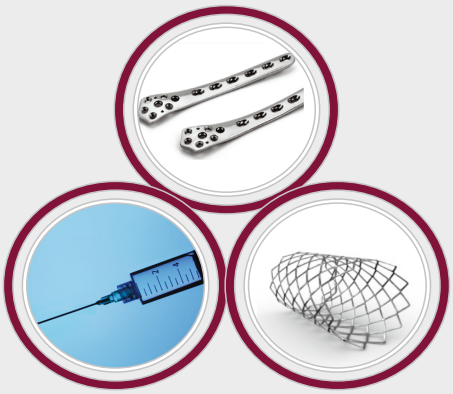
2) Biotechnological Services

- Cell-Line Study for New Molecules
- Determination of Immunoglobulin using HPLC
- ELISA Testing
- Cell Permeability Assay (CACO-2)
- Qualitative and Quantitative Testing of Protein (SDS-Page, Native Page)
- Qualitative and Quantitative Testing of Nuclease Contamination (DNase and Rnase)
- Testing of Human DNA Contamination
- Testing of Host Cell DNA
- Testing Using RT-PCR
- BSE/TSE Testing
- *In-vitro* Bio Assays

3) Microbiological Services

- Antibiotic Assays
- Assay of Vitamins
- Bio-Burden Testing
- Disinfectant Efficiency Test
- Identification and Characterization of Microorganisms
- Microbiological Testing of Formulation
- Microbial Limit Test (MLT)
- Pathogen Identification
- Preservative Efficiency Test
- Sterility Testing
- Testing of Bacterial Endotoxin (LAL Test)
- Validation of Microbial Test Methods





4) Bio - Compatibility Studies of Medical Devices

(As per ISO 10993, USFDA and EU MDR Guidelines)

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

5) Preclinical & Toxicological Services
(As per OECD, NDCT, ICH, MHRA, USFDA/EPA Guidelines)

- Acute Toxicity Studies (Oral, Dermal, Inhalation and Parenteral)
- Eye/ Skin Irritation Studies
- Skin Sensitization Studies (GPMT/ Buehler)
- Repeated Dose Toxicity Studies (Sub-acute, Sub-chronic and Chronic)
- Reproduction and Developmental Toxicity Studies (DART)
- Maximum Tolerated Dose (MTD) Studies
- Dose Range Finding (DRF) Studies
- *In-vitro* Toxicology Studies (AMES, Enhanced AMES etc.)
- Ecotoxicology Studies
- Pharmacokinetic and Toxicokinetic Study of Pharma & Biosimilars
- DMPK Study
- Efficacy Study Models (Anti-Cancer, Anti-Diabetes, Xenograft, Psoriasis etc.)
- PDE Studies (EMA/CHMP/ CVMP/ SWP/169430/2012)
- In-Silico QSAR Studies (ICH M7)
- Carcinogenicity Studies
- Neurotoxicity Studies

6) Phytochemical & AYUSH Testing Services
(As per AYUSH and other Guidelines)

- Description, Identification (Using TLC & HPLC/HPTLC)
- Physico-chemical testing of Raw material and AYUSH formulations
- Determination of Heavy Metals and Microbial Contamination
- Determination of Toxins (Pesticides, Afla Toxins)
- Extraction, Fractionation and Optimization
- Estimation of Phytochemical
- Isolation & Characterization
- Standardization of Herbal as well as Ayurvedic Medicines
- Development of Herbal Formulations
- Validation of Ayurvedic Medicine

7) Food Testing Services
(As per FSSAI, BIS, APEDA and EU Guidelines)

- Analysis of Food & Agricultural Products as per FSSAI, BIS, EIC/EIA, APEDA & European (EU) Standards
- Analysis of Residual Pesticides, Drugs and Banned colorants in food products
- Fatty Acids composition and trans fat content
- Mycototoxins B1B2G1G2M1 and Ochratoxin in various matrices.
- Proximate analysis and nutritional labeling of food products
- Shelf life estimation of packed food

8) Formulation & Development Services

- Controlled release and Sustained Release Formulations
- Excipient Compatibility Selection and Optimization
- Formulation Development For New Chemical Entities (NCE) using QbD Approaches
- Lab Scale, Pilot Plant, Scale Up Production
- Novel Drug Delivery System for Existing Drugs
- Optimization of Existing Formulations
- Tech Transfer and Commercial Production Support
- F&D in Solid Orals, Liquids, Transdermals, Water Soluble Film, Gummi, Topical Products, Parenteral, NDDS Formulations, Cosmetics

9) Dyes, Pigment & Plastic Testing Services

- Chemical testing of dyes & pigments of Textile & color Industry.
- Heavy metal Analysis
- Particle Size Measurement
- Migration Study
- Food Contact Material (FCM) Testing (EN 1935/2004)
- Bio-degradability Testing, (ISO 17556-2012, ASTM D 5988 & OECD 301)
- Extractable and Leachable Study (USP 661, USP 1661)
- MVTR Study (USP 671)
- RoSH Testing
- USP Class VI Testing

10) Research & Development Services

(DSIR approved R & D centre)

- Reverse Engineering of RLD formulation
- Design & Development of Innovative & patentable formulations
- Synthesis & process development of Pharmaceutical Herbal, Agriculture, Material science & cosmetics products Isolation, Purification & Characterization of Pharmaceutical and herbal
- Nano technology based research like Nano biosensor, Nano formulation, Nano Neutraceuticals and Nano based Cosmetics, Agriculture and Material science

11) Stability Testing Services

- Accelerated and Real time stability testing of pharmaceuticals & chemicals as per ICH Guideline (ICH Q2R1)
- All Zones Stability Testing are available including walk in stability chamber
- Accelerated Stability Study of Medical Device & Disposables (ASTM F 1980)
- Real time stability study of Medical Device & Disposables (FDA – 2020-D-0957)
- Accelerated and Real time stability study of IVD products (WHO Guideline)
- Transport Simulation Study (ASTM D4169 & ISTA)

12) Clinical Services

- BA/BE Study of Drugs as per the Regulatory guidelines of the Particular country Specified by the Sponsor
- Clinical site management as per requirement by the sponsor
- Clinical Trial of Phase II, III and IV for Synthetic Drugs and Herbal Drugs as per schedule, ICMR and ICH-GCP guidelines
- Preparation of Clinical trial Protocol for Synthetic Drug and as well as Herbal Drugs

13) Regulatory Dossier Preparation

- Preparation of CTD & e- CTD Dossier for countries like USA, Canada, Europe, Brazil, Japan, China
- Preparation of Dossier for Allopathic Formulations as well as Herbal Formulations & Medical device

14) IPR Management Services

- Patent Search, Drafting & Filing
- Trademark Search & Filing Services
- Industrial Design Search & Filing Services
- Copyright Filing Services
- Patent Prosecution with patent office of India
- Technology transfer & Licence agreements
- PCT Application Drafting & Filing
- IP Valuation & its Management
- Technology transfer & License agreements

Board of Advisors

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Former MD GITCO

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