



RESEARCH REDEFINE



ACCUPREC®
RESEARCH LABS PVT. LTD.

Ultimate solution...

FDCA LICENCE NO. GTL/37/31

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 250 plus companies in India as well as out side of India.

At Accuprec, we provides Regulatory Testing & Research based solutions in 14 different vertical.

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 Gokani (Director & CSO)

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

VISION

AIM

To become catalyst for ours client’s growth by means of conversion from **“Research to Revenue”**.



Dr. Manish A. Rachchh (Director & CEO)

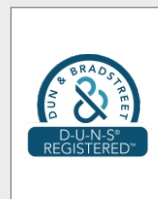


Mr. Mayur Kandoriya (Director & CMO)

MOTTO

“Uncompromised quality and prompt service”

Accreditations



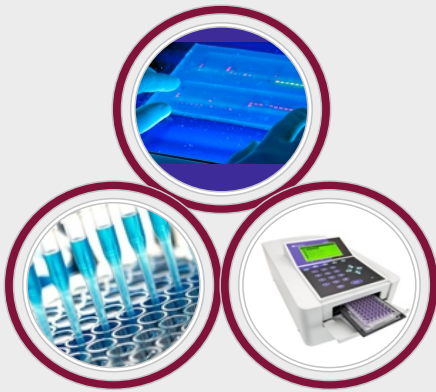
1) Analytical Testing Of Pharmaceuticals & Cosmetics

- 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 guideline.
- **NDMA** impurity testing & validation using LCMS/MS method (USFDA method)
- Nitrosamine impurities viz. **NDEA, NEIPA, NDIPA, NDBA & NMBA** testing & validation using LCMS/MS method (USFDA method)



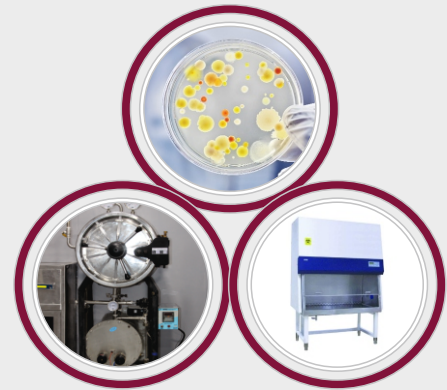
2) Biotechnological Services

- Cell-Line Study for New Molecules
- Determination of Immunoglobulin using HPLC
- ELISA Testing
- In-Vitro Cytotoxicity Study
- Qualitative and Quantitative Testing of Protein (SDS-Page, Native Page)
- Qualitative and Quantitative Testing of Nuclease Contamination (DNase and Rna se
- Testing of Human DNA Contamination
- Testing of Host Cell DNA
- Testing Using RT - PCR
- BSE/TSE Testing



3) Microbiological Services

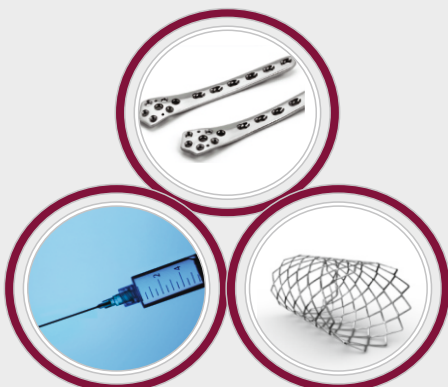
- Antibiotic Assays
- Assay of Vitamins
- Bio- Burden Testing
- Disinfectant Efficiency Test
- Identification and Characterization of Microorganism
- Microbiological Testing of Formulation
- Microbial Limit Test (MLT)
- Pathogen Identification
- Preservative Efficiency Test
- Sterility Testing
- Testing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



4) Bio - Compatibility Studies of Medical Devices

(As per ISO 10993, USFDA and MHLW Guideline)

- 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



5) Preclinical & Toxicological Services

- Anti Cancer Activity (In - Vitro/ In Vivo)
- Anti HIV Activity
- Bio - Analytical Study
- CNS, CVS, Antidiabetic Activity, Anti obesity Activity
- Customized Screening of Services
- Development of Animal Screening Models
- DMPK Study
- Pyrogen Testing
- Screening of Analgesic, Anti - Inflammatory and Anti - Arthritic Activity
- Toxicological Studies

(As per OECD, Schedule Y, ICH, MHRA and USFDA Guidelines)



6) Phytochemical & AYUSH Testing Services

(As per AYUSH and other Guideline)

- 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 Guideline)

- NABL approved Food Testing for 200+ products
- 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
- Contract Testing Services to Support your HACCP, ISO, GMP and GLP Compliance
- Fatty Acids composition and trans fat content
- Mycotoxins B1, B2, G1, G2, M1 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)
- 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, Parenterals, NDDS Formulations



9) Dyes, Pigment & Plastic Testing Services

- Chemical testing of dyes & pigments of Textile & color Industry.
- Heavy metal Analysis
- Particle Size Measurement
- Particle Size Volume Determination
- Migration Study
- Food Contact Material (FCM) Testing (EN 1935/2004)
- Bio-degradability Testing (ISO 17556-2012 & ASTM D 5988-12)

10) Research & Development Services

(DSIR approved R & D centre)

- 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 Nutraceuticals and Nano based Cosmetics, Agriculture and Material science.



11) Stability Testing Services

- Stability Testing as per ICH Guideline
- All Zones Stability Testing are available including walk in stability chamber
- Determination of Shelf life of Medical Device & Disposables



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 Y, ICMR and ICH-GCP guidelines
- Preparation of Clinical trial Protocol for Synthetic Drug and as well as Herbal Drug and Regulatory Approval there of



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 also.



14) IP Management Services

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



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Former MD GITCO



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Out Reach of Accuprec





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