

Bioequivalence and Bioavailability Services



Get your First-to-market Advantage with our Bioequivalence and Bioavailability Studies

Gain the competitive edge you need in the generics market with Ecron Acunova' exceptional Bioavailability & Bioequivalence services. Our expert team specializes in delivering efficient, high-quality outcomes that adhere to stringent regulatory standards, propelling your first-to-market strategy.

World-class facilities ensuring highest quality standards

Bangalore

D-U-N-S : 65-006-0593
FEI: 3006074041

- Bio-analytical testing services
- GLP 21 CFR Part-11 compliant
- Class 10000 room

Mangalore

D-U-N-S : 65-065-4119
FEI: 3006720730

- 80-bed facility across 2 CPUs in Manipal university hospital campus

Manipal

D-U-N-S : 91-591 -0323
FEI: 3006355435

- 150-Bed, State of the art Phase-1 and BA/BE Centre with 2 CPUs and Bioanalytical Lab near to Tertiary care hospital of Manipal University

Chennai

D-U-N-S : 67-547-5204
FEI: 3014326883

- 80-bed facility across 2 CPUs

Facility Approvals and Study Inspections



Study Specific Inspections and Approvals



Remote reviews and approvals



Our Experience and Key Differentiators

Top 10 Indian and
top 30 global pharma companies

100+
marketing authorization approvals

450+
validated bioanalytical methods

1500+
Bioequivalence studies for
submissions in 6 continents

50+
satisfied customers
(Generic & Innovator
Pharma companies)

Highly skilled team of
160+ industry specialists
76% Science Graduates
63% MD/ Masters'/PhD

Ecron Acunova harnesses the power of Clinical Electronic Data Capture for Bioavailability and Bioequivalence (BA/BE) studies.

Elevate your research with our advanced technology, ensuring precision, efficiency, and transformative insights.

World class
Facility spanning across four locations



Dedicated
Screening area



State-of-the-art
Bioanalytical Lab



Integrated
Clinical Testing Facility



Walk-in Chambers
for plasma sample and IP storage



300+ beds
with multiple CPUs



Sophisticated
Hi-end Bioanalytical Instruments



Unveiling our New Bioequivalence Center at Manipal





Our new facility with enhanced capabilities provides the perfect platform for Intensive Studies with Unmatched Expertise!



Real-time Clinical Electronic Data Capture

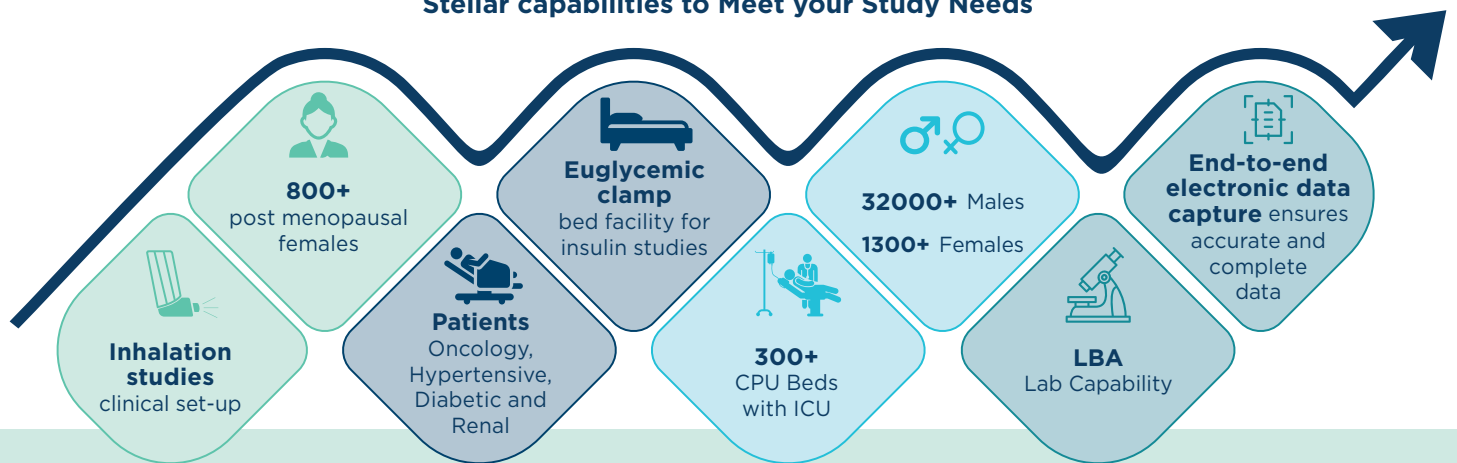
A web based, multi-lingual, end-to-end platform designed with focus on data integrity, quality & compliance – from volunteer recruitment till report/data extraction for submission.

Can be easily integrated with other systems for robust, smooth data & activities flow. Real-time direct data capture capabilities through tablets/devices & comprehensive integration with a wide range of medical devices.

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| It has undergone a comprehensive and thorough process of Vulnerability Assessment and Penetration Testing (VAPT) to ensure the highest level of security for study data. | It is 21 CFR part 11 compliant, ensuring that electronic records and signatures are trustworthy, reliable. 21 CFR part 11 compliance can help to build trust with regulatory agencies. | It offers automated validation checks and query management, ensuring accurate and complete data. | It supports CDISC standards and customizable CRFs, ensuring consistent, high quality data that is reliable and easily interpretable for informed decision making. |

Complex Generics

Stellar capabilities to Meet your Study Needs



40+ successful inspections across 7 regulators

Experts at Complex Generics

Inhalation Studies | Euglycemic Clamp Studies | Elemental Analysis
Ligand Binding Assays | Liposomal Assay | 505(b)2 Submission

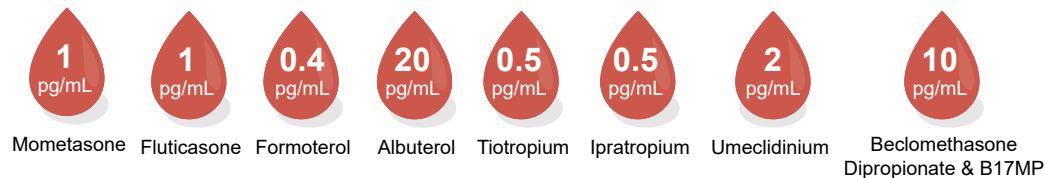
“Very impressive systems and processes, could see the consistency in study conduct”

- FDA inspector

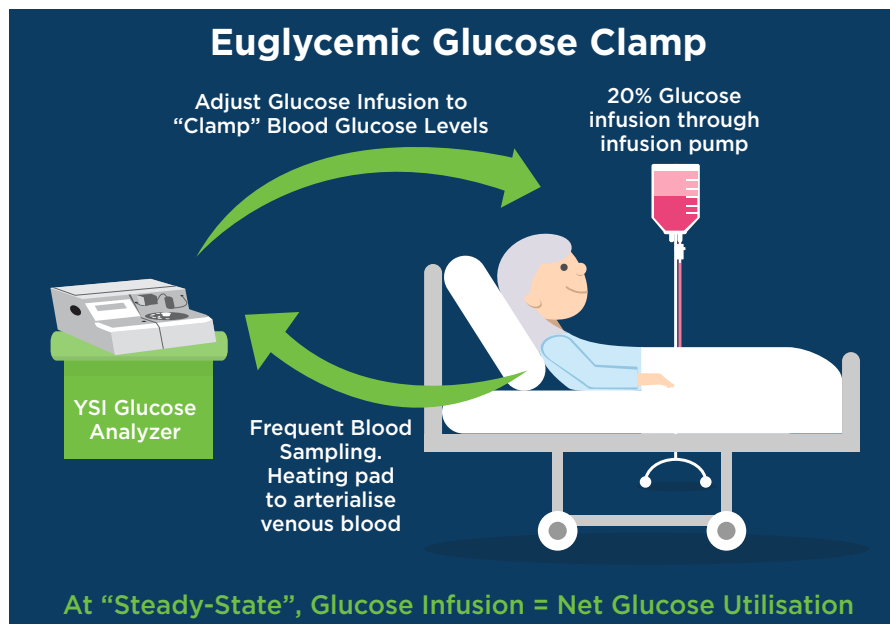
Ecron Acunova Supports Efficient Inhalation Studies

Ecron Acunova Accelerates Your Inhalation drug Journey, ensuring speed, efficiency, and Improved patient outcomes.

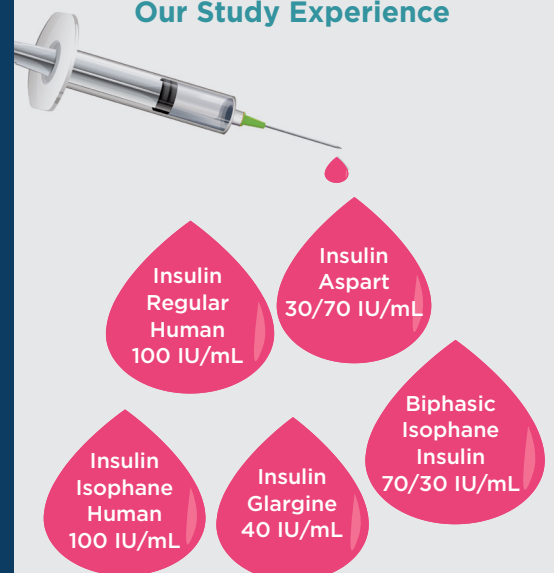
We have developed bioanalytical methods to measure



Euglycemic Clamp Studies

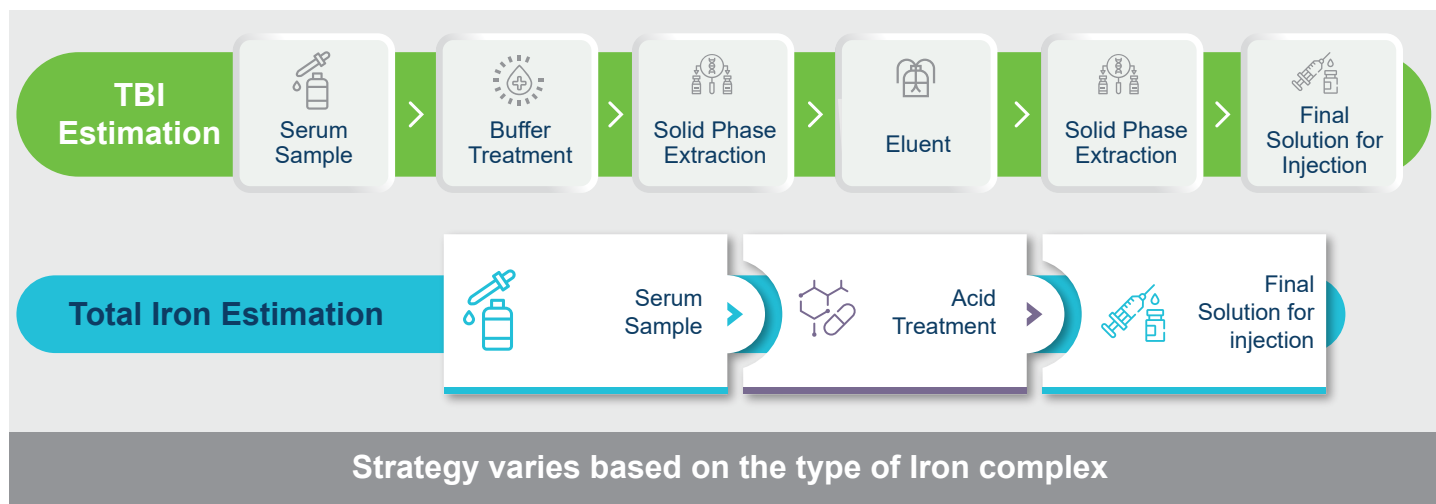


Our Study Experience



Total Iron and Transferrin bound Iron assay for Iron based oral & injection formulations and elemental analysis

Ecron Acunova has thoroughly researched the complexities of iron preparations and has established robust methodologies for evaluating Iron-Carbohydrate preparation.



Elemental Analysis

Our State-of-the-Art ICP-MS Laboratory has been supporting Elemental analysis services since 2012

Agilent 7700, 7900 ICP-MS platforms

Installed in Clean Air Room

Experienced and Expert Bioanalytical Staff

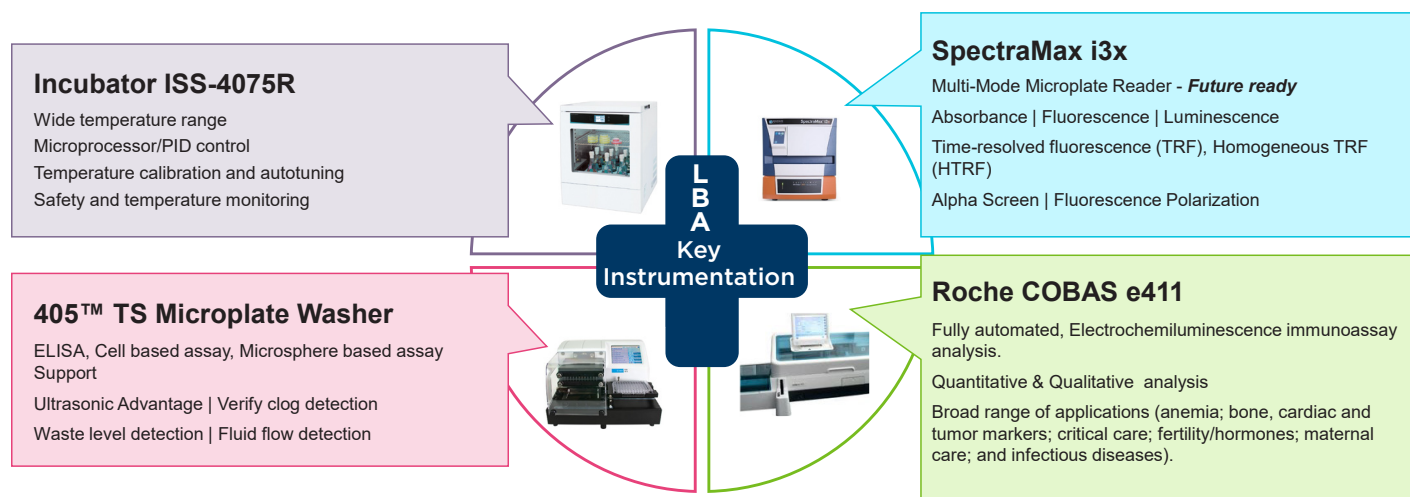
Application Software integrated with Open Lab ECM for 21 CFR part 11 compliance

Regulatory compliant systems and processes

Extensive Experience with different biological matrices

Ligand Binding Assay - Capabilities

We are the preferred choice for conducting intricate studies like the ligand binding assay.



About Ecron Acunova

Ecron Acunova offers end-to-end services to bring generic products to market quickly and effectively. We support Abbreviated New Drug Application (ANDA) according to 505 (j) or 505b (2) to the US FDA for marketing authorization in USA and across the globe. Our services include study design, study conduct, bioanalysis, data standardization and analysis, dossier preparation, and regulatory support. Ecron Acunova is a part of TAKE Solutions Limited.

For more information:

contact@takesolutions.com www.takesolutions.com/our-businesses/ecronacunova