Bioavailability and Bioequivalence Services

Helping Generics gain first-to-market advantage

Our Bioavailability & Bioequivalence team is experienced in delivering outcomes which are efficient, timely, high-quality, adhering to regulatory needs in fast track to achieve your first-to-market strategy.

Our services encompass End-to-End Bioavailability & Bioequivalence services which include study design, conduct, bioanalysis, data standardization and analysis, dossier preparation, regulatory submissions, and pharmacovigilance.

We can deliver even complicated studies with high quality outputs. We have experience in a wide variety of studies including multiple doses, dosage form, dose escalation, single and double blind, PK/PD end point studies, Glucose clamp studies, proof of concept and exploratory, repeat “first in man”, nutritional, special population, drug interaction, and more.

All of our infrastructure and systems are setup to guarantee high-quality outputs and compliance for generics companies. Our state-of-art facilities have been inspected successfully by the USFDA, WHO, Health Canada, EMA, DCGI, TGA & NPC, among other regulators. We are ISO 9001, ISO 27001, and ISO 15189 certified, and are accredited by the College of American Physicians.
End to end suite of Bioavailability & Bioequivalence Service Offerings

End to end Services and Solutions for Generics Companies

- Study Design, Study Conduct, Subject recruitment and Project Management
- Bioanalysis, PK and Statistics
- Data Standardization in CDISC-complaint format
- Medical Writing, eCTD Submission, Data Archival
- Dossier preparation
- Regulatory Submission
- Redacted reports for regulatory inspections
- Pharmacovigilance activities
- Regulatory Compliance - SOPs built upon regulatory guidelines
- Independent QA

Pharmacovigilance, Publishing and Submissions

- Smart administrative approach and adherence to the timelines are critical for the filing and in turn ROI
- Clinical facilities at multiple locations (a logistical advantage) for accommodating bigger sample size
- High-end instrumentation capacity to absorb the bolus load with shorter TAT

Clinical Capability: Database of 20K+ registered volunteers and ready access to diverse populations

- Multiple governance systems ensure 100% adherence to regulatory guidelines
  - Independent QA department with SOPs, training and audits
  - Pre-conduct study approval by Manipal University Ethics Committee – India’s 1st AAHRPP accredited EC
  - Periodic certification to ISO 9001, ISO 27001, ISO 15189, CAP
  - Self-identification with USFDA
  - Most recent inspection (May 2018) and the past inspections from USFDA have been tremendously successful with zero observations

World-class BE facilities adhering to highest compliance with attention to quality & safety at every stage standards

- 48-bed CPU in Cancer Hospital of Manipal University
- State of the art Bioanalytical Lab
- 80-bed facility across 2 CPUs in Manipal university hospital campus
- Bio-analytical testing services
- GLP 21 CRF Part-11 compliant
- 80-bed facility across 2 CPUs
Diverse populations to meet your study needs

20 successful inspections across 5 regulators in the last 10 years

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

Bioanalytical Capability: Labs at the forefront of technology

- We have state of the art GLP and 21 CFR part 11 compliant Bioanalytical labs located in Manipal and Bangalore
- Bioanalytical Labs are equipped with 12 LC-MS/MS (02 Sciex API 6500, 04 Waters Xevo TQ-S, 03 Thermo Ultra & 03 Thermo Discovery Max) including UPLC, ICP-MS (Agilent 7700x in Class 10000 clean air lab facility)
- New methods can be developed and validated in 4 weeks

Library of 250+ validated Assays applied across 1000+ studies

- LCMS/MS for small and large molecule
- ICP-MS for trace elements
- Precision levels of up to 0.5 pg/mL
- 08 different matrices including bone and skin

Tailored multi-analyte methods ready in 4-5 weeks

- Multiple approaches with different instrument platform
- Highly sensitive method for Mometasone (0.5 pg/mL), Fluticasone (1 pg/mL) & Formoterol (0.4 pg/mL)

Expertise in macromolecules

- E.g., Insulin, Glargine, Octreotide etc.,
- Expanding our expertise in mAbs
Our Experience and Key Differentiators

- Our practice of delivering high quality and compliant studies in a cost effective manner and within timelines, have earned us long standing client loyalty
- We help bring your products to market faster
- New methods can be developed in 4 weeks
- Our PK domain expertise is often sought by formulators to make improvements

**Key Differentiators**

- 1000+ Bioequivalence studies for submissions in 6 continents
- 100+ marketing authorization approvals
- 250+ validated bioanalytical methods
- 50+ satisfied customers (Generic & Innovator Pharma companies)
- Highly skilled team of 50 specialists led by 8 qualified medical practitioners and 3 PhDs

**Delivering Priority Submissions for Clients (Examples):**

- Reduced “Protocol to CDISC Submission” Cycle Time by 50% for a NCE-1 Submission to USFDA
- Reduced “Protocol to CDISC Submission” Cycle Time by 69% for a First to File (FTF) submission to USFDA

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**About TAKE Solutions**

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

**For more information**

Americas +1 609 720 1002  Europe +49 69 668 0300  APAC +91 44 4590 9000

contact@takesolutions.com  www.takesolutions.com  /company/take-solutions