

Advinus Drug Development Services

Innovating Solutions for Pharma R&D



About us

- Pharma R & D organization promoted by **TATAs - one of India's largest and most respected business house**
- India's leading **pre-clinical service provider** (CMC, DMPK and Pharm tox)
- Committed and excellent team of over 270 scientists
- Over 220,000 square feet of state of the art laboratory
- **Highly accredited GLP facility**



Value Proposition

- Over 17 years of experience in conducting regulatory GLP studies
- Experienced management team that has filed multiple INDs and NDAs
- Only facility to be **GLP certified by Germany, Netherlands and India**
- **First AAALAC accredited lab in India**
- Completed more than 3300 GLP studies
- **Data accepted by USFDA, TPP (Health Canada) & EMEA**
- **First company in India to implement 21 CFR Part 11 compliance systems (Watson, Nova LIMS, Provantis)**
- Multiple shots at goal by leveraging the Advinus and India's cost advantage
- Dedicated project management support to manage complex projects
- Timelines that match the best in the industry



Our Service Offering

Process Development & Synthesis

- Custom synthesis
- Intermediates
- Salt form & polymorph selection
- Process development for NCEs
- cGMP capability upto kilo quantity

Analytical R&D and Pre-formulation

- Process chemistry and pre-formulation / formulation support
- Stability studies for API
- Impurity profiling and characterization
- Physical chemical properties

Safety Assessment

- Discovery support
- Acute / sub chronic and chronic studies
- Genotox studies
- Reprotox studies
- Safety pharmacology

DMPK

- CYP studies
- CaCO-2 & MDCK permeability
- Stability in microsomes & hepatocytes
- PK studies (Mouse, Rat and Dog)
- Mass balance & tissue distribution
- Metabolite profiling
- Discovery support

Bio-analysis

- Method feasibility, development and validation
- Preclinical toxicokinetic analysis
- Preclinical and clinical PK analysis
- BA / BE analysis
- Drug-drug interaction analysis
- High throughput analysis of biological samples

Clinical Development

- First time in humans
- Special populations
- Drug-Drug interactions
- Biopharmaceutical evaluation of NDDS
- PK / PD correlation

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