+91 7406041119
Venugopal@colliculusdataresearch.com
Madhapur, Hyderabad, INDIA

COLLICULUS

Case Study

BA/BE Study for a Generic Antihypertensive Drug

Client's Business Influence

The successful completion of the BA/BE study had a significant impact on the company's business:

✅ Regulatory Approval: The study met all FDA bioequivalence criteria, enabling a smooth ANDA submission.

💰 Market Entry: Company launched its generic product in the US market within 12 months, capturing a 10% market share in the first quarter.

📊 Cost Savings: In-house development and analytics reduced outsourcing costs by 30%.

🧠 Reputation Boost: The success positioned company as a reliable player in the global generics market, leading to new partnerships and licensing deals.

Project Scope:

One of the Indian pharmaceutical company, aimed to develop a generic version of Losartan Potassium 50 mg. To support its ANDA (Abbreviated New Drug Application) submission to the US FDA, the company needed to demonstrate bioequivalence between its formulation and the reference listed drug (RLD).

The scope included:

- Designing and executing a BA/BE clinical trial
- Conducting pharmacokinetic (PK) and statistical analysis
- Preparing a regulatory submission package

Methodology/ Approach:

Study Design

- Type: Randomized, open-label, two-period, two-sequence crossover
- Subjects: 24 healthy adult volunteers (18–45 years)
- Dosing: Single oral dose of 50 mg
- Washout Period: 7 days
- Sampling: Blood samples collected over 48 hours
- Bioanalysis: LC-MS/MS method for plasma concentration

PK Parameters Evaluated

- Cmax (Maximum plasma concentration)
- Tmax (Time to reach Cmax)
- AUC_0–t and AUC_0–∞ (Area under the curve)
- t½ (Elimination half-life)

Statistical Analysis

- ANOVA for log-transformed PK parameters
- 90% Confidence Intervals calculated for Cmax, AUC_0–t, and AUC_0–∞
- Bioequivalence Criteria: 90% CI within 80%–125%