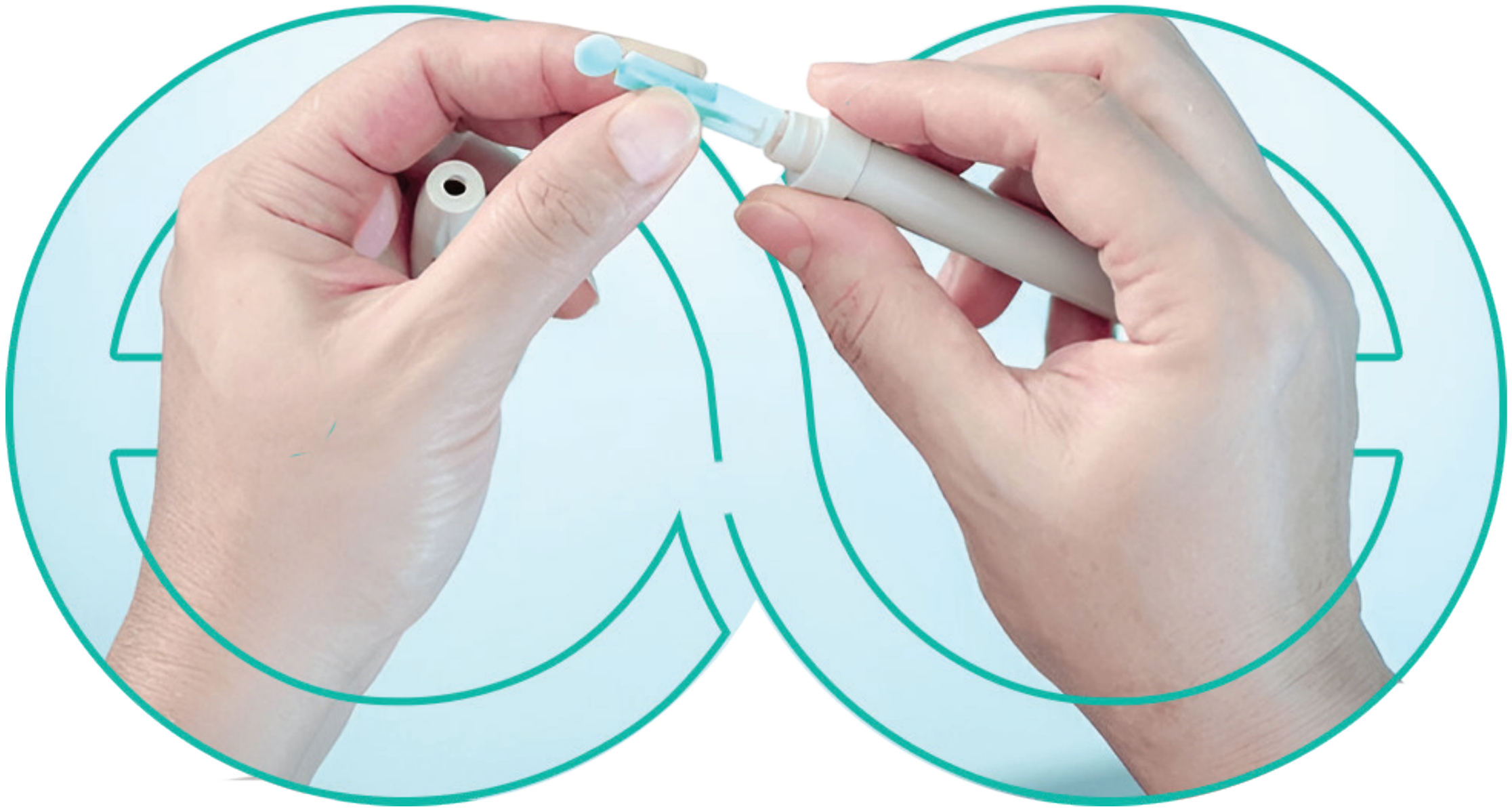
Veeda™
Lifesciences



Ferric Carboxymaltose (FCM): Bioequivalence-Validated Strategies Driving Global Regulatory Success

Veeda Lifesciences: Expertise That Builds Trust with Global Clients

Direct Regulatory Engagement: USFDA & EMA

Study Portfolio: 5 Healthy Volunteer Studies and 3 Patient PK Studies and >30 Feasibilities

80% success rate

Proven Enrolment Capacity: 80+ Volunteers & 300+ Patients

Meeting USFDA and EMA Submission Requirements: A Rigorous Similarity Proof Framework

In-Vitro Similarity - Our Detailed Approach

- **Q1/Q2 Similarity:** Verifying both qualitative and quantitative consistency with the reference product.
- **Particle Size Distribution & Characterization**
  - Z-average size, PDI or D_{50}, SPAN
  - At least 10 datasets across 3 batches (Test & Reference)
  - Population BE, 95% upper bound limits

In-Vivo Bioequivalence – Customized Study Options

Option 1: Patient Bioequivalence Study

- **Study Population:** Adults with iron deficiency anemia and chronic renal disease.
- **Strength & Protocol:** Using a 750mg formulation, administered at a specific push rate.
- **Analyte Focus:** Measuring FCM Associated Iron (FAI) or, alternatively, Total Iron (TI) and Transferrin Bound Iron (TBI) to establish bioequivalence.

Option 2: Healthy Volunteer Bioequivalence Study

- **Study Population:** Healthy subjects, selected with defined exclusion criteria.
- **Product Strength:** A 100mg dose tailored for healthy volunteers.
- **Consistent Analysis:** The same rigorous analyte measurements (FAI, TI, TBI) ensure dependable bioequivalence outcomes.

Robust Study Designs: Prioritizing Safety & Accuracy

Subject Safety & Selection:

- Comprehensive screening: Lab parameters (serum iron, transferrin, etc.), vital signs, ECG
- On-site safety: Presence of an Intensivist
- Controlled housing: From 1 day pre-dose to 2 days post-dose

Sampling Protocol:

- Intensive sampling: 3 pre-dose, every 10–15 minutes up to 2.5 hours, and a final sample at 144 hours (25–30 total samples)
- Standard blood volume: 4mL per sample

Study Structure:

- Design: Parallel, two-arm study (Test & Reference)
- Phases:

Pilot Phase

18–24 subjects per arm

Pivotal phase

75–80 subjects per arm (scalable up to 200)

Advanced Analytical Capabilities

- **In-House Methods for Analytes Measurement:**
  TI, TBI, and FCM Associated Iron (FAI)
- **State-of-Art Instrumentation:**
  - ICP-OES
  - SEC coupled with ICP-MS for enhanced sensitivity
- **Detailed Performance Metrics:**
  - **Linearity Range:** 10 mcg/ml to 600 mcg/ml (for FAI)
  - **Processing Volumes:** 0.10 mL for TI and 0.075 mL for TBI
  - **Run Time:** 7 minutes for TI and 4 minutes for TBI

Challenges and Future Directions:

- **Iron Species Separation:** Efficient separation of Drug-Bound Iron (DBI), Free Radical Iron (if present), and Transferrin-Bound Iron (TBI) in serum/plasma using SEC-LC-ICP-MS.
- **Method Optimization:** Careful tuning of the mobile phase, size exclusion column, and reconstitution solution to ensure method robustness and reproducibility.
- **Carryover Minimization:** Precise selection of auto-sampler rinsing solutions to reduce carryover, especially with higher Free Iron (FAI) concentrations in patient samples (~300–500 µg/mL).
- **Hemolysis Impact:** Exclude hemolyzed samples from analysis to avoid interference in Total Iron and Transferrin-Bound Iron quantification, ensuring accurate pharmacokinetic and statistical evaluation.

Our Scientific Leadership Team

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