Injectable Drug Development Support

Complete Solutions for Injectable Drugs Nearing Patent Expiry: Ensuring Seamless Development & Market Readiness

Supporting You Across the Entire Drug Development Lifecycle

Preclinical

- Discovery Services
- Preclinical Toxicology
- Chemistry
- Bioanalysis

Biopharma

- Clinical Bioanalysis solution for Bio Therapeutics
- Non-Clinical Characterization Solutions – Discovery Biology, Bioprocess, and Analytical Characterization

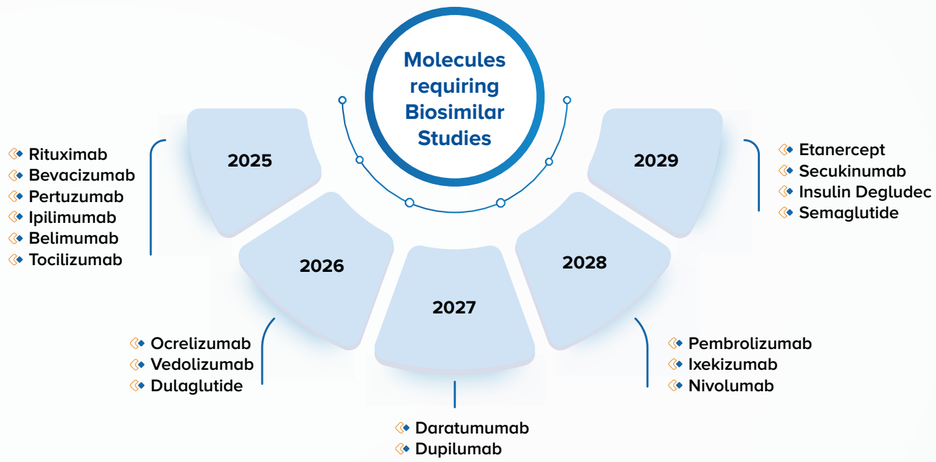
Clinical Studies

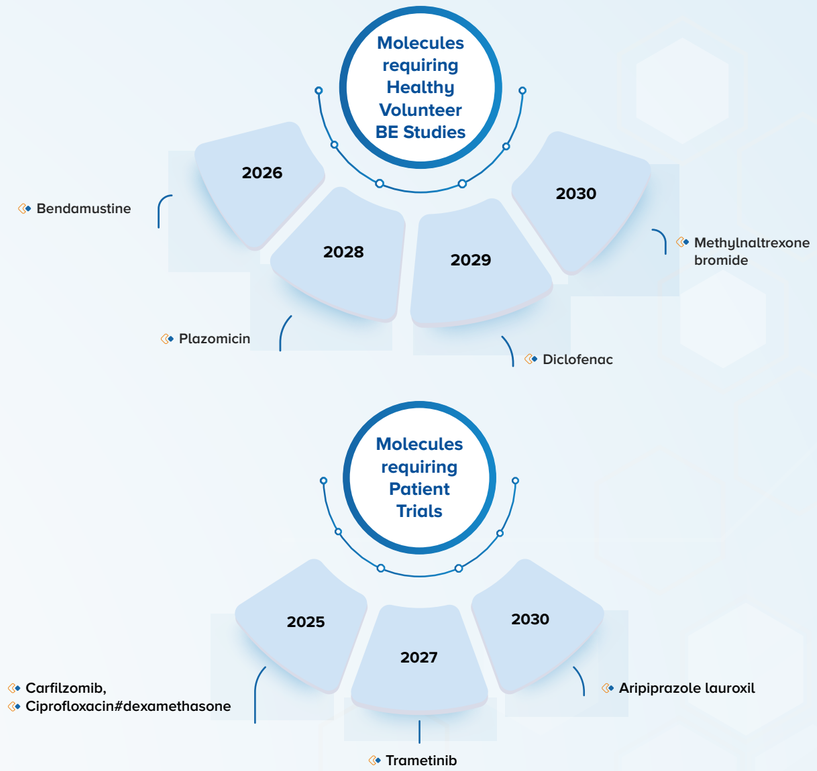
- Phase I Clinical Pharmacology studies for NCEs & NBEs
- Phase II- Phase III trials for NCEs & NBEs
- Phase IV & PMS Studies
- BE studies for Complex Injectable Drugs (both Healthy and Patient)

Bioanalytical

- Method Development and Validation for NCEs and Generics

Injectable Drugs Coming off Patent in the Next Few Years





Injectable Drug Development comes with Unique Set of Challenges

Patient Recruitment and Retention:
Discomfort associated with injections may deter some individuals from participating.

Administration Complexity:
Ensuring patient compliance can be more difficult compared to oral medications due to the invasive nature of injections.

Storage and Handling:
Injectable drugs need specific storage for stability. With extensive relabeling experience, changes in labeling due to regulations or trial modifications are efficiently managed, ensuring trial compliance & integrity

Safety and Monitoring:
Injectable can cause immediate adverse reactions, requiring close monitoring during and after administration.

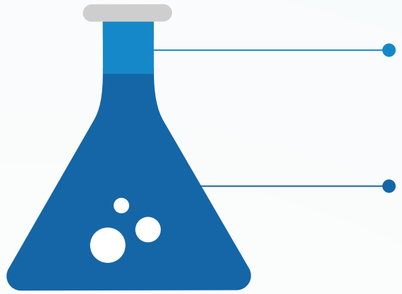
Dosing Precision:
Trials requiring dose adjustments based on patient response or pharmacokinetic data add complexity to maintaining dosing precision.

Regulatory Approval Processes:
The approval process can be lengthy and complex, requiring comprehensive data on safety, efficacy, and manufacturing practices

+91 79677 73000 info@veedalifesciences.com www.veedalifesciences.com

Veeda's Expertise in Injectable Studies

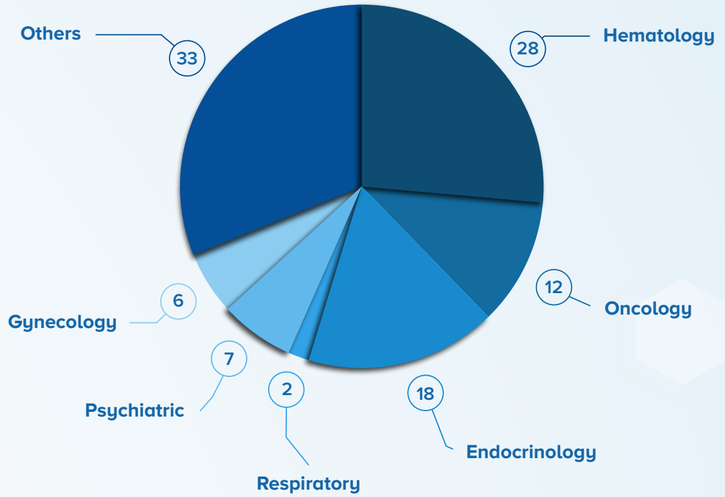
Comprehensive Bioequivalence Research: 106 Healthy Volunteers and Patient Studies



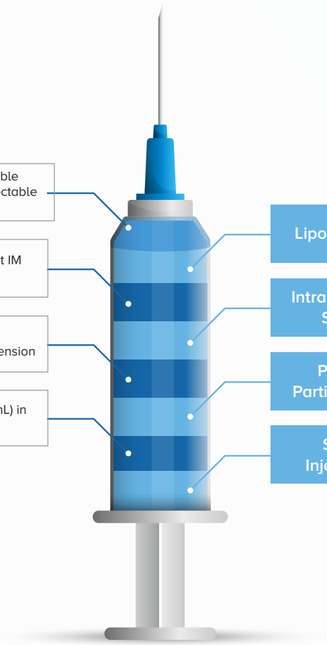
Patients - **23 studies**

Healthy Volunteers - **83 studies**

Trusted Companion for Injectable Drug Development Across Diverse Therapy Areas



Wide Experience Across Different Complex Formulation



Injectable Suspensions	Methylprednisolone Acetate Injectable Suspension, Octreotide Acetate Injectable Suspension
Injectable Solutions	MPA 80 mg/mL Injection, Fulvestrant IM Injection
Extended-Release Injectable Suspensions	Examples: Paliperidone Palmitate Prolonged-Release Injectable Suspension
Prefilled Syringes	Examples: Pegfilgrastim (6 mg/0.6 mL) in Single-dose prefilled syringe
Liposomal Injections	Examples: Doxorubicin Hydrochloride Liposome Injection
Intramuscular Depot Suspensions	Examples: Leuprolide Acetate 30 mg intramuscular injection for Depot Suspension
Protein-bound Particle Suspensions	Examples: Paclitaxel protein-bound particles for injectable suspension
Solutions for Injection/Infusion	Examples: Ferric Carboxymaltose solution for injection/infusion

Bioanalytical Method Validation

Experts in utilizing advanced techniques such as mass spectrometry and HPLC for precise and thorough analysis.

Successfully supported a range of injectable studies through a range of validated methods via LC-MS/MS, like injectable suspensions (e.g., Octreotide Acetate), protein-bound particle suspensions (e.g., paclitaxel), liposomal injections (e.g., doxorubicin & Amphotericin B), subcutaneous injections (e.g., Phytonadione) and many more.

Advanced Analytical Techniques and Clinical Bioanalysis for Injectable Biosimilars

Bioanalytical Expertise

Specializing in clinical and bioanalytical evaluation, with advanced techniques such as ELISA and LC-MS/MS for immunogenicity assessment.

Peptides Expertise

Advanced analytical techniques for peptide characterization, peptide PK/PD studies, and peptide mapping to ensure a comprehensive analysis for various peptides like Insulin, Desmopressin, Leuprolide, and Octreotide.

Biosimilars Experience

Extensive experience in the development and evaluation of biosimilars, including ADL-018 (XOLAIR), a recombinant DNA-derived monoclonal antibody.

Experience with Different Molecules

Teriparatide, Tocilizumab, Romiplostin, FSH (Follicle Stimulating Hormone), and C-Peptide.

+91 79677 73000 info@veedalifesciences.com www.veedalifesciences.com