

Integrated Solutions for Generic & Novel GLP-1 Receptor Agonists: Spanning Preclinical to Clinical Development



Overview

Veeda's integrated approach to GLP-1 Peptide development encompasses a multi-stage solution including Preclinical, Clinical, Bioanalytical & Non Clinical Characterization evaluations, highlighting our expertise as a Contract Research Organization (CRO) providing end-to-end solutions.

GLP-1 Receptor Agonists in Diabetes Management

Glucagon-Like Peptide-1 receptor agonists (GLP-1 RAs) are a class of medications used in the management of type 2 diabetes.

Molecules	
Exenatide	Liraglutide
Albiglutide	Dulaglutide
Lixisenatide	Semaglutide

Veeda's Integrated Solutions for GLP-1 Receptor Agonists

Preclinical Assessments

- ◆ Bridging Comparative Studies : PK study in rats, repeat dose toxicity study in rats with TK and immunogenicity
- ◆ Albumin & Protein Binding assay, Acute study in rats, In vitro and In vivo Geno toxicity studies
- ◆ Reproductive toxicity, Carcinogenicity study using RasH2 transgenic mice and rats

Our Experience in Preclinical Safety and Efficacy Assessment

Toxicology Studies, Analytical Assessments, and Immunogenicity Evaluations of GLP-1 RAs such as Liraglutide and Semaglutide

In Vitro Assays

- ◆ Binding kinetics of GLP-1 analogs to human GLP-1 receptor: Surface Plasmon Resonance (SPR) assay
- ◆ Adaptive Immunogenicity of IIRMI: Using human PBMCs and isolated blood cells
- ◆ In Vitro potency of GLP-1 analogs in GLP-1 overexpressing cell lines
- ◆ Innate Immunogenicity of IIRMI: Human PBMC assay and specific PRR-overexpressing cell lines

Primary Structure Characterization

- ◆ Intact Mass
- ◆ Peptide Mapping (enzyme-based)
- ◆ Amino acid & Terminal Sequencing (enzyme-based)
- ◆ PTM Identification and Quantification
- ◆ Impurity Identification and Characterization
- ◆ pI and Molecular Heterogeneity: CE-SDS, CZE, cIEF

Higher-order Structure Analysis

- ◆ Secondary Structure
- ◆ Oligomer and Aggregation

Clinical & Bioanalytical Solutions

Clinical Solutions:

- ◆ Early phase [Phase 1] clinical pharmacology studies
- ◆ Healthy Volunteer Bioequivalence Studies
- ◆ Complex Studies involving Glucose clamp
- ◆ Type 2 Diabetic Phase II/Phase III Trials

Veeda's Experience across Antidiabetic Drugs & Complex Healthy Volunteer Studies for GLP-1 RA Molecules:

- ◆ Phase I healthy volunteer study for Antidiabetic drug
- ◆ 16 Glucose clamp studies across various insulin products such as Insulin Glargine, Insulin Aspart, and Insulin Wosulin
- ◆ Complex healthy volunteer studies for GLP-1 receptor agonist (GLP-1 RA) molecules, including Liraglutide and Semaglutide

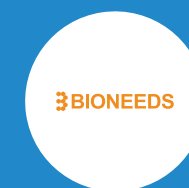
Comprehensive Bioanalytical support for Clinical Comparability Studies:

- ◆ Blood Sample Measurement for both reference and biosimilar GLP-1 RAs
- ◆ Pharmacokinetic (PK) calculations and statistical analysis
- ◆ Immunogenicity studies to assess the immune response
- ◆ Tailored bioanalytical methods specifically for different GLP-1 analogues

To know more about our Solutions for Generic and Novel GLP-1 Receptor Agonists write to us at info@veedacr.com



info@veedacr.com
www.veedacr.com
+91 7967773000



bionees@bionees.in
www.bionees.in
+91 8162214400