



- Veeda offers a full range of consulting, regulatory, laboratory and clinical development services to support biosimilar product development.
- Our team of Clinical Research professional, Physicians, Medical Writers, Safety Experts with extensive experience of working in more than 20 biosimilar molecules for Indian and Global Registration.
- Completed Projects
 - Comparative PK and PD study on GCSF, Erythropoietin, Streptokinase.
 - Glucose Clamp studies on Insulin Aspart and Insulin Glargine.
 - Pharmacodynamic & Immunogenicity analysis for Enoxaparin.
- Feasibilities and ongoing discussion
 - Interferon Beta, PTH, Ranibizumab, Bevacizumab, Trastuzumab, Cetuximab and Adalimumab.

BIOSIMILAR ANALYTICAL – EXPERIENCES / CAPABILITIES

- Completed Enoxaparin PD end point and Immunogenicity studies [03 studies for US FDA, 01 study each for EU and ANVISA].
- Pharmacodynamic endpoint-Anti-Xa detection and Anti-IIa detection using Chromogenic method.
- Immunogenicity-Anti heparin PF4 screening assay & Total Ig GAM screening assay using ELISA technique.
- TFPI detection using ELISA technique, Linearity range: 0.050 IU/mL to 0.200 IU/mL.
- Heparin Clotting assay Coagulation method, Linearity range: 0.100 IU/mL to 1.00 IU/mL.
- IgG, IgA & IgM Screening assay using ELISA technique.
- Total no of sample Analyzed
PK-14784, PD-3866 & Immunogenicity – 3783 samples.

RECENT EXPERIENCE OF LARGE MOLECULES BY LIGAND BINDING ASSAY:

Sr. No.	Analyte	No. of Samples Analyzed	No. of Samples Analyzed for ISR	% of ISR Samples within Acceptance
1	G-CSF	2142	158	98.7%
2	Insulin Aspart	2139	158	94.9%
3	C- Peptide	2400	176	98.2%