

VEEDA LARGE.
MOLECULES
CAPABILITIES AND
EXPERIENCE



veeda clinical research®

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.

Large Molecules by LC/MS/MS:

Human Insulin : Insulin Glargine Method Under development by LCMSMS, approach is to have intact molecule analyzed in MS (SH-8060)
(As Multiple molecule MRM).

- Proposed Linearity Range - 50 pg/mL-10000 pg/mL/
- The other analogs of insulin (Glargine, aspart are also planned to develop).
- The other Insulin analogues like Insulin Aspart is also in the pipeline.

Why partner with Veeda?

- Experienced technical staff for handling different Bioanalytical issues.
- Variety of Mass platform (from sub ng to sub pg level) to handle different molecules.
- Privately owned company with no conflict of interest.
- Assured Business Continuity.

Recent Experience of Large Molecules by Ligand binding assay:

Veeda has recently developed and validated below large molecules as per current EMEA guidance using commercially available kits by ELISA technique of G-CSF, Insulin Aspart, C – Peptide, using validated methods study samples were analyzed as below:

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%
4	PTH	340	34	88.33%

Recent Method validation

ECLIA – (Electrochemiluminescence Immunoassay)

1. Insulin – LLOQ 10 pmol/L,
2. C-peptide – LLOQ 40 pmol/l

ELISA (Enzyme-linked immune sorbent assay)

1. Teriparatide –LLOQ 15 pg/mL