



One Stop Hub for Biopharma Solutions



Services & Capabilities



Test Facility

Vimta's Biopharma is equipped with state of the art instrumentation

- » LC-MS Triple TOF 6600
- » Capillary electrophoresis PA800+
- » Spectra max i3X multimode micro plate reader
- » Bioplex- 200
- » UPLC and HPLC with PDA
- » ELSD, RI and RF detectors
- » Dynamic Light Scattering (DLS)

Our product expertise: Lot release & characterization

Peptides & Biosimilars

- » Liraglutide
- » Semaglutide
- » Vasopressin
- » Salmon Calcitonin
- » Glucagon
- » Lanreotide
- » Octreotide
- » Plecanatide
- » Teriparatide
- » Abaloparatide
- » Exenatide
- » Icatibant
- » Linaclotide
- » Teduglutide
- » Desmopressin
- » Insulin
- » Adalimumab
- » Rituximab



Experience

Other & Complex Generics

- » Sucralfate
- » Iron Sucrose
- » Betadex Ether
- » Colesevelam
- » Zolmitriptan
- » Enoxaparin characterization
- » Glatiramer acetate

Areas of expertise

- **Secondary Messenger Assays:** Relative potency estimation by drug induced intracellular cAMP
- **Proliferation Assays:** *In vitro* potency assay for various growth factors
- **Clotting Factor Assays:** Potency assay for anti-factor IIa & Xa assays for low molecular weight heparin & heparin
- **CPER Assays:** Relative potency estimation for anti-viral products by CPER assays
- **Neutralization Assays:** Anti-drug antibody confirmation test by drug efficacy neutralization
- **Immunoassays:** ELISA based immunorecognition assays for different biosimilars
- **Innate Immune Response Modulating Impurity (IIRMI):** Assessment through cell based assay
- **Impurity Profiling:** Co-eluting Impurities by QTOF
- **Immunogenicity:** ADA assays for Pre-clinical and clinical studies
- **PK/PD Studies:** Validated assays for Pre-clinical and clinical studies
- ***In vitro* Bioequivalence Studies:** Complex generics as per product specific guidance
- **Polydispersity:** Molecular weight distribution

Techniques

- » SDS-PAGE
- » Western blot
- » Iso-electric focusing
- » Intact mass & HRMS
- » Charge variant analysis
- » Disulphide mapping
- » N-and C-terminal sequence by LC/MS
- » Intact molecular weight by LC/MS
- » Disulfide bond position by LC/MS
- » Peptide mapping
- » CD- Secondary & Tertiary structure
- » Dynamic Light Scattering (DLS)
- » Aggregates by SEC
- » Charge heterogeneity by IEX
- » Deamidation & oxidation
- » Peptide mapping LC/MS
- » MW purity by CE-SDS
- » Impurity profile by cr LC/MS bbw

BIOASSAYS

Bioassays are critical in evaluating potency of various biomolecules and peptides at each stage of drug discovery, development and manufacturing. Bioassays that support lot release, stability, comparability and extended characterization, have the additional requirements to be robust, precise and, in the case of potency assays, suitable for use in a GMP-compliant environment.

Vimta develops and validates bioassays in accordance to applicable guidelines: ICH Q6B, USP Chapter 1032, 1033 and statistical analysis of biological assays by USP 1034 and E.P.5.3.

GMP Work flow at Vimta

