

Peptides: One Partner. Complete Solutions.



Octreotide

Semaglutide

Teriparatide

Liraglutide

Leuprolide
Acetate

Preclinical Solutions for Peptides

GLP Toxicity Studies

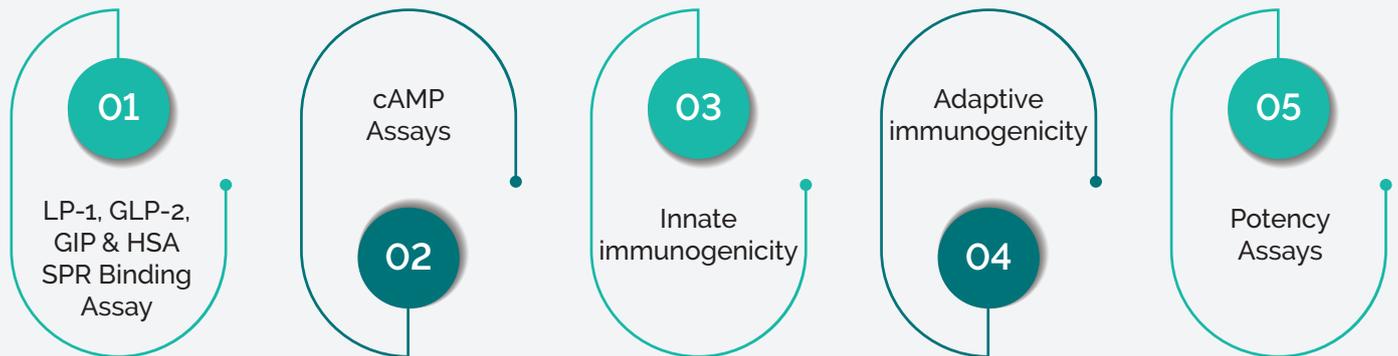
- IND or NDA enabling
- 27500+ GLP Studies Executed

Infrastructure

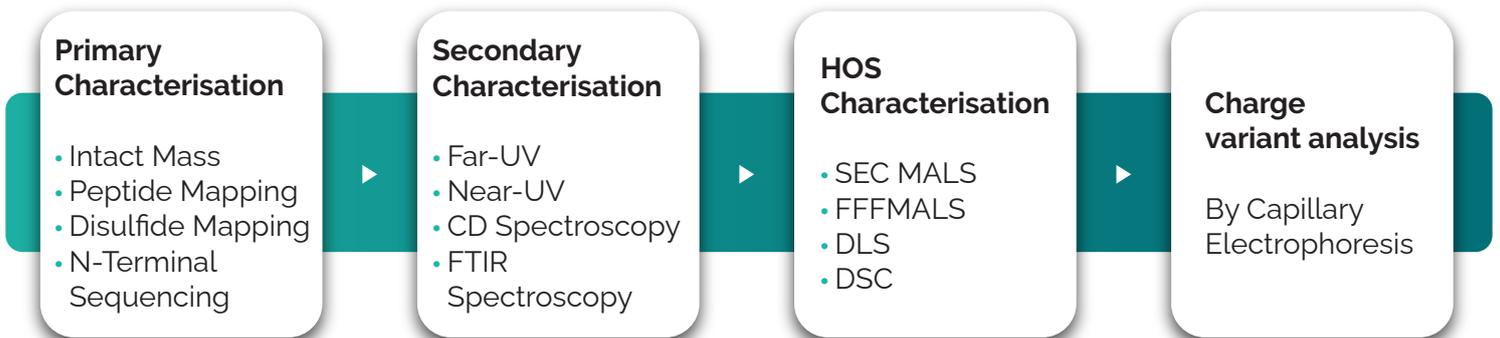
- 25000+ sq ft built up area
- 115+ animal rooms
- 450+ team strength

- Long-term toxicity studies like Chronic, Carcinogenicity, DART, Juvenile toxicity, Neurotoxicity etc.
- MTD/DRF/Repeat Dose Tox Studies
- PK (Rodents/Non-Rodents) with Bioequivalence
- Complex tissue distribution studies
- Associated bioanalytical activities like TK/Immunogenicity/biomarker assessment etc
- GLP batch release assays (DS/DP)

Biological Sciences Expertise for Peptides



Analytical Solutions for Peptides



Advanced Analytical Instruments for Peptide Characterization

- High resolution mass spectrometry (Waters Xevo G3, thermo Q-exactive)
- CD Spectroscopy (Applied Photophysics)
- (High Performance Liquid Chromatography) HPLC, - (Shimadzu prominence I series)
- SEC/FFFMALS (postnova)
- FTIR (Bruker)
- Nano DSC (TA instruments)
- DLS (ANTON PAAR)
- SCIEX PA 800, Capillary electrophoresis

Supporting **10+** Biopharma Studies

Your Partner for Solving Complex Clinical Challenges



15
Healthy Volunteer & Patient
PK Studies

300+
Healthy Volunteers
Enrolled

90+
Patients
Enrolled

Comprehensive infrastructure and expertise to execute peptide Studies

- 30 Bedded Phase I units
- Medical team with ACLS and BLS certification.
- Team experience >400 successful glucose clamp studies ranging from 8 hrs to 36 hrs
- 91,000+ Healthy Volunteer Database

Bioanalytical Techniques and Methods for the Accurate Quantification and Analysis of Peptides

Analytical Techniques

- Separating
- Detecting
- Quantifying

Sample Preparation Techniques

- Extraction
- Purification
- Concentration of peptides

Ensuring Optimal Chromatographic Conditions

GLP-1: Comprehensive Bioanalytical support for Clinical Comparability Studies

- Serum/Plasma measurement for both reference and biosimilar GLP-1 RAs
- Pharmacokinetic (PK) estimations and statistical analysis
- Immunogenicity studies to assess the immune response
- Tailored bioanalytical methods specifically for different GLP-1 analogues

Molecules	Challenges	Solutions	Results
Desmopressin	<ul style="list-style-type: none"> Detection limit 20x below Cmax sensitivity/selectivity against endogenous matrix. 	<ul style="list-style-type: none"> SPE cleanup & sub-micron Reversed-phase LC; Sciex 6500+ LC-MS; 	<ul style="list-style-type: none"> Linear 1.056–264 pg/mL ≥98% acceptance
Ocaterotide	<ul style="list-style-type: none"> Low pg/mL quantitation Matrix effects. 	<ul style="list-style-type: none"> Optimized mass transition Ion exchange SPE Specialized peptide column 	<ul style="list-style-type: none"> Linear 20 pg/mL–10 ng/mL No carryover or matrix interference Consistent recovery
Liraglutide	<ul style="list-style-type: none"> Very high molecular weight (~3751 Da). Adds hydrophobicity, altering chromatographic behaviour and ionization efficiency in LCMSMS. Non-specific bindings and carryover issue 	<ul style="list-style-type: none"> Optimized Stable ion-pair for consistent signal Peptide Specific columns and gradient program to resolve interfering peaks and eliminated matrix effect. Optimized autosampler rinsing situation & rinsing cycle to minimized carry over and reduce overall run time 	<ul style="list-style-type: none"> Linearity 0.8ng/mL to 80.0ng/mL. No matrix effect observed. No carry over observed.
Teriparatide	<ul style="list-style-type: none"> Low sensitivity and reproducibility for ADA assay 	<ul style="list-style-type: none"> Homogenous sample incubation MRD optimization 	<ul style="list-style-type: none"> Sensitivity of 39 ng/mL with consistent results High reproducibility in clinical samples



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Excellence
In Everything