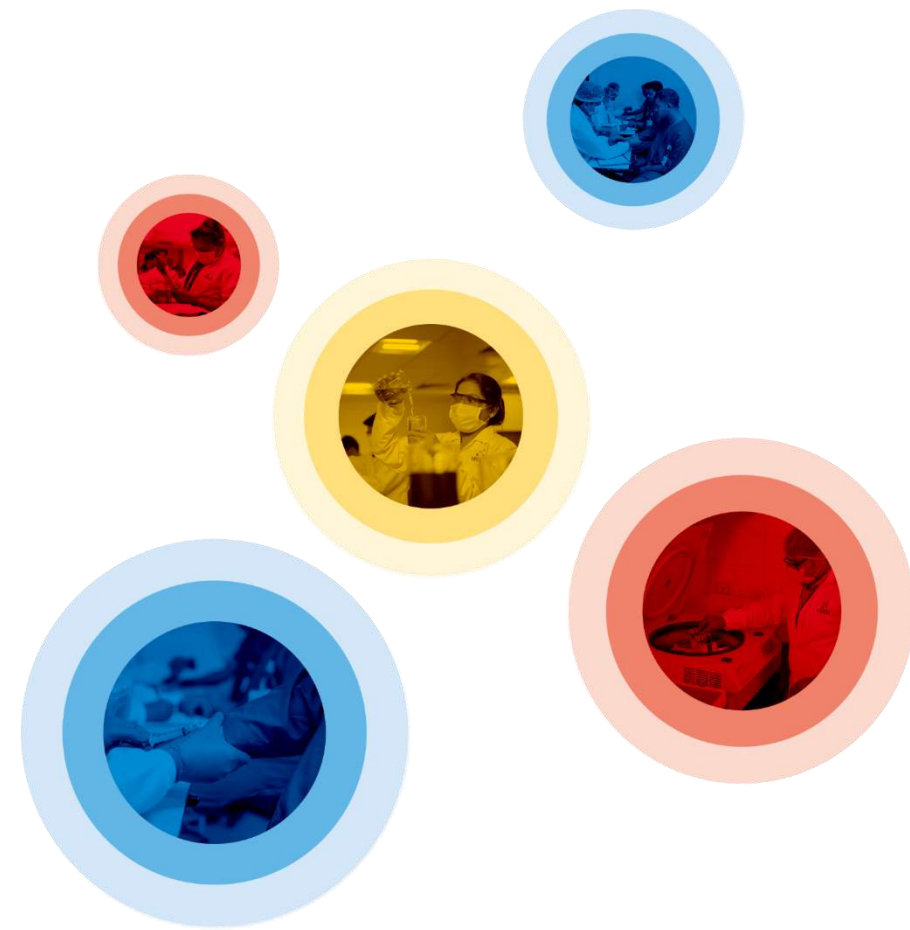




Global Clinical Development Partner



Providing Quality Bioanalytical Services



veeda clinical research®

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Testimonials

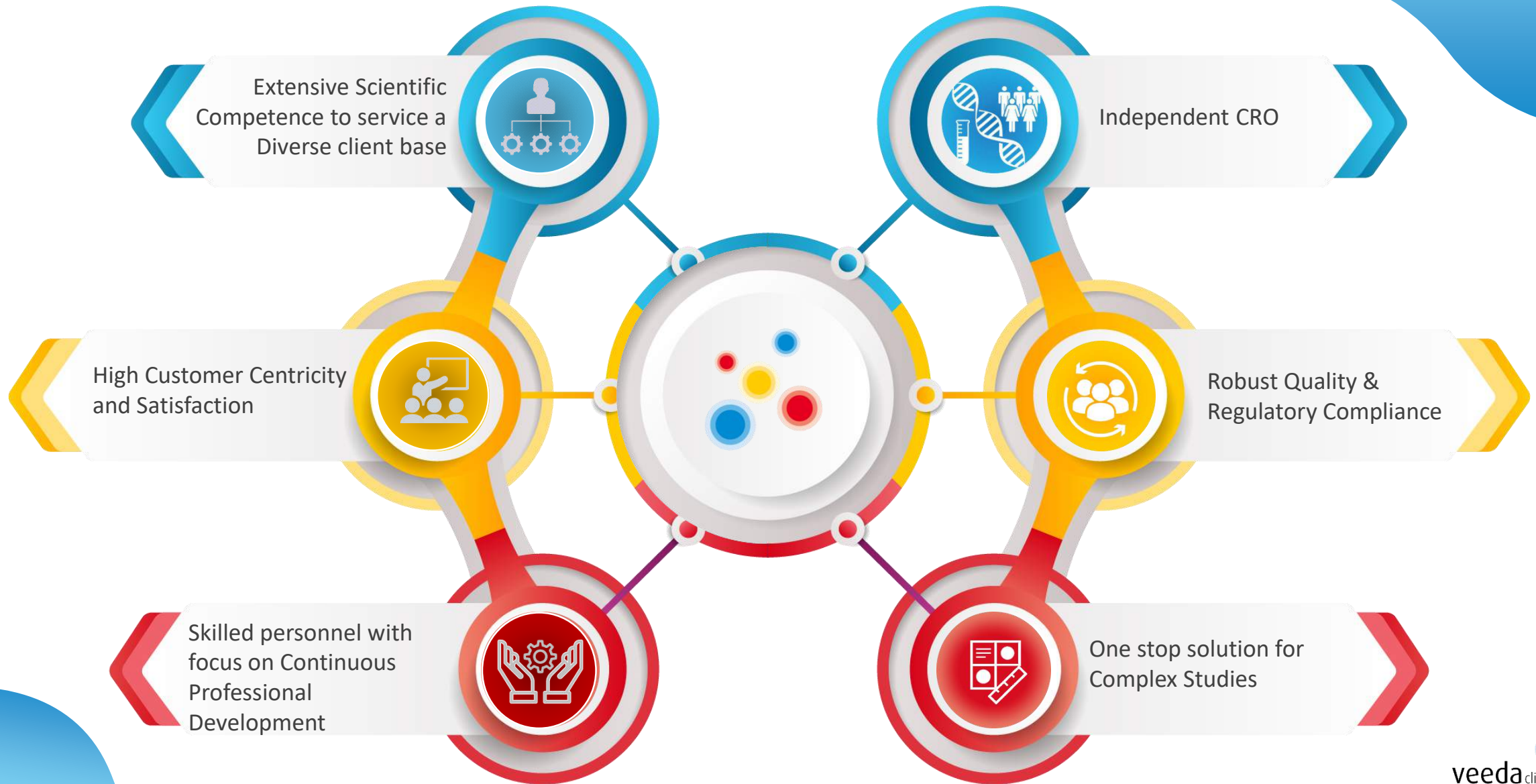


Achievements



The Veeda Advantage

2



Corporate Philosophy

3



Vision

In an industry where innovation is increasingly multifaceted and collaborative, we aspire to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide for their critical product development programs.



Mission

To be the pre-eminent independent Indian contract research Organisation, with global execution capabilities, distinguished by the breadth of our services and by excellence in the quality of our : Scientific and regulatory knowledge; Research design, execution and insights; and Client centricity.

Our Values



Honesty
and Integrity



Humility



Openness



Excellence



Innovation

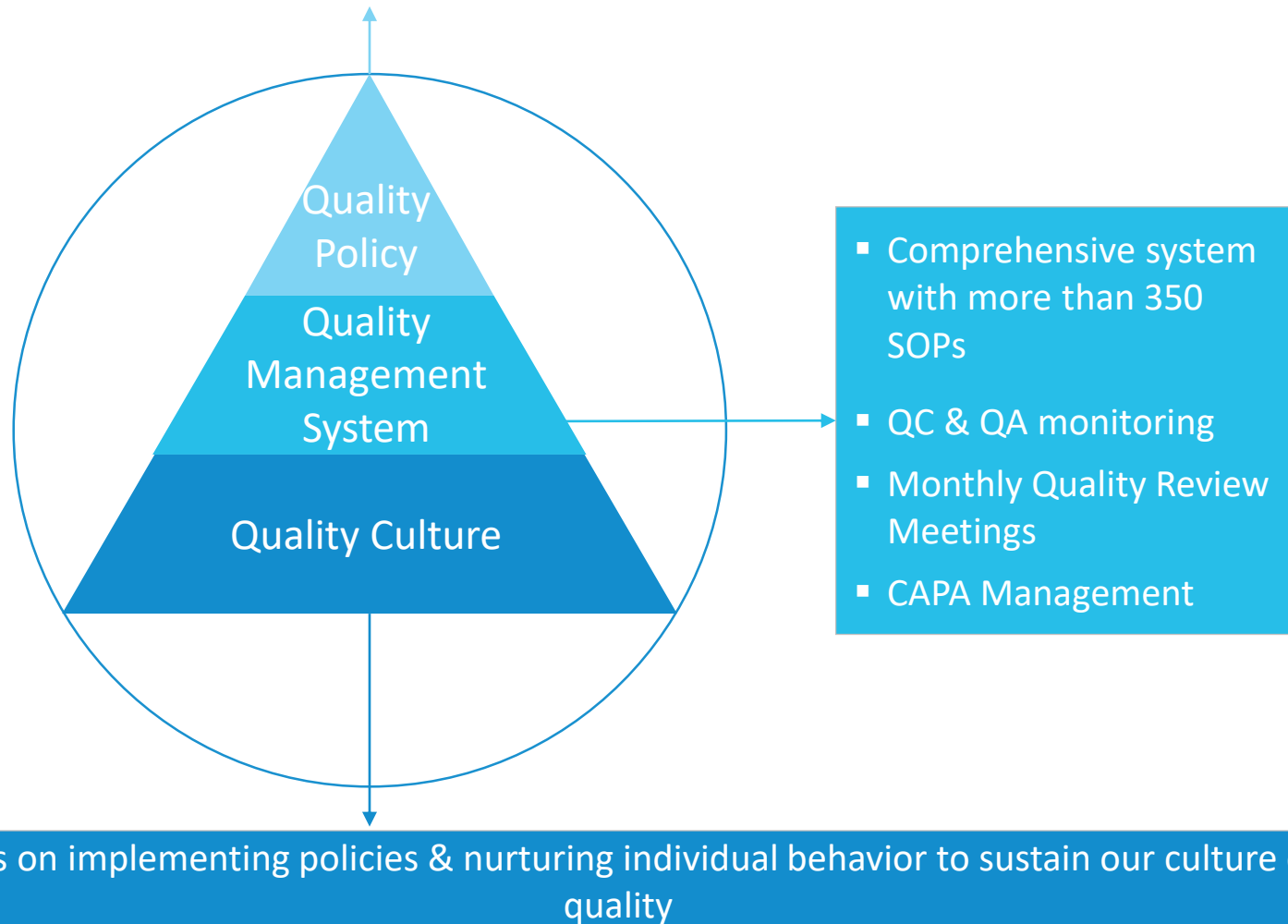


Nurturing Individual
Growth

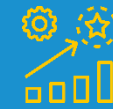
Quality Structure

4

“Veeda’s management is committed to continuous improvement in the effectiveness of our Quality culture, to providing quality research solutions that meet sponsor and regulatory requirements and to protecting the rights, safety and well being of the study volunteers”



Balanced Score Cards (BSC) for augmenting corporate strategy



Quantifiable Performance Metrics for all departments



Individual KPI's & KRA's linked to BSC



Continuous process improvement

Regulatory Credentials



*FDA : 17 AUDITS FOR PATIENT BASED STUDIES
16 AUDITS FOR HEALTHY SUBJECTS STUDIES

BIOANALYTICAL INFRASTRUCTURE

- **46 LC-MS/MS machines**
 - Insignia - 33
 - Vedant - 13
 - API 5500/4000/3200/3000/2000
 - Shimadzu 8060/8050/8040
 - Quattro Premier
- **2 ICP-OES**
- **Watson LIMS**

Storage Capacity



Plasma Sample:

45 Deep freezers with capacity to store 11,25,000 samples at -80 C°



IP Storage:

- 3 Walking type stability chambers with overall capacity to store 34000 Ltr for retention at room temperature
- 4 Humidity chambers with overall capacity of 3200 Ltr
- 4 Pharmaceutical refrigerators having storage capacity of 3550 Ltr at 2-8 C°



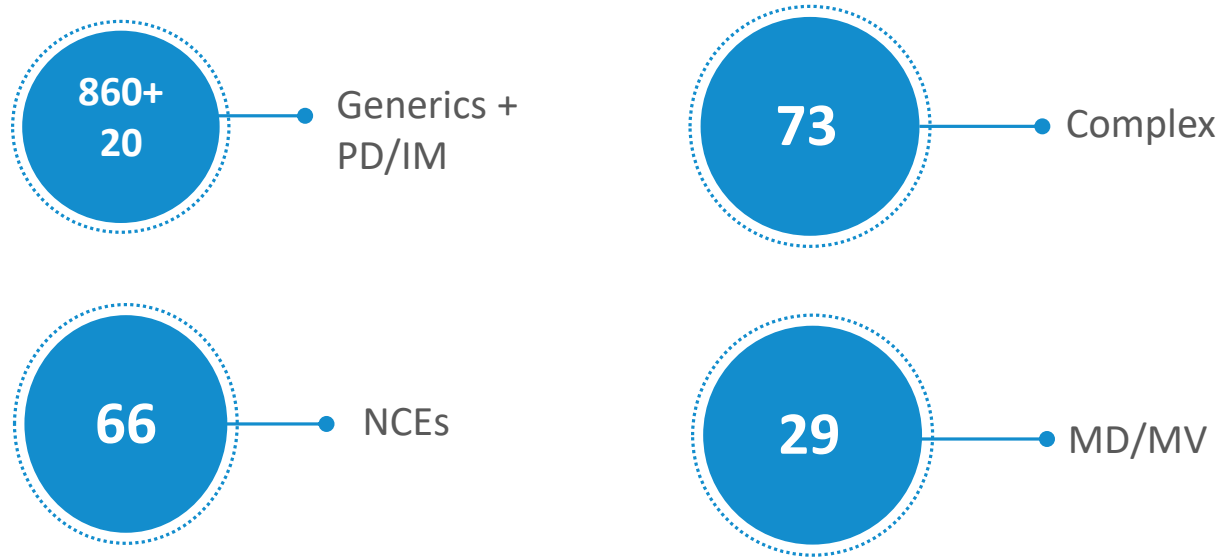
Archival: Capacity to archive approximately 51000 files

BIOANALYTICAL CAPABILITIES

Bioanalytical Capabilities

Types of Methods

Total available Bioanalytical methods are more than 920



Experience

- No. of studies done- >3600 (BA/BE)
- BR only study- >500 Studies
- ISR- %- >98%

State of the art

- Capability to develop methods with lowest quantification level- up to 0.1 pg
- Methods developed for:
 - Endogenous molecules
 - Hormones
 - Steroids
 - Inhalation formulation
 - Elemental Bioanalysis
 - Immunogenicity
 - Large molecules/ECLIA/ELISA
- Multiple analysis in single injection
- Central labs for Phase II / Phase III studies
- Tissue distribution studies

BIOANALYTICAL SERVICES - HIGHLIGHTS

Bioanalytical Services (Complex Molecules)

Amino Acids Analysis:

Separation of 20 amino acids.

Simultaneous analysis of 20 amino acids after derivatizing with AccQ Tag ultra-reagent kit and then detected on LCMSMS. All 20 amino acids have been separated chromatographically.

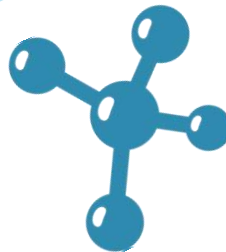
Calibration range of all amino acids has been adjusted such that all endogenous amino acids from human plasma are quantified.

1

Peptides (small molecules) by LCMSMS:

Desmopressin; Leuprolide; Octreotide

2



4

Endogenous Compounds:

Estrone (Unconjugated) +Estradiol (Unconjugated);
Isotretinoin; Levothyroxine

3

Enantiomers (Chiral Methods):

R-trans & S-trans Tranilcypromine; R & S
Lercanidipine; R-SSS & S-RRR Nebivolol

Bioanalytical Services (Complex Molecules)

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Elemental Analysis (By ICP-OES):

Total iron and Transferrin Bound Iron; Potassium; Lithium.
For Transferrin bound iron the serum samples are filtered through SPE cartridges to remove free and formulation bound iron while the filtrate contains TBI which is further analyzed by ICP OES..

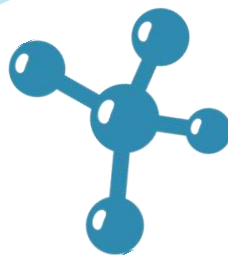
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Liposomal Formulation :

Doxorubicin; Amphotericin Challenges faced are the leaching of free from Liposomal formulations during sample handling, sample shipment and storage. Bursting of Liposomes during Thawing of samples.

To overcome the challenges stabilizing buffer is added to all samples and storage of samples at -78 C with controlled temperature shipments. Thawing and Processing at Controlled temperature during analysis.

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Protein Bound Formulation :
Paclitaxel

7

Biomarker analysis:
 α 1 Acid Glycoprotein by HPLC-UV

Bioanalytical Services – Central Laboratory

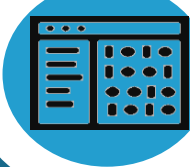
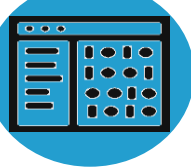
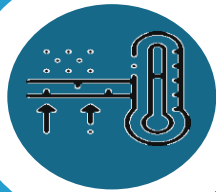
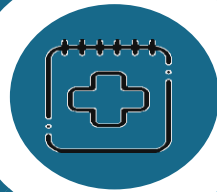
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Project Management

Lab Manual Preparation

Analyte Testing

Reports Presentations



Sample Storage &
Management

Kit preparation and
supply

Data Management
(PK Data – through
WATSON LIMS)

1.

Multicenter study (which involved more than 35 sites (150 subjects, 10 Analytes)).

- ❖ Required screening sample analysis within 10 days from sample collection–.
- ❖ Estimated 10 analytes for this study- Total 4 bio-analytical methods .
- ❖ Provided sample collection kits to all sites- within stipulated time



2.

Sponsor- Global Pharma company since 2009

- ❖ Type of studies : NCE – Multisite
- ❖ Total Studies : 144
- ❖ Total Samples: 1,61,613
- ❖ Total Methods: 58
- ❖ Services Provided: Sample Management (receipt, logging in LIMS for reconciliation), method development, method validation and analysis of NCEs .
- ❖ For safety analysis, sample receipt to analysis within 5 days
- ❖ Sponsor specific reports with e-CTD
- ❖ Exploratory studies, e.g. skin tissues , plasma protein binding experiment, chiral impurity estimation in the sample

Bioanalytical Services – Large Molecules

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Biosimilars (PK Assay) by ELISA :

G-CSF, Insulin Aspart, Teriparatide (PTH)

PD Assay :

C-Peptide (ELISA), Enoxaparin (Anti-Xa & Anti-IIa by Chromogenic method)

Bioanalytical Services Large Molecules

Human Insulin Glargine and Metabolites by LC/MS/MS Method

under final development stage on LC/MS/MS (Shimadzu 8060) (Using multiple charge MRM)

Immunogenicity Assay by ELISA:

Enoxaparin, PTH

- i. Screening assay
- i. Confirmatory Assay
- ii. Titer Assay

Recognitions

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Organization	Award Category
	Best Clinical Research Organization - India
	Clinical Trial Company of the Year
	Bharat Udhog Ratan Award in Clinical Research

Organization	Award Category
	Top CLRO Company
	Best Quality Clinical Research Services in India



Organization	Award Category
	National Excellence Award
	Best Pharmaceutical CRO
	Best Clinical Research- India
	Best Clinical Research- India
	Mark of Excellence
	Indian Clinical Research company of the year
	

Organization	Award Category
	Best Quality Clinical Research Organization in India
	Best Quality Clinical Research Organization in India
	Indian Clinical Research company of the year

Thank You



Partners in Creating a Healthier Tomorrow

For any further assistance kindly write to us at info@veedacr.com