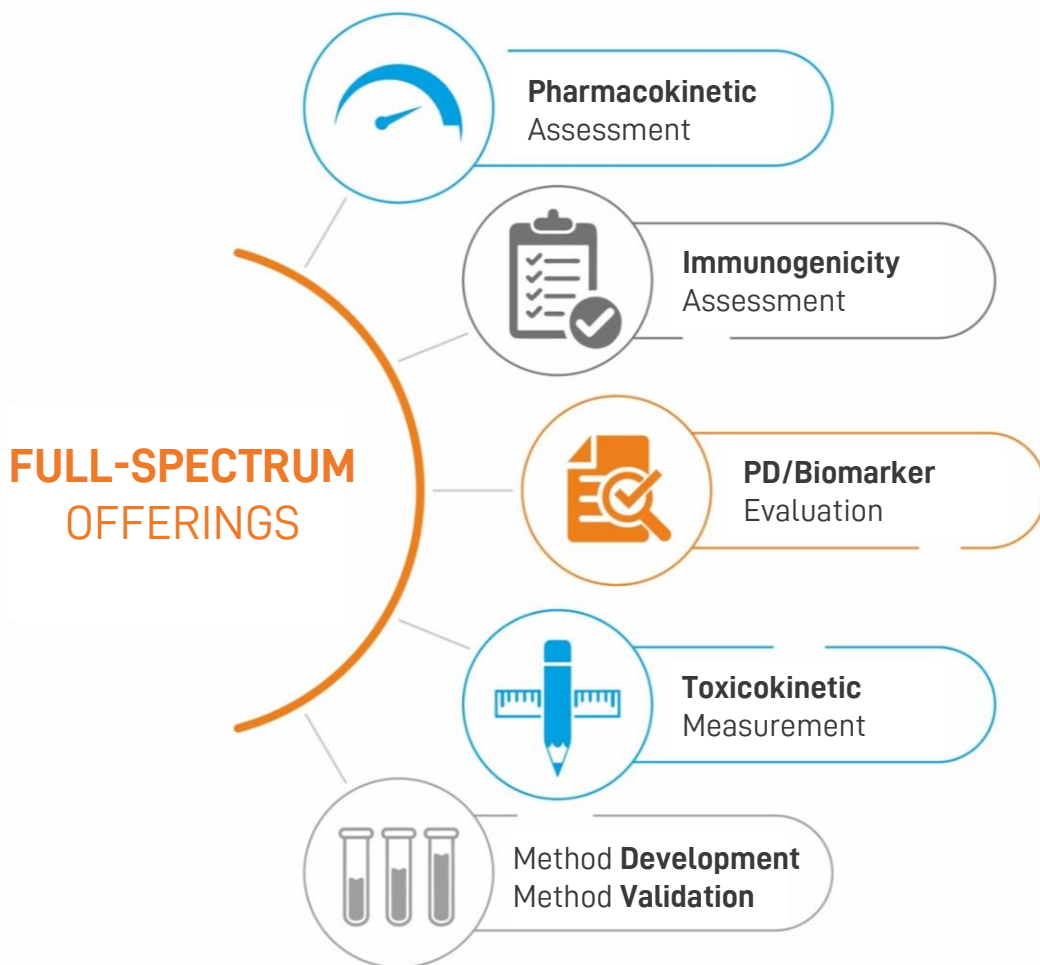


Accelerating **Biosimilar** Development

Biosimilars & Large Molecule Services



Bioanalytical expertise

- PK assays
- Immunogenicity assays (ADA)
- Neutralizing Antibody (NAb) Assays
- Pharmacodynamic (PD) Biomarker Assays

Analytical Platforms

- Enzyme-Linked Immunosorbent Assays (ELISA)
- Electrochemiluminescent Assays (ECLIA)
- In-vitro diagnostics (for Biomarkers)
- MSD Reader
- Cell Based Assays (for NAb)
- Flow Cytometry

Value Additions

- Antibody sourcing & Antigen Affinity-based purification.
- Conjugations: Biotin, Digoxigenin, HRP, Ruthenium

Extensive Experience

Biosimilar	Pharmacokinetics Assay	Immunogenicity Assay		Pharmacodynamics Assay
		Anti-drug antibody	Neutralizing antibody	
Bevacizumab	✓	✓	✓	-
Denosumab	✓	✓	✓	✓ (P1NP, CTx, NTx)
Adalimumab	✓	✓	✓	-
Ranibizumab	✓	✓	✓	-
Trastuzumab (SC)	✓	✓	✓	-
Pertuzumab	✓	✓	✓	-
Rituximab	✓	✓	-	✓ (CD 19)
Romiplostim	✓	✓	-	-
Teriparatide	✓	✓	✓	✓ (Serum Calcium)
Follicle-stimulating hormone (FSH)	✓	✓	-	✓ (β - Estradiol)
Filgrastim	✓	✓	✓	✓ (CD34+)
Pegfilgrastim	✓	✓	-	✓ (ANC)
Vedolizumab	-	✓	-	-

Large Molecules / Therapeutic Proteins / Biosimilars

S.N.	Drug Name	Assay Platform	Matrix	Range
1	PEG G-CSF	Sandwich ELISA	Human Serum	100 to 6400 pg/mL
2	Teriparatide	Sandwich ELISA	Human Serum	10 to 400 pg/mL
3	Bevacizumab	Sandwich ELISA	Human Serum	150 to 6000 ng/mL
4	Denosumab	Sandwich ELISA	Human Serum	40 to 1280 ng/mL
5	Adalimumab	Sandwich ELISA	Rabbit Serum	50 to 3200 ng/mL
6	Adalimumab*	Sandwich ELISA	Human Serum	50 to 3200 ng/mL
7	GCSF	Sandwich ELISA	Human Serum	100 to 6400 pg/mL
8	rHu-FSH	Electrochemiluminescence Immunoassay	Human Serum	0.156 to 20 mIU/mL
9	Ranibizumab*	Sandwich ELISA	Human Serum	200.0 to 6400.0 pg/mL
10	Romiplostim*	Sandwich ELISA	Human Serum	0.04 to 5.00 ng/mL
11	Bevacizumab*	LC-MS/MS (6500 QTRAP)	Human Serum	5 to 500 µg/mL
12	Glucagon	LC-MS/MS (Waters XEVO TQ-S)	Human Serum	0.2 to 10 ng/mL
13	Teriparatide*	LC-MS/MS (6500 QTRAP)	Human Serum	5 to 500 pg/mL
14	Trastuzumab	LC-MS/MS (6500 QTRAP)	Human Serum	5 to 500 µg/mL
15	Pertuzumab*	Sandwich ELISA	Human Serum	40 to 1280 ng/mL

*: Developed method available

Immunogenicity Assessment

S.N.	Drug Name	Assay Platform	Matrix	Assay
1	PEG G-CSF	ECLIA (MSD)	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
2	PEG-GCSF	Cell-based assay	Human Serum	Anti-Drug Neutralizing Antibody Assay
3	GCSF	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
4	GCSF	Cell based assay	Human Serum	Anti-Drug Neutralizing Antibody Assay
5	Teriperatide	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
6	Teriperatide	ELISA	Human Serum	Crossreactiity of anti-teriparatide antibody to native PTH
7	Teriperatide	Cell-based assay	Human Serum	Anti-Drug Neutralizing Antibody Assay
8	Romiplostim	ECLIA (MSD)	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
9	FSH	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
10	FSH	Cell-based assay	Human Serum	Anti-Drug Neutralizing Antibody Assay
11	Ranibizumab	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
12	Ranibizumab	ELISA	Human Serum	Anti-Drug Neutralizing Antibody Assay
13	Rituximab	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
14	Bevacizumab	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
15	Bevacizumab	ELISA	Human Serum	Anti-Drug Neutralizing Antibody Assay
16	Denosumab	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
17	Denosumab	ELISA	Human Serum	Anti-Drug Neutralizing Antibody Assay
18	Adalimumab	ELISA	Rabbit Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
19	Trastuzumab	ELISA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
20	Pertuzumab	ECLIA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
21	Pertuzumab	ECLIA	Human Serum	Anti-Drug Neutralizing Antibody Assay
22	Trastuzumab (SC)	ECLIA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
23	Trastuzumab (SC)	ECLIA	Human Serum	Anti-Drug Neutralizing Antibody Assay
24	Vedolizumab	ECLIA	Rabbit Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays
25	rH Hyaluronidase	ECLIA	Human Serum	Anti-Drug Antibody Screening, Confirmatory & Titer Assays




Excellence Validated

Successfully cleared **MHRA & FDA** Inspections for **Biosimilar Studies**.



Bioanalytical Package	Regulatory Authorization
PEG-GCSF (PK, PD, ADA, nAb)	Dossier reviewed by US FDA . No observations in CRL
rh-PTH (PK, PD, ADA, nAb)	Dossier reviewed by EMA . No major observations.
rh-Romiplostim (PK, ADA)	Approved by DCGI ; (Romy [®] , World's 1 st Romiplostim Biosimilar) Drug approved for Marketing in India
rh-Ranibizumab (ADA)	Approved by DCGI , (Razumab [®] , World's 1 st Ranibizumab Biosimilar) Drug approved for Marketing in India.

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