

Project Management

Dedicated Project Manager handling all queries & ensuring smooth operations



Globally Accredited Contract Research Organization

1 st GLP Test Facility in India	German Health Ministry (1992-2011)	W & V The Netherlands (1999-2011)	Indian GLP Authorities (since 2005)
1 st OECD certified facility in India	India received full adherent status to Mutual Acceptance of Data from the OECD in March 2011		
1 st test facility to be audited by USFDA	For GLP studies submitted as part of IND (2012 and 2016)		
1 st AAALAC certified facility in India	(since 2001)	(since 2020)	
ISO 17025:2005 for Medical Devices, biomaterials and ophthalmic devices testing	ISO 9001:2015 for contract services in manufacture, test and stability study of Pharmaceutical intermediates, NCEs/APIs		

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Advinus



Custom Bioanalytical Testing for your Biologics Pipeline

- monoclonal antibodies
- novel biologics
- fusion proteins
- gene therapy products
- vaccines

Wide range of services to support you in Pre-clinical And Clinical Studies



Immunogenicity studies

Biologics like antibodies, enzymes and peptides are produced in living organisms through recombinant technology. Therefore, they can cause immune response in host which should be assessed carefully as it can lead to serious safety concerns.

- Develop and validate highly sensitive methods to detect low levels of Anti Drug Antibody (ADA) in presence of circulating drug under GLP setup
- Tiered approach [Screening, confirmatory, titre and Neutralizing Antibody (NAb)] for immunogenicity assessment following FDA Guidance
- Generate, characterize and label polyclonal antibody (for use as positive control, capture and detection) as per assay requirement

Allergic reactions

Anaphylactic reactions

Reduction in efficacy

Induction of autoimmunity

Regulated Bioanalysis (PK/TK) studies

- Develop or transfer and validate assay as per FDA guidelines that are specific, sensitive and customized for your biologic
- Generate critical reagents like antibodies for use as capture and detection
- Customized approach for various classes of biologics using different assay formats
- Fully functional GLP laboratory with 14 dedicated SOPs

Biomarker assays

Offering a range of protein biomarker services for all stages of research, from ready-to-run assays through to assay development and validation. Eurofins offers biomarker testing services which covers a broad range of therapeutic areas.

Bioassays

Demonstrating potency and efficacy through biological functional characterization is an important factor for the success of a biologic product. This characterization is performed based on the mechanism of action of the biologic using assays such as ELISA, enzyme assays, signaling pathways, proliferation assays, CDC and ADCC.

Serological assays for Vaccines and Gene therapy products

We offer services for measurement of antigen specific antibody for evaluating novel vaccine and gene therapy products.

Experience in various classes of Biologics

Class	Name	PK	ADA	NAb	Functional Bioassay
Novel Biologics	A	■	■	■	
	B		■		
	C	■			
	D	■	■		
	E		■	■	
Fc Fusion Proteins	A	■	■		
	B	■			
Monoclonal Antibodies	A	■	■		
	B	■	■		
	C	■	■		
	D	■			
	E	■	■		
Peptides	A	■	■	■	■
	B		■		■
	C				■
	D				■

Polyclonal Antibody Generation

Extensive Experience in generating custom Polyclonal Antibody as per project requirement

Applications

- Positive control for immunogenicity assay
- Capture and/or detection reagent for PK/TK assay

Polyclonal Antibody generation for

- Antigen: Biotherapeutic, full-length or truncated antibody, peptide

