



THERAGEN  
MOLECULAR  
INNOVATIONS  
PRIVATE LIMITED

**Our mission is to provide high quality recombinant products including mAbs, Fabs, Proteins, Hormones, Peptides - novel and biosimilars. The company provides support for R&D, proof-of-concept, scale up, analytical services and regulatory submissions.**

## UPSTREAM SERVICES

- Cloning gene of interest in high expression vectors. Identification of suitable host for the recombinant protein production.
- MCB/WCB preparation and characterization. High-throughput screening of clones.
- Media optimization to enhance protein yield. Small scale fermentation - Shake flask.
- Fermentation from 1L to 50L scale.
- Fermentation - Microbial, yeast and mammalian.
- Various level operations like biomass clarification, lysis, etc.,

## INFRASTRUCTURE

- Fermenter - 16L NLF & 50L Laboratory Pilot (Bioengineering)
- Applied Biosystems PCR Machine (ThermoFischer)
- Stacking Shaker Incubator (Scigenic Biotech)
- Biosafety Cabinet (Healforce)
- Bioanalyzer (YSI 2900)
- Axiolab 5 Microscope (ZEISS)
- Sorvall Lynx 6000 Centrifuge (Thermo Scientific)
- Homogenizer (GEA Nirosoavi)
- Mixing Vessel (Nitsen Technologies)



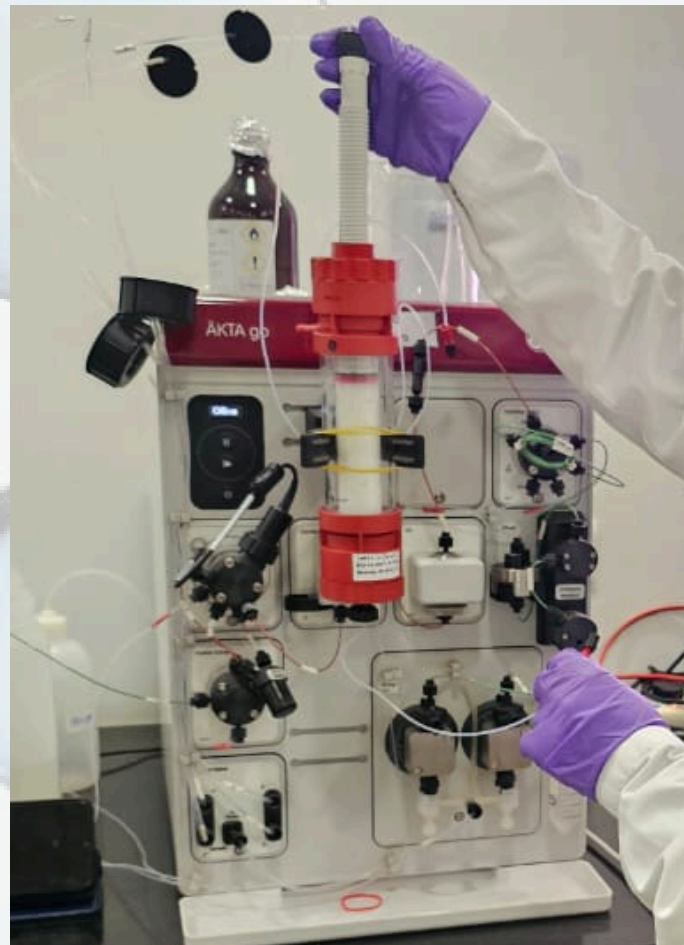


## DOWNSTREAM SERVICES

- Multiple protein purification techniques including Affinity, Ion Exchange, Gel filtration, HIC and Endotoxin removal Chromatography.
- Selection and optimization of purification resins. Purification of inclusion bodies.
- Dialysis/Buffer exchange using TFF.
- Method development for purification of tagged/native protein to transfer to a cGMP facility.

## INFRASTRUCTURE

- AKTA Pure 150 (GE)
- AKTA Go (GE)
- AKTA Prime plus (GE)
- Pellicon TFF Manual System (Merck)
- Labscale TFF System (Millipore)
- TFF Holder (Sartorius)
- Peristaltic Pumps (Master Flux)
- Spectrophotometer (Biorad)
- Various Columns & Accessories (XK, BPG Columns)

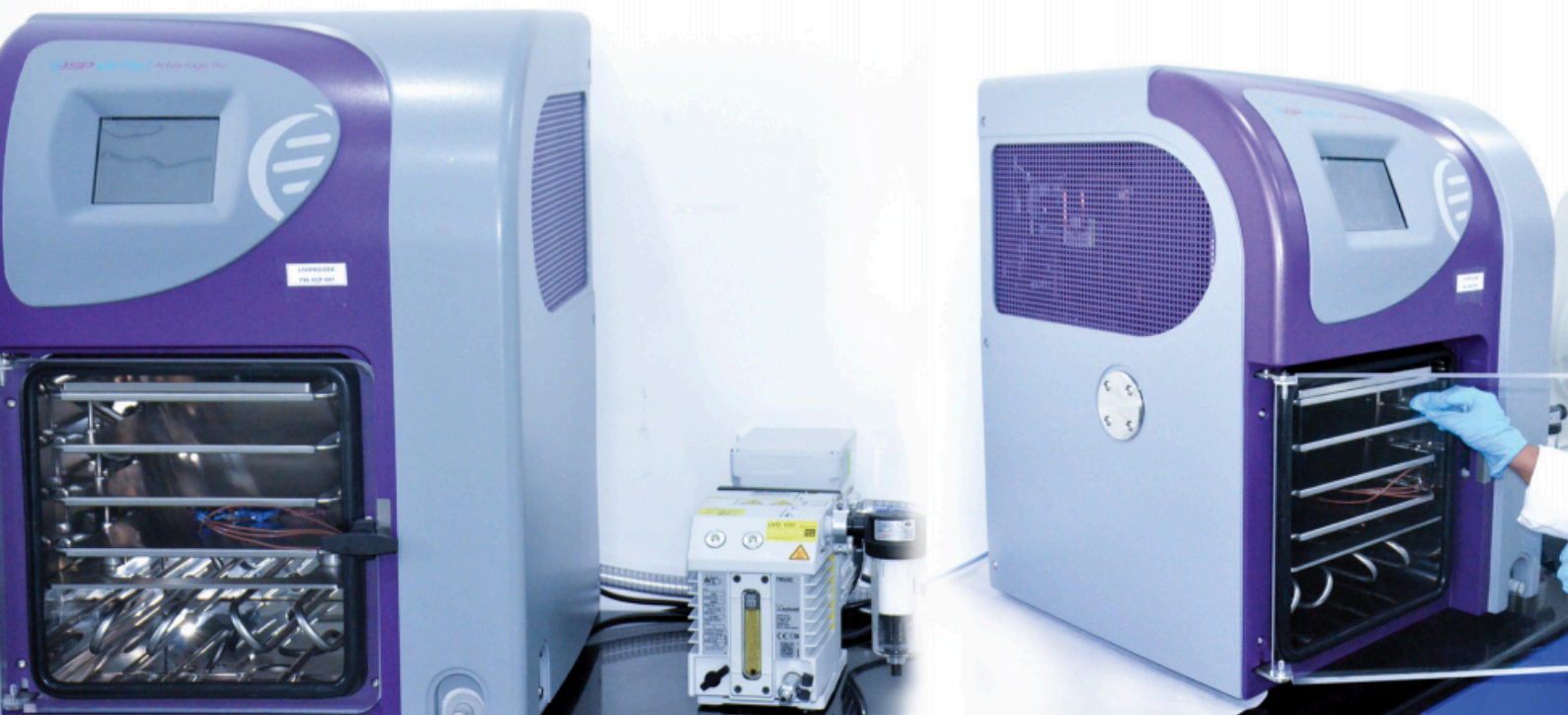


## FORMULATION SERVICES

- Optimization and selection of excipient.
- Liquid and powder formulation.

## INFRASTRUCTURE

- Labscale TFF System (Millipore)
- pH and Conductivity meters (Mettler Toledo)
- Lyophilizer (SP VirTis AdVantage Pro)
- Spectrophotometer (Eppendorf)
- Osmometer (Knauer)



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# BIOANALYTICAL SERVICES

- Efficacy of analyte: ELISA (Direct/Indirect) to determine Affinity, EC50, as well as to support PK/PD.
- Characterization of analyte: HPLC (SEC, RP, IEX), QELISA, Bioassay, Native-PAGE, Western blotting and Relative stability.
- Impurity analysis: HCP, HCDNA, ET, Residual Antibiotic testing, Ligand leachate assay, Sterility assays.
- Cell based assay: Bioassay development and validation with various cell lines to determine IC50 as per ICH guidelines.

## INFRASTRUCTURE

- HPLC Systems (Agilent 1260 Infinity II, Shimadzu LC-2010 HT)
- Multimode Reader (Synergy H1)
- Centrifuge (Thermo Heraeus X3R, Eppendorf 5430R)
- Orbital Shaker OS3 (EPS)
- Mammalian cell culture lab with BSL-2 safety cabinet
- Primary cell culture facility
- CO<sub>2</sub> Incubator (Eppendorf)
- Axiolab 5 Microscope (ZEISS)
- Eco line Incubators (Stericell)
- Gel Electrophoresis, Western Blotting, Gel Doc XR+ (Biorad)



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