Stelis Biopharma

Unit 1

State-of-the-art process and analytical development facilities for small-scale early and late-stage development studies of drug substance and drug product and initial technology transfer activities across multiple modalities.

Our process development labs are equipped with best-in-class modern instrumentation that enable our experts to offer different analytical, developmental and characterization services for a wide range of biological and biopharmaceutical products conforming to global regulatory standards throughout their lifecycle. We combine deep industrial expertise, innovative solutions and technologies, for providing customized process solutions to our clients with robust scalability and efficient process transferability.

Process Development capabilities for developing biologics

- Cell culture/fermentation process optimization
- Comprehensive analytical and bioassay development and validation
- Process scale-up and technology transfer for drug substance and drug product
- Developing and qualifying scale down models for each unit operation to support manufacturing team
- Risk assessment using FMEA tool to identify CPPs/ KPPs
- Process characterization to develop operating and design space for the CPPs and KPPs for manufacturing support
- Developing a control strategy to support manufacturing team
- Product characterization biosimilarity and/ or product comparability package

We embrace quality at every step of integrated process development and manufacturing.

Our Unit-1 facility at Jigani, is designed to support process development activities for the various drug substance and drug product candidates with high quality data and reports.

Analytical Method Development and Qualification

- RP, NP, HILIC, IEX and SEC methods
- Impurities, purity, content estimation
- Impurity clearance methods
- Characterization methods
- Transfer, verification and qualification

Scale-up Lab Facility

- Capability to convert drug substance to stable formulations and fill finish formats
- For mammalian upstream and downstream process scale-up studies: 50L
- For microbial upstream and downstream process scale-up studies: 5L and 20L
- Flexibility in operations - single-use or multi -use depending on process requirements

Structural Characterization and Confirmation

- Amino acid sequence
- Amino acid composition
- Terminal amino acid sequence (MS/MS sequencing)
- Peptide map
- Disulphide bridges
- Carbohydrate structure

In-Process Analytics

- From early to late phase of bioprocess monitoring, SDS page, HPLC/UPLC –UV/ PDA/Fluorescence/CAD/ELSD
- Process monitoring and developing controls
- Process-related impurities analysis
- Product-related impurities analysis
- Oxidation / deamidation / truncation products
- Aggregation analysis

Quality Control

- Stability studies on drug substance and drug product as per ICH guidelines
- Animal efficacy and toxicology studies
- Quality control required for dossier submission
  - Identity
  - Potency/Efficacy
  - Advanced (characterization)
  - In-process validation

Product Characterization

- Glycan profiling
- Structural characterization
- Thermal analysis
- Intact mass analysis
- Peptide mass fingerprinting
- Sequence confirmation
- Disulfide bond and sulfhydryl group confirmation
- Identification of post translational modifications (PTMs)
- Process/product related modifications or impurities
- Determining secondary and tertiary protein structure

List of Abbreviations

- FMEA- Failure, Method and Effect Analysis
- CPPs- Critical Process Parameters
- KPPs- Key Process Parameters
- ICH- International Council on Harmonisation

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