TechEx.in
Tech Transfer Hub at Venture Center
Supported by NBM - BIRAC

Technical Brief

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Trastuzumab Biosimilar

About Trastuzumab

Trastuzumab, sold by Roche under the brand name Herceptin among others, is a human monoclonal antibody used to treat breast cancer and stomach cancer. It is specifically used for cancer that is HER2 receptor positive, and is currently the only FDA-approved therapeutic antibody for HER2-positive breast cancer. However, treatment costs for trastuzumab are prohibitively high, with treatment costing up to 15,000 dollars per patient. Thus is an urgent need for process innovation to reduce costs.

Technology Offering

- Novel use of CFIR for viral clearance that allows continous viral clearance
- ·Upstream and downstream process development complete
- Titer of 2.0-2.3 g/L in 10L bioreactor
- Purification yield of 90%
- ·Analytical and functional similarity to innovator molecule has been established
- Novel continuous processing platform that results in reduction in cost of manufacturing by 70% for clinical and 35% for commercial production

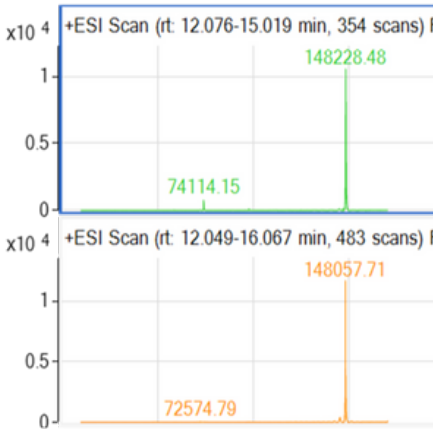
Market Potential

Global trastuzumab biosimilars market is expected to grow from $1.22 billion in 2020 to $1.4 billion in 2021 at a compound annual growth rate (CAGR) of 14.8% and is expected to reach $4.25 billion in 2025 at a CAGR of 32%. There are 5 global players and 5 Indian companies working on Trastuzumab biosimilar.

Current Technology Status

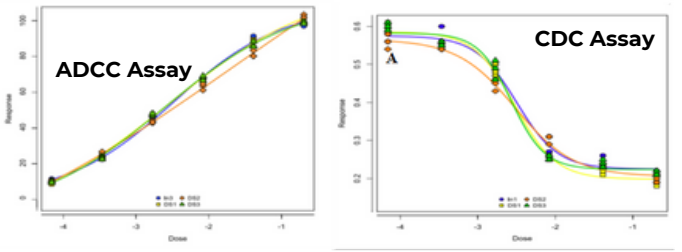
- Development of Hypotheses and Experimental Designs Done
- Non-clinical *in-vitro* studies: Physicochemical characterization for Biosimilarity Done
- Non-clinical *in-vitro* studies: Functional characterization for Biosimilarity Done

Selected Biosimilarity Data



Comparison of intact mass analysis between innovator and drug substance (DS).

Binding Activity and KInetics



Name of the Sample	FcRn KD (M)	FcγRIIIa KD (M)	Binding activity
Innovator	4.28E-08	1.33E-07	No difference
DS	2.19E-08	1.76E-07	

Sequence similarity to in-silico trastuzumab sequence

Sample	Chain A (%)	Chain B (%)
Herclon (Roche)	98.76	99.7
DS	99.05	99.85

For more info and biosimilarity data, please click:

Tech Pitch PPT Tech Pitch Video

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