

Technical Brief

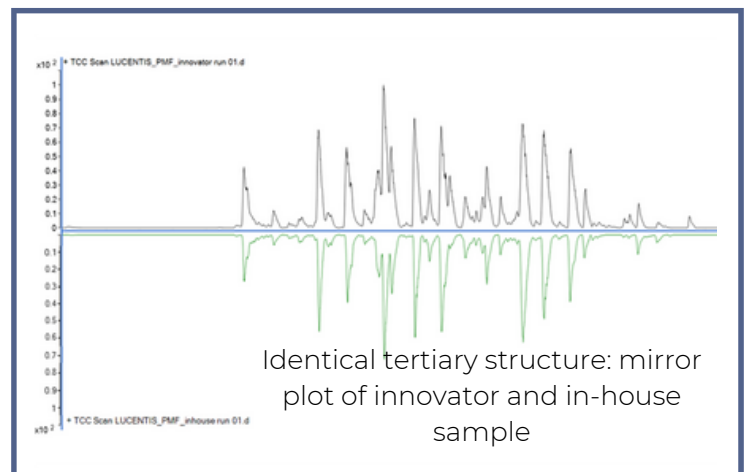
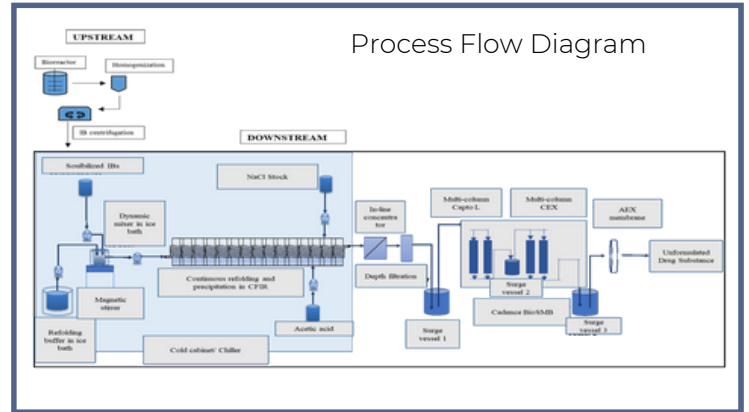
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Ranibizumab Biosimilar

About Ranibizumab

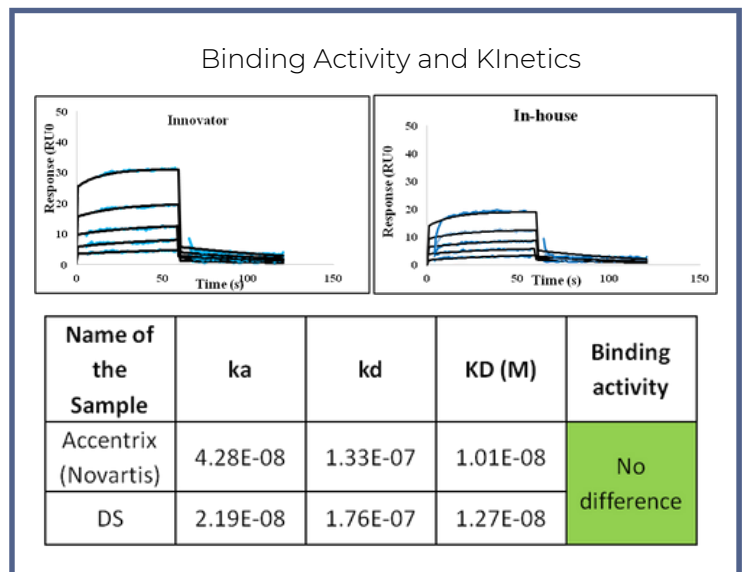
Ranibizumab, sold by Genentech (Roche)/Novartis under the brand name Lucentis is a recombinant humanized monoclonal antibody and VEGF-A antagonist. It is used in the treatment of eye disorders such as neovascular (wet) age-related macular degeneration (wAMD), Macular edema following retinal vein occlusion (RVO), Diabetic macular edema (DME), and others. However, treatment costs are prohibitively high, costing upwards of 150 dollars per injection. Thus, there is an urgent need for process innovation to reduce costs.

Selected Biosimilarity Data



Technology Offering

- Upstream and downstream process development complete
- Titer of 50 mg purified protein/ L reactor
- Purification yield of $23 \pm 2\%$ (refolding to formulation)
- Purification yield of 70% (capto L chromatography to formulation)
- Novel refolding process with a refolding yield of 30-35% vs the industry standard of 15%.
- Analytical and functional similarity to innovator molecule has been established
- Novel continuous processing platform reduces the cost of manufacturing by 80% for clinical and 75% for commercial production.



Market Potential

The global age-related macular degeneration (AMD) market stood at \$ 1.58 billion in 2020 and is projected to reach \$ 2.64 billion by 2026, growing at CAGR of 8.93% between 2021 and 2026. There are 2 global players and 1 Indian company working on Ranibizumab 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

For more info and biosimilarity data, please click:

[Tech Pitch PPT](#)

[Tech Pitch Video](#)