

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). However, treatment costs are prohibitively high, costing upwards of 150 dollars per injection.

Technology Offering

- Clone, upstream and downstream process
- Upstream: Single fermentation batch required: Antibody fragment expression using duet vector system.
- High throughput dilution-based refolding process with refolding yield of 40-45 %. Dilution-based refolding is the only scalable alternative for large scale production of antibody fragments
- Downstream: Purification process of recombinant AbF from inclusion bodies
- Novel multimodal chromatographic purification steps > 2X improvement in productivity
- Purification platform applicable to in-vitro refolded and soluble expressed antibody fragments
- Overcomes requirement for affinity chromatography, a cost center; uses anion and cation exchange, reducing cost by 33%

Market Potential

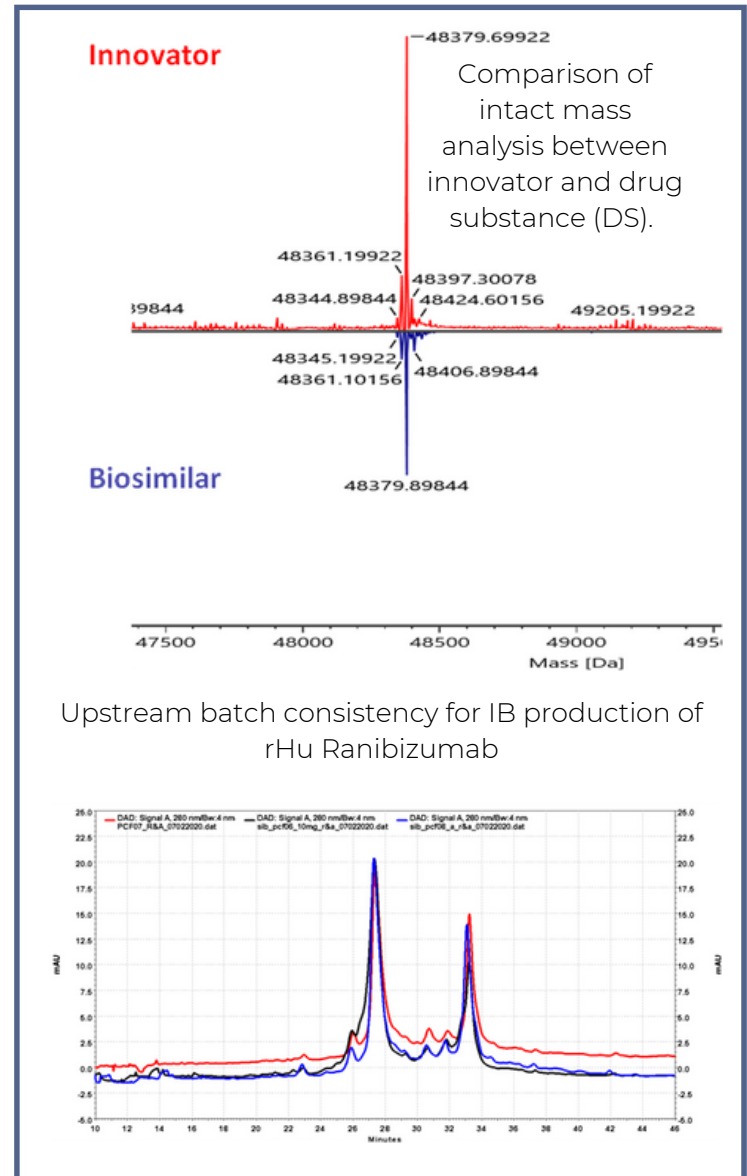
The global age-related macular degeneration (AMD) market stood at \$ 1.58 billion in 2020 and is projected to reach \$ 2.64 billion by 2026, growing at CAGR of 8.93% between 2021 and 2026. There are 2 global players and 1 Indian company working on Ranibizumab biosimilar.

For more info and biosimilarity data, please click:

[Tech Pitch PPT](#)

[Tech Pitch Video](#)

Selected Biosimilarity Data



Upstream batch consistency for IB production of rHu Ranibizumab

Current Technology Status

- Development of Hypotheses and Experimental Designs Done
- Protein expressed at 10 L scale reactor
- Completed five consistency batches at 10 liter scale
- Achieved yield of 2.81 ± 0.10 g/L
- Non-clinical *in-vitro* studies: Physicochemical characterization for Biosimilarity Done
- Non-clinical *in-vitro* studies: Functional characterization for Biosimilarity Done