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Biosimilar biologics development: A case – study on targeted control of variants and impurities

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Abstract

They have been developed to treat several life – threating and chronic indications. Monoclonal antibodies, insulin and its analogues etc. have been demonstrated to be effective against the intended target indication. With the expiry of the patents for several of these biologics drugs, manufacturers around the world are developing biosimilars to these biologics. Biosimilars present a significant opportunity for the healthcare systems to mitigate challenges pertaining to accessibility and high cost of medication. The physico – chemical characterization and establishment of statistical similarity of the biosimilar to the innovator is complicated by the presence of inherent heterogeneity in these biologics caused by post – translational modifications. These heterogeneities like charged variants, glycosylation variants and size variants could impact the safety, efficacy and shelf – life of the drug product.

While efforts are taken to match the product quality in biosimilars by optimal selection and development of the cell – line, clone and cell – culture process; any residual variability can be further controlled effectively in the downstream purification steps. In this presentation, we will demonstrate that implementation of preparative chromatographic steps can target and control variants (charged, size and sequence) and impurities. The process development approach, optimization of operation conditions, defining the target and selection and use of analytical or PAT tools will be presented through various cases – studies. The work is unique to demonstrate the effective use of predictive models in these chromatographic steps to develop operation – friendly processes and seamlessly attain the target range of variants in the output.

This approach for biosimilar development absorbs the variability incurred due to upstream processing, feed quality and downstream operating conditions and consistently attain the target product quality with the maximum possible yield.

Biography

10+ years' experience in purification process development, process characterization, viral safety and scale – up of Novel and Biosimilar MABs at R&D group in Biocon. Expertise in chromatographic processes to resolve closely – related product variants and impurities. Currently an Associate Scientific Manager at R&D group, leading a team of highly motivated scientists involved in purification process development and characterization.

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