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Mixed mode chromatography in biosimilars development – Overview

Vivek Halan

Zumutor Biologics Pvt Ltd, India

Market for therapeutic proteins such as monoclonal antibodies (mAbs), growth hormones, other recombinant therapeutic proteins has grown tremendously in the last two decade. To compete in the biopharmaceutical market, we should identify, develop the high product producing clone and find the best conditions to purify to highest purity, good recovery with good quality in the early stage of development. Biosimilars that is similar biological product (similar to originator or innovator product) are increasingly being developed by many companies and used as therapeutics for treating various diseases worldwide. There is a lot of scope to improve in biosimilar story. Biosimilar products are approved through stringent regulatory pathways in highly regulated markets such as the US, EU, Japan, Canada and Australia following loss of exclusivity of their originator reference product. With recent advancements, biosimilars are produced in high quantity, which is close to 10 to 12 g/L. This gives rise to many challenges to downstream processing the biosimilar product. Generally, maintenance of the chromatography resin performance is also a major concern in large-scale manufacturing of monoclonal antibodies. One of the critical step is Capture stage- Protein A Chromatography which incur at least 30 to 40 percentage of downstream processing cost. Many biopharma players are working towards Non-Protein A downstream process development. Multimodal chromatography, one such a chromatography can be a best replacement to Protein A Affinity chromatography. Mixed mode or multimodal chromatography involves selective interaction between chromatography ligand with the analyte molecule through different types of interactions which can be either ionic, hydrophobic or else may involve hydrogen bonding, or even Van der Waals interactions. Many MMC resins are commercially available and this type of chromatography can be used as a Capture step to purify monoclonal antibodies and also can be employed in intermediate and polishing step, where MMC can remove endotoxins, HCDs better than conventional ion exchange chromatography. The elution behavior of MMC using either pH or salt gradient is better in terms of impurities removal and product recovery. The binding capacities of some mAbs are higher in MMC resins than Protein A resins. MMC can efficiently separate insoluble aggregates than other chromatography. MMC can be used widely in biosimilar development; still there is a requirement to understand and demonstrate the efficiency in commercial aspect. I would like to discuss on the role of MMC in biopharmaceuticals. My discussion is intended for audience from biopharmaceutical industry as well as active collaborators from academic institutes.

vivek.halan@zumutor.com