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Development of capture and polishing chromatography steps using Sartorius CIM monolithic chromatography technology for a novel AAV serotype

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Chromatography techniques for the purification of common Adeno-Associated Virus (AAV) such as AAV1, AAV2, and AAV9 are generally well understood and require product-specific optimization. AAV affinity resins are commonly evaluated for primary chromatography of the common serotypes; however, function, capability, and performance with novel or less common serotypes is a gap. For polishing chromatography, the primary objective for an AAV process is enrichment of full capsids, where anion exchange chromatography (AEX) is commonly used in a bind and elute mode. A common challenge with the enrichment of full capsids is achieving the necessary resolution to convert the elution to a step gradient while not sacrificing recovery or purity. Here, a comparison of a commercially available affinity resin to Sartorius CIM SO3 for capture chromatography was completed, demonstrating the Sartorius CIM SO3 as beneficial option for capture chromatography of a novel AAV serotype. The study demonstrates a >40X improvement in recovery when compared to the affinity resin as well as an improvement in processing time. A polishing step was developed utilizing the Sartorius CIM QA demonstrating a step gradient elution is achievable while maintaining high recovery and enrichment of full capsids.

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