

# Evaluation of Single-use Tangential Flow Filtration Technology for Purification of Activated Polysaccharides Used in Conjugate Vaccine Manufacturing

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## Abstract

Over the past decade, single-use tangential flow filtration (TFF) technologies have emerged to reduce system preparation time, promote fast and flexible product change over, and ultimately shorten process development and manufacturing time/cost. In this study, the performance of a recently developed Pellicon® single-use TFF capsule was compared against traditional Pellicon® cassette by assessing TFF process performance (such as flux, residuals clearance, and yield) and post-purification product attributes (such as concentration and mass-weighted average molecular weight). Good scaling was shown by comparing process performance and product attributes across different scales and formats. Additionally, similar TFF process performance and post-purification product attributes were observed for the single-use capsule compared to the reusable TFF cassettes. The capsule requires a smaller flush than the cassette, and it is easier to use since it does not require a compression holder or pre-sanitization. The results provide insight into the application of the single-use TFF capsule and scalability of TFF processes for the purification of conjugate vaccines.

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