

392a Simulation of Centrifugal Recovery of Protein in Biopharmaceutical Production Using Atspin Simulator

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This paper presents a new approach to complement the conventional approach in primary recovery of protein after fermentation using centrifugation in manufacturing biopharmaceutical drug substances such as antibodies [1].

Centrifugal separation is known to be complicated and exhibits non-linear responses not readily amendable to prediction and scale-up as with depth filters and membranes. A numerical AT-SPIN simulator, developed for spintube and disk stack centrifuge respectively, has been used to assist biotechnology separation. The simulator has been validated through testing. Numerical simulations are used to complement centrifuge runs in all phases of drug substance development from laboratory screening, to piloting and production. Among numerous applications, the simulator is used to provide protocol for laboratory/pilot/production tests, analyze laboratory/pilot/production test data, scale-up centrifuges, optimize and troubleshoot pilot/production centrifuge, and further support “scale-down” testing. In this paper, examples will be drawn on the important primary recovery of protein from respectively mammalian cells, yeast, and bacteria cells using disk stack centrifuges of different sizes and capacities. The AT-SPIN simulator can also be employed for simulating separations and purification in pharmaceutical production other than primary recovery such as separation after crystallization, precipitation or washing of crystals.

Keywords:

Centrifugation, biopharmaceutical, spintube, disk stack, centrifuges, biotechnology, bioseparation, AT-SPIN Simulator, numerical simulation, optimization, scale-up, mammalian cells, yeast, bacteria.

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