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LABORATORY SCALE CONTINUOUS LINEAR PURIFICATION AS A DEVELOPMENT TOOL FOR RECOMBINANT BLOOD PROTEIN PROCESSING, USING CHROMATOGRAPHIC RESINS AND MEMBRANES.

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Continuous processing offers significant advantages for the processing of unstable recombinant products such as therapeutic plasma proteins. As such we have established a development platform to assess potential purification steps as part of a continuous linear process using a standard AKTA Explorer. Following a consistent format of IEX membrane to HIC membrane to affinity resin, we were able to rapidly investigate multiple purification pathways for a recombinant blood protein. Using membranes as the first two steps enables a 3-step purification process to be carried out in 3 to 4 hours, with a total turnaround of 5 to 6 hours including regeneration and re-equilibration, at laboratory scale and depending on the specific pathway. This development method allowed for a direct comparison between multiple purification pathways, assessing overall recovery, pathway consistency, product quality and product purity over the 3 steps. Ligands tested include cation & anion exchangers, phenyl, phenyl boronate and an immobilised affinity peptide. It is envisaged that once a purification pathway has been decided upon, processing speed could be around 1 L per day without significant scale-up.