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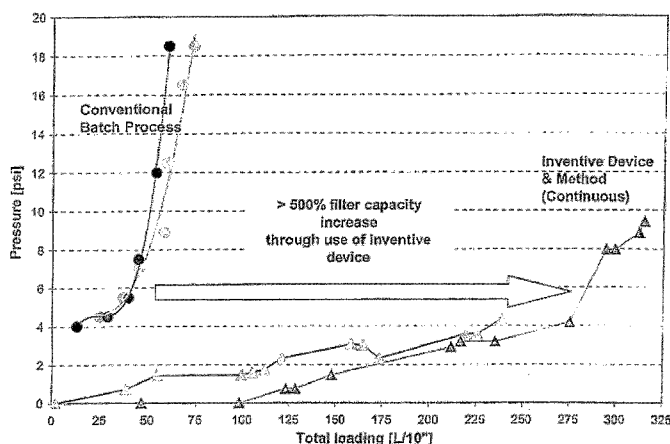
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(54) Title: DEVICES AND METHODS FOR INTEGRATED CONTINUOUS MANUFACTURING OF BIOLOGICAL MOLECULES

Example comparison of total load capacities per 10" of filter capsule for conventional batch process and embodiment of inventive device and method for continuous particle removal (integrated continuous filtration process) using identical commercial filter capsules. Example method producing recombinant blood coagulation Factor VIII shown.



(57) Abstract: The present invention relates to a process and apparatus for purifying a molecule of interest from a heterogeneous clarified fluid mixture. The apparatus of the invention generally comprises a continuous perfusion fermentation system, a continuous particle removal system integrated with the perfusion fermentation system; and a continuous purification system integrated with the particle removal system, which is maintained under sterile conditions. The process comprises filtering a heterogeneous clarified fluid mixture by continuous ultrafiltration at a specific flow rate below the transition point of the molecule of interest in the pressure-dependent region of the flux versus TMP curve, wherein the specific flow rate is maintained substantially constant throughout the continuous ultrafiltration.