

MSS2022

HYBRID

Illustration of a Monolith-Based Chromatography Process to Prepare EV

Simon Staubach¹, Pete Gagnon¹, Katja Vrabec¹, Tjasa Lojpur¹, Sebastijan Peljhan¹, Sara Primec¹, Bernd Giebel² & Ales Strancar¹

¹BIA Separations/Sartorius, Ajdovscina, Slovenia,

²Institute for Transfusion Medicine, University Hospital Essen, University of Duisburg-Essen, Essen, Germany.

The manufacture of EV-based therapeutics demands for scalable technologies. When it comes to clinical phases, the necessity for excellent purity of the product is frequently overlooked. Both ribonucleic acid and protein impurities must fall below the set guideline limits. Chromatographic monolith-based approaches are required to attain this goal. We achieve this level of purity by processing conditioned media from mesenchymal stromal/stem cells with an anion exchange chromatography and a combined Tangential Flow Filtration (TFF). As a part of this process, we integrated a nuclease digestion step into the phase of TFF. We were able to produce scalable high purity extracellular vesicles using this technique and we demonstrate the uniqueness of monolith-based chromatography by illustration of the procedure.