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PATfixTM - At-line monitoring of impurities and critical quality attributes in biopharmaceutical up- and downstream processes using HPLC fingerprinting

Ingo Nagler, Aleš Štrancar[1], Sebastijan Peljhan[1], Tomas Kostelec[1], Romina Žabar[1], Blaž Goričar[1], Vid Skvarča[1], Valentin Steinwandter[3], Patrick Sagmeister[3] and **Vignesh Rajamanickam[2]**
BIA Separations, Slovenia

The most commonly used gene transfer vectors are adeno- associated viruses, vaccinia viruses, adenoviruses, lentiviruses, retroviruses and pDNA. Due to their large size and sensitivity to pH, temperature and shear forces, purification is challenging and time-consuming. Consequently a fast and efficient downstream processing purification method is required to isolate sufficient amounts of vectors with the final purity and state that conforms to stringent regulatory demands. Convective interaction media (CIM) monolithic columns provide a robust platform for the purification of viral particles for vaccines and gene therapy. Pores are replaced by large channels allowing unrestricted flow of large biomolecules, eliminating diffusion and allowing flow-independent resolution and dynamic binding capacity. These properties, along with low back- pressure, lead to higher purity, recovery and efficiency in the downstream process. The poster presents multiple examples where monolithic chromatographic column are used as capture or polishing step in a process. Viruses (Adenovirus, Lentivirus), vaccines (Influenza A H1N1) and pDNA are shown as case studies for their respective downstream processes. The properties of monolithic columns allow their use both as capture step where high flow rates are required to capture and concentrate the particles, as well as polishing. Characterized by very high resolving power, monoliths can separate empty and full capsids of Adeno-associated virus and discriminate between pDNA isoforms (supercoiled, linear, open- circular).

Biography

BIA Separations is the leading developer and manufacturer of Convective Interaction Media (CIM) monolithic columns for fast purification of biomolecules. Our goal is to provide the best solutions in downstream processing and analytics, with the goal of saving our customers valued time and costs during the production of their desired biomolecules. We have over 20 years' experience in chromatographic purification of large biomolecules including viruses, VLPs, phages, pDNA, antibodies (IgM, IgG), proteins, as well as removal of viral particles, endotoxins and proteins from different biological matrices. We provide products that range from small analytical columns to large industrial prep-scale columns (including cGMP and disposable units in IEX, HIC, affinity and customized formats) as well as method development services.

Ingo.nagler@biaseparations.com

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