## **Sepax Monthly Features**



## UPDATE

3rd Edition of USP Draft Guidelines on Analytical Procedures for Quality of mRNA Vaccines and Therapeutics Released with Sepax Columns Continuing to be Selected in Helping Set the Standards

The US Pharmacopeia (USP) mentioned three Sepax columns again in the third draft edition of the guidelines for analytical procedures and best practices to support the assessment of common quality attributes of mRNA vaccines and therapeutics:

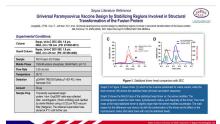
- SRT SEC-1000, 5 μm 1000 Å, 7.8 × 300 mm *mRNA Aggregation* (PN: 215950-7830)
- Proteomix RP-1000, 5 μm, 1000 Å, 2.1 × 100 mm mRNA Percent of Fragments (PN: 465950-2110)
- Zenix SEC-300, 3 μm, 300 Å, 4.6 × 150 mm mRNA Aggregation Quantitation (PN: 213300-4615)



The oxidation of the complementarity-determining region (CDR) in monoclonal antibodies (mAbs) is a critical quality attribute that can affect the clinical efficacy and safety of recombinant mAb therapeutics. In this new study from Henlius Biologics, a robust hydrophobic interaction chromatography (HIC) method was developed to quantify and characterize CDR oxidation variants in mAb-A by using Sepax Proteomix Butyl-NP5 analytical and preparative columns.

- Proteomix ButyI-NP5, 5 µm, Non Porous, 4.6 x 250 mm (PN: 431NP5-4625)
- Proteomix Butyl-NP5, 5 μm, Non Porous, 10 x 250 mm (PN: 431NP5-10025)





## LITERATURE REFERENCE

Sepax Unix-C SEC Columns Accurately Detect the Different Engineered Regions and Protein Sequence Modification to Further RSV Research and Vaccine Development

Sepax Unix-C SEC-300 columns were used to detect the different engineered regions in the RV1/3 in this recent Janssen study on RSV. The study results conclude that our columns demonstrate that the SEC-MALS method can accurately detect protein sequence modification for prefusion f which is critical for future vaccine development:

• Unix-C SEC-300, 1.8 μm, 300 Å, 4.6 x 150 mm (PN: 231300-4615)

