45 cm ID OPUS® Pre-Packed Disposable Chromatography Columns

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Summary
• Repligen’s OPUS® (Open Platform User Specified) Pre-Packed Disposable Columns with internal diameters up to 45 cm, and column heights from 5 cm and up, offer a flexible, scalable, and economical solution for the purification of biological products
• Design of the columns permits uniform flow distribution, making OPUS® columns ideal for upscaling and downsampling purification processes. Column characteristics are not compromised during transportation
• Ability to reliably clean the column even of small molecules makes OPUS® platform ideal for multi-run campaign use

Packing Performance
Method:
• Column packed with Sepharose® 6 FF resin was tested for quality at 100 cm/h
• Resolution of molecular weight markers was tested at 30 cm/h

Packing Acceptance Criteria:
• Plates/m: >1500
• Asymmetry: 0.8-1.6

Conclusions:
• Symmetrical peaks – optimum flow distribution
• Well resolved peaks on SEC separation – column packed well

Cleanability of the 45 cm ID OPUS Column
Method:
• Colorimetric measurement of phosphate reduction on a 45 cm x 20 cm OPUS® Sepharose® 6 FF column upon water washing

Conclusions:
• 45 cm ID OPUS® column design allows for perfect cleaning in less than 2 CVs
• Column can be used for multi-cycle campaigns that require cleaning in between runs

Transportation Qualification
Method:
• A 45 x 20 cm pre-packed OPUS® column was subjected to rigorous ISTA (procedure 2B) test for transportability:
  • High temperature (38 °C) and high humidity for 36 hours
  • Low temperature (4 °C) and low humidity for 36 hours
  • Compression testing (840 lbs or 381 kgs on top of crate)
  • 2 hours of random vibrational testing
  • 8 drop tests
  • Visual inspection and packed column performance assessed

Conclusions:
• Packaging withstood the rigors of a commercial shipping environment
• Chromatographic performance maintained after shipping

Scale-up of a Challenging Separation of Antibody Species to a 45 cm ID OPUS® Column

Method:
• Separation of low molecular weight species from an antibody on an 1.1 cm ID, 5 cm ID, and OPUS® 45 cm ID column packed with SP Sepharose®
• Challenging separation:
  • Wash of low molecular weight with 130 mM NaCl buffer
  • Elution of monomeric enriched fraction with 150 mM NaCl buffer

Results:

Conclusions:
• 45 cm ID OPUS® columns deliver expected scalability outcome for a difficult separation process
• Product purified on 45 cm ID OPUS® column has similar quality attributes as that purified on smaller columns IDs

Economic Payoff

Model Assumptions:
• 1 batch/campaign, 2 cycles/batch
• Assumes no column re-packs
• Includes time required for procurement, documentation & engineering prep, packing, purification, and storage

Conclusions:
• Pre-Packed Columns Eliminate Many Steps
  • Column packing buffer prep
  • Resin prep (de-flea)
  • Column packing
  • IQ/OQ
  • Column documentation
  • Column unpacking
  • Unpacked column cleaning
  • Cleaning verification (unpackaged column)

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