Shipping Qualification: 10-30 cm ID OPUS® Columns

Introduction

OPUS® (Open Platform User Specified) Pre-packed Disposable Chromatography Columns are designed to deliver the industry required flexibility of multi-use applications in downstream processing. Constructed from a medical grade polypropylene homopolymer, OPUS® columns are configurable for any industry standard size, chromatography resin, and bioprocessing application. As such, OPUS® columns must be able to withstand the rigors of commercial shipping to be suitable for use in a typical downstream processing campaign for monoclonal antibodies, recombinant proteins, or vaccines. In this Tech Note, transportation experiments were performed to insure the delivered product has the same performance characteristics as the manufactured one.

Methods and Materials

For this study, OPUS® 20 cm internal diameter columns were used to evaluate the stability of the packed bed, robustness of the column hardware, and durability of the packaging during commercial shipping. The OPUS® 20 cm design is representative of Repligen's Pre-Packed Disposable columns with internal diameters ranging from 10 – 30 cm. All columns in this size range have consistent design parameters, packing procedures, and performance characteristics (visit www.repligen.com/opus for more information).

1. ISTA Procedure 1A: Packaging Qualification

A 20 x 10 cm OPUS® Column packed with a Sepharose® 4FF was subjected to a rigorous shipping study following the International Safe Transit Association's (ISTA) Procedure 1A[1]. Tests included:

- Fixed displacement vibration test: ~ 15,000 vibrational impacts over 64 minutes
- Shock-drop tests: 70 cm (24 inches) free fall drops on corners, edges, and faces of the packaging

2. Commercial Shipping Test

A 20 x 20 cm OPUS® Column packed with SP Sepharose was shipped 6000 miles by truck and air. The column was assessed for chromatographic efficiency by measuring the number of theoretical plates per meter, and asymmetry. To demonstrate the packed bed was unaffected by shipping, both down-flow and up-flow applications were conducted to assess changes in column performance.

Acceptance Criteria

- Column integrity by visual inspection
- Column performance (HETP, asymmetry). The column is considered to be well packed if the number of theoretical plates per meter is greater than 1500, and the asymmetry is between 0.8 and 1.6. For post shipping and/or packing validation studies, the number of theoretical plates per meter and asymmetry should conform to results obtained pre-study.

[1] The International Safe Transit Association (ISTA) is the author of test procedures that define how packages should perform to ensure protection of their contents. ISTA has created the leading industry test standards and is trusted worldwide to inform global manufacturers how to survive the ever-changing hazards of a global transportation environment, as well as the more familiar challenges at home. ISTA pioneered package performance testing over 60 years ago and is now the most trusted, knowledgeable, and respected authority in package-performance testing. See www.ista.org for more information.

Results

1. Visual Inspection:

a. ISTA Procedure 1A: Packaging Qualification
   I. Packaging: The packaging passed the ISTA 1A tests. Minor abrasion resulted from the vibration testing and some crushing of the corners and edges occurred as a result of the drop testing.[2]
   II. Column: The 20 x 10 cm OPUS® column was found to be undamaged and intact

b. Commercial Shipping Test:
   I. The 20 x 20 cm OPUS® column was found to be undamaged and intact

2. Column Performance Testing:

a. **ISTA Procedure 1A:** The 20 x 10 cm OPUS® Column packed with Sepharose 4FF column was evaluated for the number of theoretical plates/m and asymmetry before and after the ISTA shipping study.

Figure 1: Pre-ship (80 cm/h)

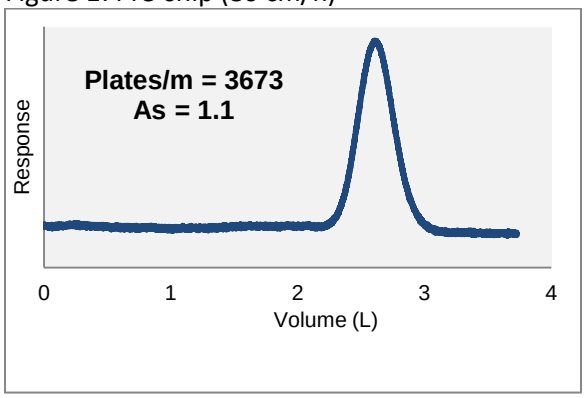
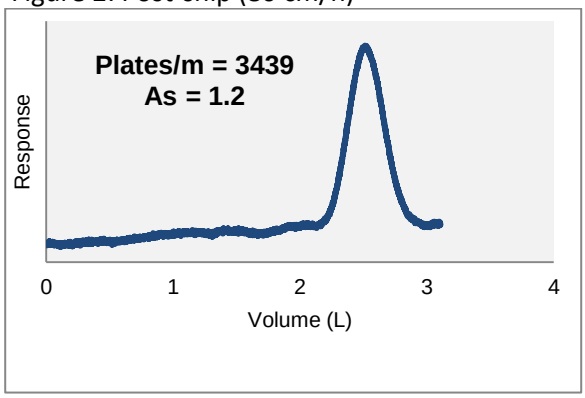


Figure 2: Post-ship (80 cm/h)



Figures 1 and 2 show the number of theoretical plates per meter was above the minimum acceptance criteria, and asymmetry was within acceptable limits. The chromatographic performance results were slightly different, but similar enough to show performance was maintained.

b. **Commercial Shipping Test:** The 20 x 20 cm OPUS® Column packed with SP Sepharose was tested before and after the air and ground transportation study.

[2] Repligen Bioprocessing Technical Brief: ISTA Shipping Test Summary: 20 cm ID OPUS® Column

Figure 3: Pre-ship: down flow

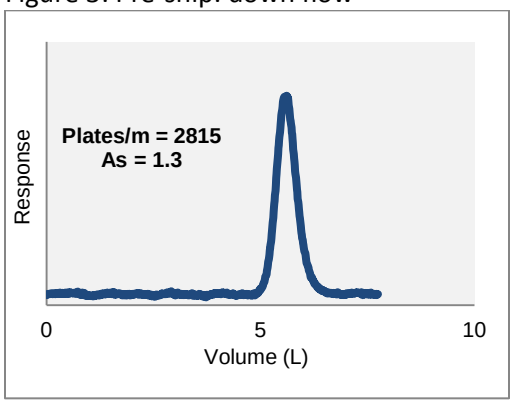


Figure 4: Post-ship down-flow

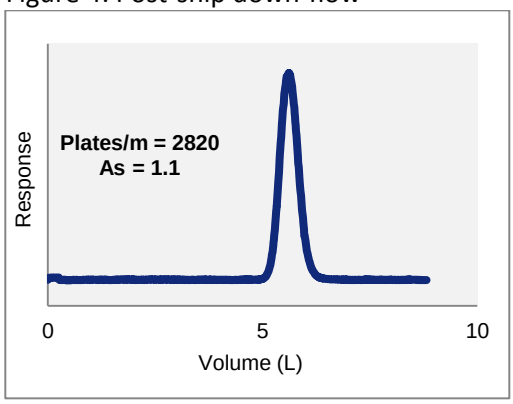
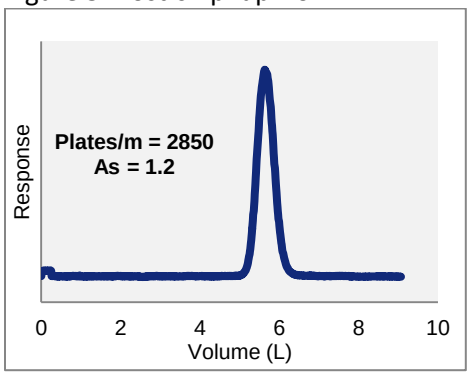


Figure 5: Post-ship: up-flow



Conclusions

The transportation experiments have demonstrated the rugged nature of OPUS® columns through both the ISTA Packaging Validation and Commercial Shipping tests. The results from the studies show there is no substantial difference in column performance characteristics after shipping and handling.

Furthermore, the data provides concrete evidence the column bed was not disturbed during shipping. In summary the following was observed:

- No significant damage to the shipping container
- No damage to the column structure
- No discernible change in the packed bed
- No significant differences in chromatographic performance

Post shipping, the number of theoretical plates per meter and asymmetry were maintained when the column was tested in down-flow, as well as when the column was tested in up-flow.

OPUS® Columns, which are designed to be used around the globe and in many different applications, have shown to be rugged enough to withstand the harsh environments of commercial shipping. Additional studies must be performed to confirm similar results with other chromatography resins, however, these tests are beyond the scope of this study report.