JSR Life Sciences

Chromassette®: Examples of Recently Tested Resins Suggest Wide Applicability of the Technology

Introduction

Chromassette® is a modular chromatography technology that offers the separation capabilities of conventional chromatography plus the convenience, scalability and other benefits of a pre-packed cassette. Each Chromassette cassette is distinguished by a novel internal scaffold that provides consistent "wall support" to all resin beads. This enables high flow-rates to be used with any type of resin regardless of bead rigidity or bed volume. Unlike traditional columns, which scale-up non-linearly, the cassettes are 3-D printed in a form that allows for easy stacking and which enables resin volumes to scale linearly. Sizing the appropriate bed volume to match desired protein load is much easier to achieve with Chromassette. As a result, Chromassette can help attain high productivity in purification processes designed for single-use, rapid cycling, and continuous processing.

This application note details bed integrity testing of some resins recently packed in Chromassette devices prior to shipment to end users.

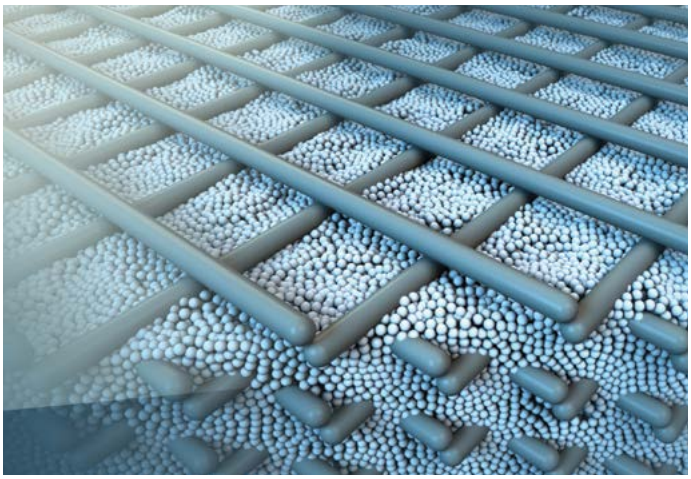


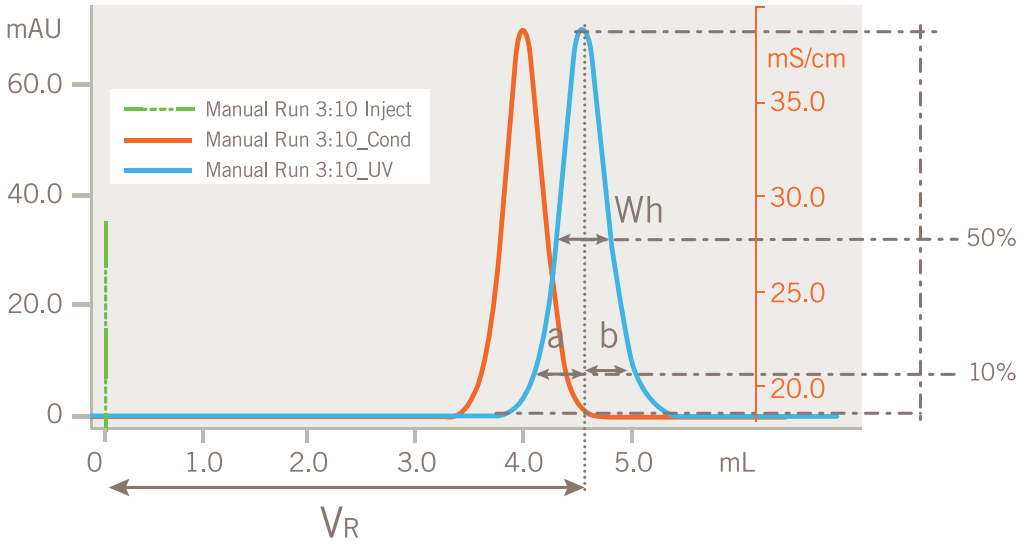
TABLE 1: CONDITIONS USED FOR CHROMASSETTE TESTING

Loading Buffer	Loading buffer (0.1 M NaCl in DI Water)
Injection Buffer	1.0 M NaCl in DI Water
Injection Volume	100 µL (6 cm bed height Chromassette), 200 µL (20 cm bed height Chromassette)
Linear Flow Rate	100 cm/h

Materials and Methods

Just as with a column, theoretical plate height (HETP) and asymmetry (As) values are determined, to gain insight to Chromassette bed integrity. These values can be determined using an injection pulse of NaCl in water. HETP and As values depend on the test conditions used and can only be used as a reference. Test conditions should be kept constant when comparing other experimental results to these values.

FIGURE 1: EXAMPLE OF AN INTEGRITY PEAK



$$HETP = \frac{L}{N}$$

$$N = 5.54 \times \left(\frac{V_R}{W_h}\right)^2$$

$$h = \frac{HETP}{d_{50v}}$$

$$As = \frac{b}{a}$$

Using the conductivity curve, HETP and As values are calculated:

HETP = theoretical plate height (cm)
L = bed height (cm)
N = number of theoretical plates
V_R = volume eluted from the start of sample application to peak maximum
W_h = peak width measured as the width of the recorded peak at half of the peak height
h = reduced plate height
d_{50v} = mean diameter of the beads (cm)
As = asymmetry factor
a = ascending part of the peak width at 10% of peak height
b = descending part of the peak width at 10% of peak height

Results and Conclusions

A wide range of chromatography resins featuring different base-bead chemistries, particle sizes and ligands have been packed in Chromassette process development (PD) cassettes. Some examples are given in Table 2 and 3. The PD Chromassette cassettes packed include both 6 cm and 20 cm bed heights. Integrity evaluation of As and N were conducted using the methods described above. In all cases the resins packed easily and, even with little experience of a particular resin type, reasonable As and N values were obtained (Table 2 & 3) as were good chromatograms (Figure 2). Results suggest that Chromassette can be packed with any commercial resin. Results similar to those shown here will be provided with each Chromassette device.

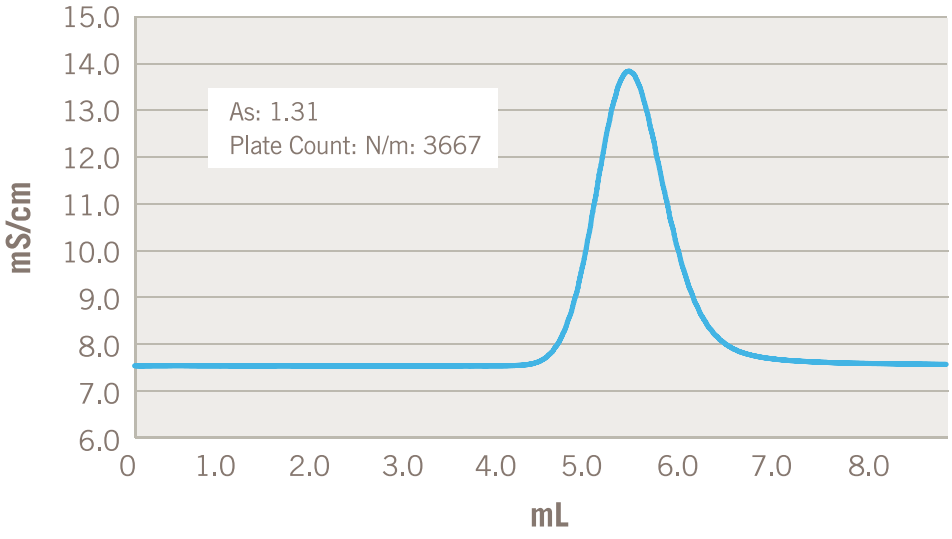
TABLE 2: . RESINS PACKED IN 6 cm BED HEIGHT CHROMASSETTE PD DEVICES

RESIN NAME	CHROMASSETTE (L = 6 cm)	
	As	N/m
Amsphere™ A3	1.31	3667
Capto™ Phenyl (high sub)	1.48	3750
Capto™ Q	1.14	2883
Fractogel® EMD SO3- (S)	0.88	3733
Fractogel® EMD TMAE (S)	0.83	4067
MabSelect SuRe™	1.30	3367
MabSelect SuRe™ LX	1.40	2250
MacroCap™ SP	1.20	2833
Q Sepharose™ High Performance	1.52	4233
Toyopearl® NH_2-750F	1.42	3100

TABLE 3: RESINS PACKED IN 20 cm BED HEIGHT CHROMASSETTE PD DEVICES

RESIN NAME	CHROMASSETTE (L = 20 cm)	
	As	N/m
Amsphere™ A3	1.49	2140
CHT™ Hydroxapatite Type I	1.34	1705
Fractogel® EMD SO_3- (S)	0.95	4225
MabSelect SuRe™	1.35	2875
MabSelect SuRe™ pcc	1.19	2265
Sephacryl™ S-300 HR	1.23	2500
Q Sepharose™ Fast Flow	1.24	2335
SP Sepharose™ Fast Flow	0.96	2850

FIGURE 2: REPRESENTATIVE INTEGRITY PEAK FROM 6 cm BED HEIGHT CHROMASSETTE PACKED WITH AMSPHERE A3



References

1. MacroCap Data File 28-4005-84 AA, 01/2006 and AB dated 09/2011, GE Healthcare Bio-sciences AB
2. Protein Chromatography: Process Development and Scale-Up, Giorgio Carta and Alois Jungbauer, Wiley-VCH, Weinheim, 2010.

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For more information visit www.jsrlifesciences.com
EMAIL: chromassette@jsrlifesciences.com

NORTH AMERICA
JSR Life Sciences
JSR Micro, Inc.
1280 North Mathilda Avenue
Sunnyvale, CA 94089
408-543-8800

ASIA
JSR Corporation
1-9-2 Higashi-Shimbashi
Minatoku, Tokyo
105-8640 Japan
+81-3-6218-3557

EUROPE
JSR Life Sciences
JSR Micro NV
Technologielaan 8
3001 Leuven
Belgium
+32-16-668-721