

GoPure™ Prepacked Columns

Rick Garretson

Business Development Manager

GoPure™ Prepacked Columns

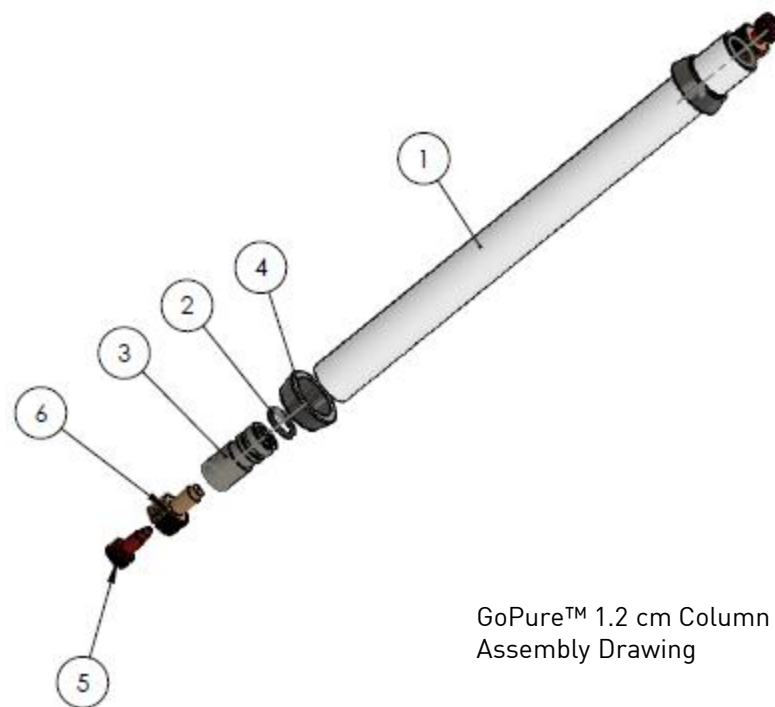
Product design

- Dimensions

Diameter (cm)	Length (cm)	Column Volume (mL)
1.2	5, 10, 15, 20	5, 11, 17, 22

- Design

- Flexible bed heights available in 1 cm increments
- POROS® and non-POROS® resin packing capability
- Standard NPT threaded connection
- Maximum Pressure: 6 Bar (Hardware only)
- Hardware chemical resistance aligned with bioprocess applications

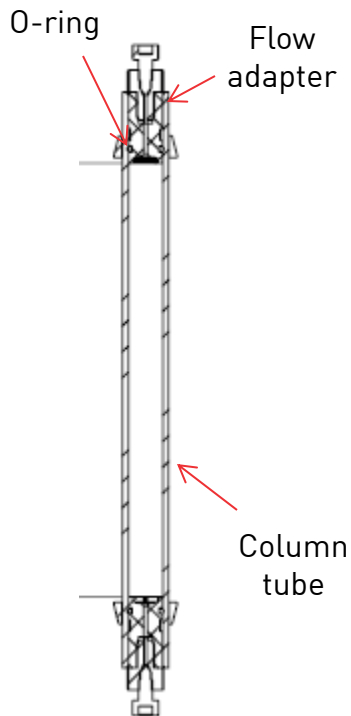


GoPure™ 1.2 cm Column
Assembly Drawing

Packing Specifications:
Plates / Meter: POROS® resin ≥ 4000; non-POROS® resins meet or exceed vendor claims
Asymmetry: 0.80 – 1.60
Permeability: Resin dependent, measured at defined flow rate
Column Test Certificate included

GoPure™ Prepacked Columns

Materials of construction

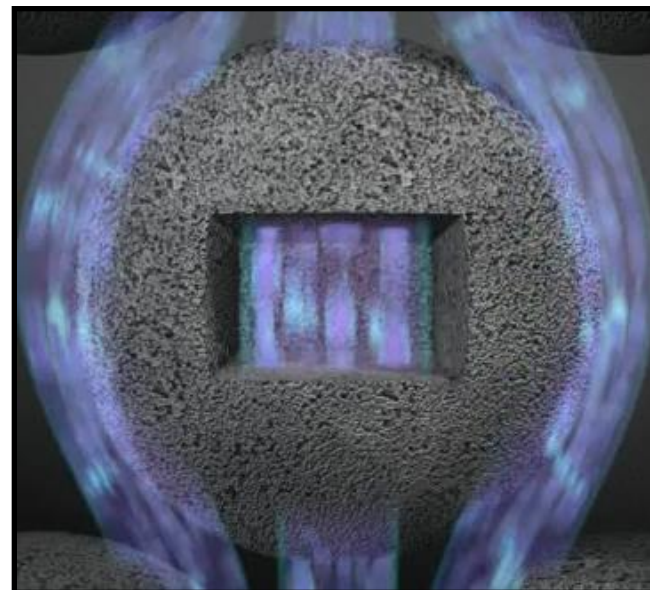


GoPure™ Column Part Description	Wetted Part	Quantity Used	Material
Column tube	Yes	1	Polypropylene
O-Ring	Yes	2	Ethylene Propylene
Lower Swage Ring	No	1	316 Stainless Steel
Flow Adapter	Yes	2	See detail below
Unitary End	Yes	1	Nylon 6,6
Frit, 10 micron (Titanium)	Yes	1	Titanium
Upper Swage Ring	No	1	316 Stainless Steel

GoPure™ Prepacked Columns

Standard columns with POROS® resins

- Column Hardware
 - Flexible bed heights available in 5 cm increments
- POROS® Resins
 - HS50 - XS
 - MabCapture™A - HQ50
- Column Qualification
 - Asymmetry: 0.80-1.60
 - Plates / meter: ≥ 4000
 - HETP: ≤ 0.025 cm
 - Pressure at defined flow rate



Unique POROS® bead technology

- GoPure™ Packing Service for:
 - Non-Poros resins
 - User defined bed heights
 - Other user defined requirements

GoPure™ Column Packing Service

Quotation process-input

Information Required

1. Contact information

2. Column details

Column dimensions

Resin manufacturer, resin name and part number

Requirement for post-pack sanitization

Requested delivery date

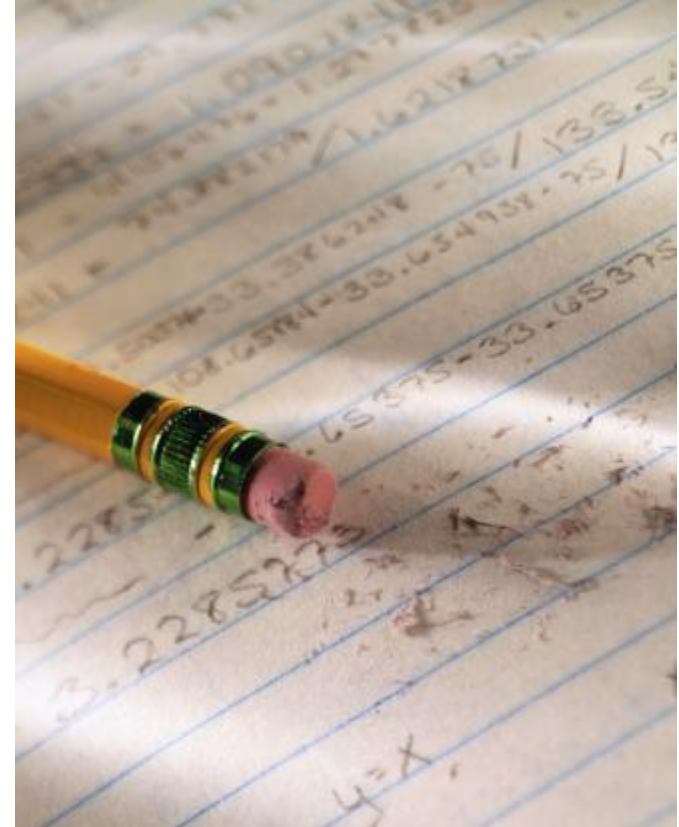
Number of columns

Shipping and storage temperature

Shipping solution

Requirement for bioburden/endotoxin

Other requirements



GoPure™ Column Packing Service

Quotation process-output

Proposal includes:

- Quotation information
 - Product number
 - Product description
 - Price
 - Delivery time
- Cover letter
 - Column specifications
 - Other deliverables



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Thermo Fisher Scientific
POROS Chromatography
35 Wiggins Ave
Bedford, MA 01730
www.lifetechnologies.com

Dr. J. Smith
Process Development
Blotech R Us
Innovation Dr.
Somewhereville

Dear Dr Smith:

Attached you will find a quotation (No. D1194370) for a GoPure™ MabSelect SuRe 1.2 cmD x 20 cmL having a part number GPC4445551.

In addition to the information in the quotation, this letter serves to confirm the following column specifications and other deliverables included in the quoted price.

GoPure™ Column Specifications

Column Dimensions:	1.2 cmD x 20 cmL
Chromatography Resin Description:	MabSelect SuRe Protein A
Chromatography Resin Manufacturer:	GE Healthcare
Chromatography Resin Part Number:	17-5438-XX
Post-Pack Sanitization:	None

Column Qualification Specifications

Asymmetry:	0.8 – 1.6
Efficiency (N/m):	≥ 2000
Permeability (psi):	≤ 3 bar@300cm/hr

Shipping and storage: 18% Ethanol/100 mM Phosphate Buffer, pH 7

Other Deliverables: None

Resin required for packing 27 mL per column

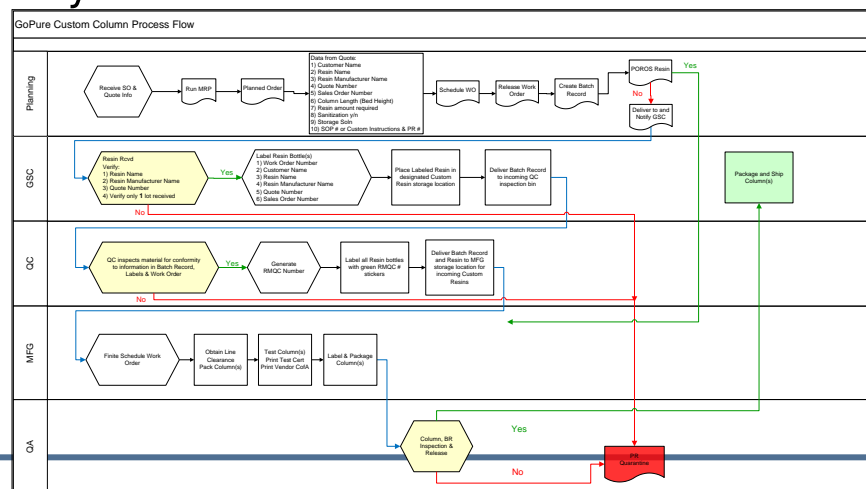
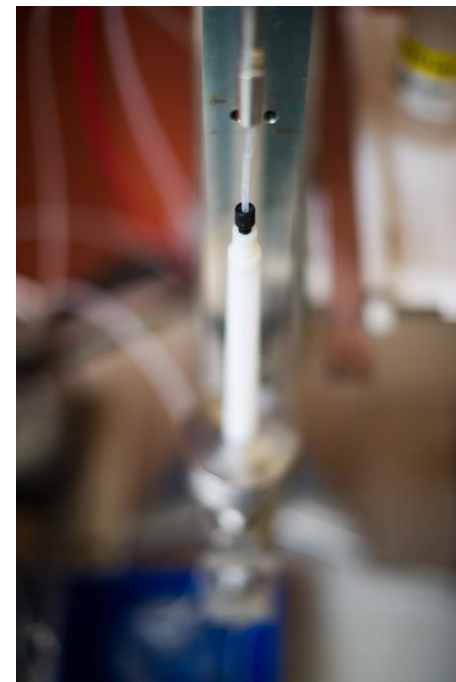
Thank you for your interest in Thermo Fisher's GoPure™ packing service and if this proposal is acceptable, please remember to include the quotation number on chromatography resin shipped to:

Life Technologies
2 Preston Court
Bedford, MA 01730
Attn: GoPure Custom Pack

GoPure™ Column Packing Service

Internal traceability, Validated business process


- Quote number on shipping documents
 - Unique resin identifier
- Upon receipt, resin is labeled and segregated
 - Customer name
 - Quote number
 - Work order number
 - Sales order number (Internal LTC order tracking)
 - Resin details
- QC inspection for accuracy and release of resin to manufacturing






GoPure™ Column Packing Service

Labeling & Documentation


Column Label


Non Print Area	REF 0000000000
GoPure™ XXXXXXXXXXXXX	
1.2 cmD X 00 cmL	
LOT 0000000000	
SN 0000000000	
Bedford, MA	Made in USA

applied biosystems® by life technologies™	REF 0000000000
Store at:  8 °C 2 °C	
GoPure™ Column	
1.2 cmD X 00 cmL	
XXXXXXXXXXXXXXXXXXXX	
LOT 0000000000	
SN 0000000000	
RESIN LOT: 000000000000 Column Vol: 00000 mL Contains: 18% Ethanol	
XXXXXXX is a registered trademark of XXXXXXXXXXXXXXX	
For Research Use Only. Not for use in diagnostic procedures.	
For support visit us at: www.lifetechnologies.com	
 Life Technologies Corporation, Bedford, MA	Read SDS Made in USA



Box Label

GE Healthcare		Certificate of Analysis
Product: Phenyl Sepharose™ High Performance		Code Numbers: 17-1082-01 17-1082-02 17-1082-04 17-1082-60 17-1082-99

		
Column Test Certificate		
GoPure Column; 1.2 cmD		
REF (Product Number) Resin Name Resin Vendor Bulk Media Lot Number GoPure Batch Number GoPure Serial Number Column Dimensions (cmD x cmL) Column Volume (mL) Manufacturing Date Expiration Date Sanitization (0.5M NaOH, 30 minutes) Storage Buffer		
TEST	SPECIFICATION	RESULT
EFFICIENCY		
Plates/meter (N/m)		
HETP (cm)		
ASYMMETRY		
Asymmetry	0.80 - 1.60	
PERMEABILITY		
Pressure (psi)		___ @ ___ cm/hr
Approved By: _____ Date: _____		
Quality Assurance		
For Research Use Only. Not for use in diagnostic procedures Manufactured in compliance with our ISO 9001 and ISO 13485 certified quality management system. Site: Bedford, MA, USA XXXXXXXXXX is a registered trade mark of XXXXXXXXXXXXXXX For more information, email us at cofarequest@lifetech.com		

gr-Health: 2017-03 gr-Health: 2012-03 AS 45-6002-85 Ed. A1 Quality Assurance by: Sten Pettersson not valid without a signature 20-0000-15-1-1-1 100-000-000-000 1000-000-000-000
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Column Test Certificate & Resin Vendor COA

GoPure™ Prepacked Columns

Qualification and separation results vs. self-packed column

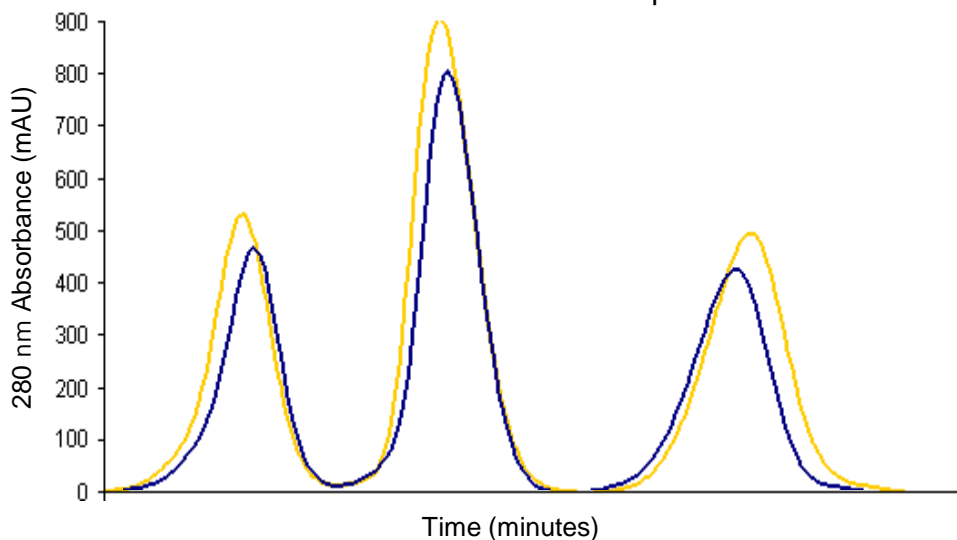
POROS® XS Column Qualification Results

	Plates/m	Asymmetry	Max. Conductivity (mS/cm)	Retention Vol. (% CV)
GoPure Column	4436	0.80	46.4	0.90
Self-Packed Column	4544	0.85	46.4	0.93

Column Qualification Conditions

Column: see below
 Equilibration: 0.1 M NaCl
 Plug: 1.0 M NaCl
 Injection Amount: 2 % CV
 Flow Rate: 100 cm/H

GoPure vs. Self-Packed Columns: Separation on POROS XS



Column Formats

GoPure Column: 1.2 cmD x 10 cmH (11.3 mL)
 Self-Packed Column: 1.0 cmD x 10 cmH (7.9 mL)

Separation Format

Protein Load Volume:
 3 mL GoPure; 2 mL Self-Packed
 Linear Flow Rate: 300 cm/H
 Buffer A: 20 mM MES, 25 mM NaCl pH 6.2
 Buffer B: 20 mM MES, 1M NaCl, pH 6.2
 Gradient: 15 CV to 100% Buffer B

GoPure™ Pre-Packed columns provide equivalent process performance compared to traditional self-packed columns

Bulk resins

- XS 50 µm Bulk Resin
- MabCapture™ A Resin
- Heparin 50 µm Bulk Resin
- HQ 50 µm Bulk Resin
- HS 50 µm Bulk Resin
- D 50 µm Bulk Resin
- PI 50 µm Bulk Resin
- R1 50 µm Bulk Resin
- R2 50 µm Bulk Resin

NEW

POROS XS
>100mg/mL
Capacity Resin
for Mabs



Analytical columns

- Protein A 20 µm Columns, PEEK™
- Protein G 20 µm Columns, PEEK™
- CaptureSelect™ 20µm Columns, PEEK
- AL 20 µm Columns, PEEK™
- EP 20 µm Columns, PEEK™
- OH 20 µm Columns, PEEK™
- PI 20 µm Columns, PEEK™
- HS 20 µm Columns, PEEK™
- S 20 µm Columns, PEEK™
- MC 20 µm Columns, PEEK™
- HP 20 µm Columns, PEEK™
- R2 20 µm Columns, PEEK™
- R1 20 µm Columns, PEEK™

NEW



Disposable columns

- GoPure™ 0.5 cm Diameter Column
- GoPure™ 1.2 cm Diameter Column

NEW



GoPure
Disposable
Columns
*Connect
and GO*

POROS[®] Chromatography Resins and Columns
Supporting BioAnalytical and BioProcess Applications

GoPure Prepacked Columns

Validation study preparation made simple

Rick Garretson

Business Development Manager

GoPure™ Prepacked Columns

Delivering flexibility, reproducibility for process validation studies



Save Time: Packing multiple columns , a low value activity, consumes many days

Flexible: Bed heights and resins tailored to your process

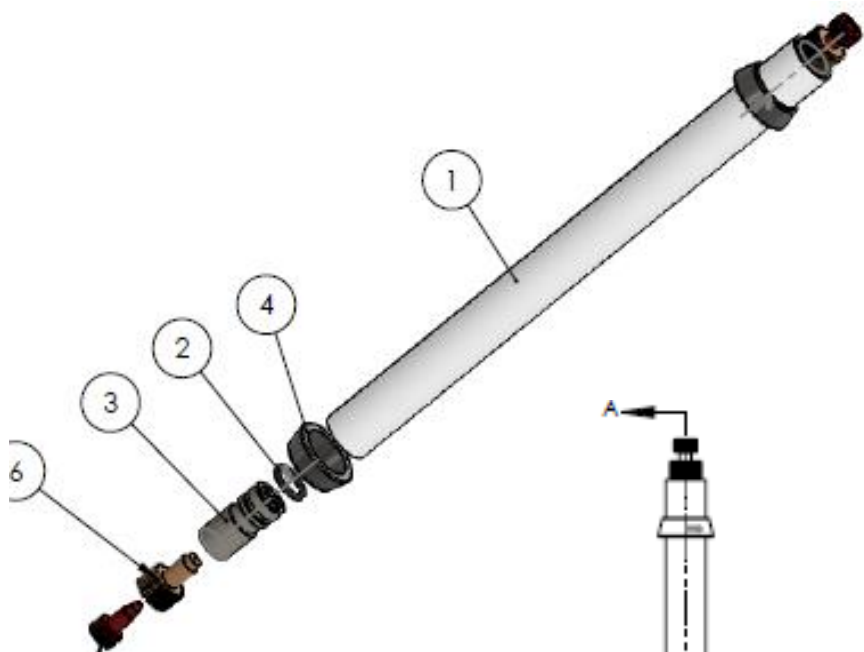
Reproducible: Qualified, reproducible prepacked columns

Cost Effective: Equivalent in cost to self-packed columns

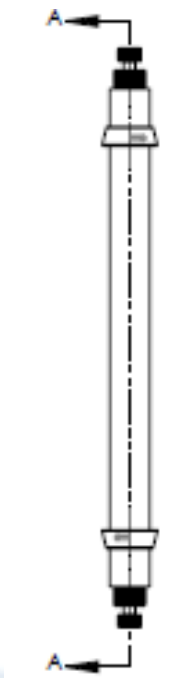
Needs	GoPure™ columns offer
Flexibility	Multiple column bed heights and resin types
Save Time	Allows redeployment of PD scientists to higher value activities
Reproducibility	Reproducible performance within a lot and between lots
Representative of Larger Scale	Column qualification results consistent with larger diameter columns Bed heights mimic process requirements
Cost Effective	Equivalent cost when compared to packing a traditional column
Quality	Packed with semi-automated packing equipment and supported by ISO 9001 and 13485 quality management standards

GoPure 1.2 cmD Columns

Flexibility



Packing Specifications:
Plates / Meter: POROS® ≥ 4000;
non-POROS® meets or exceeds
vendor claims
Asymmetry: 0.80 – 1.60
Permeability: Resin dependent,
measured at defined flow rate
Column Test Certificate included

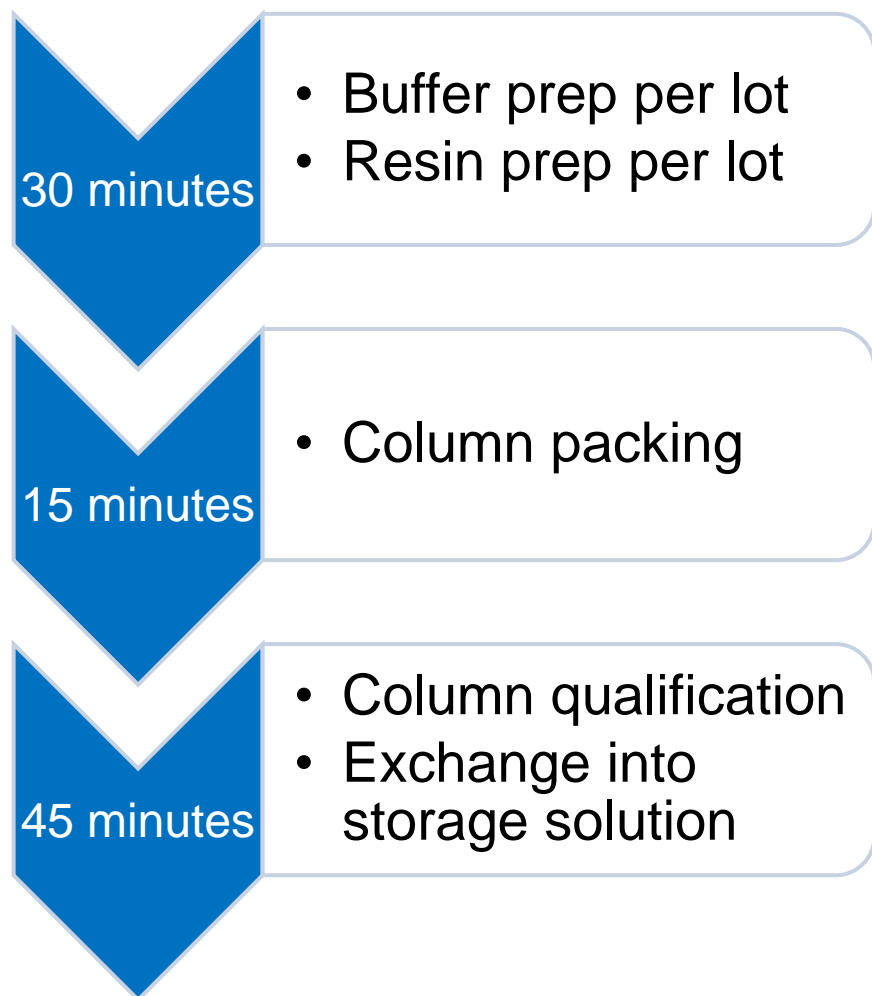


Column Design

- Diameter: 1.2 cm
- Bed height: 3 to 20 cmL
 - 1 cmL increments
- Bed height variability: +/- 3 mm
- POROS and non POROS resins
- Qualified
 - Asymmetry
 - Plates/meter
 - Permeability

GoPure 1.2 cmD Columns

Lab scale column packing workflow



Time Saving Assumptions

- Packing a 1.2 cmD x 20 cmL column requires about 1 hr
- Commonly, three purification (unit operations) steps per process
- Phase III process validation studies require about 20 columns per unit operation

Time Savings Calculation:

- $20 \text{ columns} \times 1 \text{ hour} \times 3 = 60 \text{ hours, or } 1.5 \text{ weeks}$

GoPure 1.2 cmD Columns

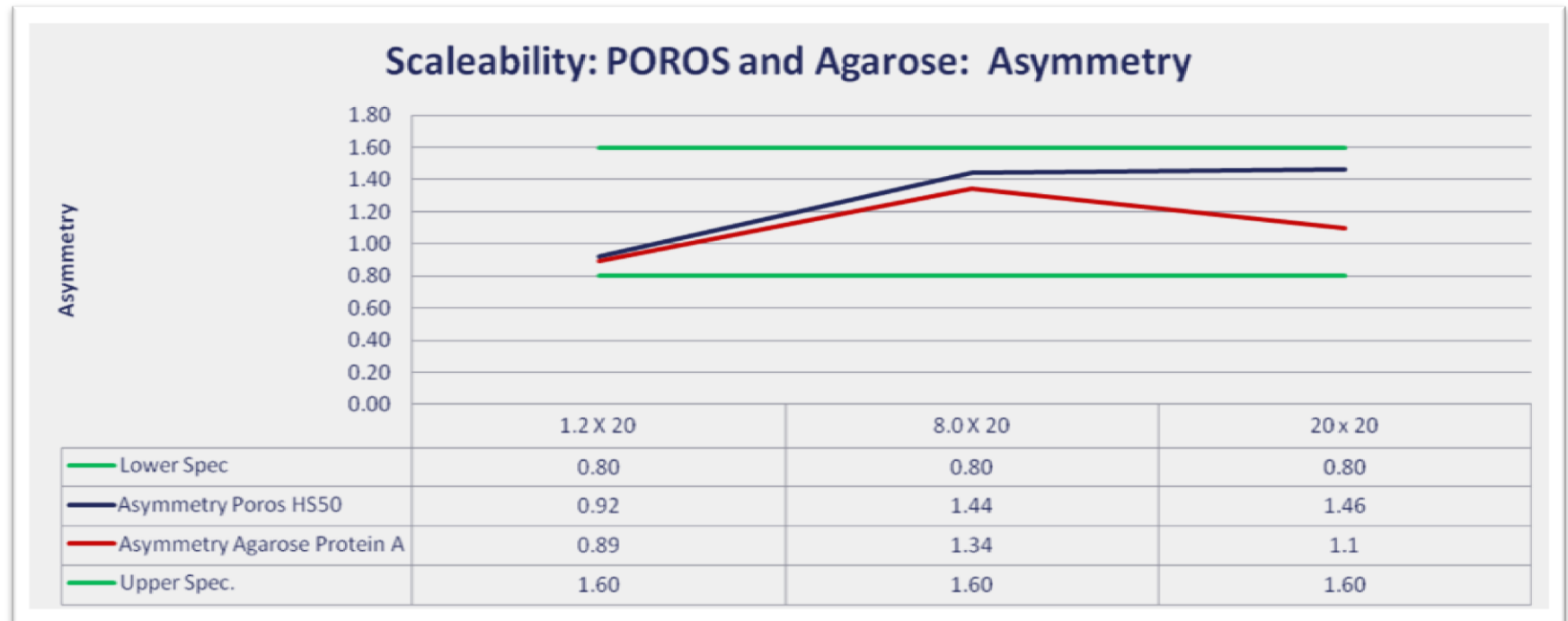
Reproducibility of column performance

POROS Resin	HS50		HQ50		Mab Capture A	
Column Dimension (cmD x cmL)	1.2 x 10	1.2 x 20	1.2 x 10	1.2 x 20	1.2 x10	1.2 x15
Date of Manufacture	6/2/2011	2/16/2012	6/2/2011	3/8/2012	12/4/2011	9/17/2010
Number of columns in lot	7	10	7	10	6	12
Asymmetry Specification	0.80-1.60					
Average Result	1.06	1.09	1.36	1.38	1.17	1.22
Std. Dev.	0.07	0.05	0.10	0.06	0.05	0.08
CV%	6.9	4.2	7.4	4.5	4.5	6.9
Efficiency Specification (Plates/Meter)	≥ 4000					
Average Result	7037	5663	6019	4532	8729	8900
Std. Dev.	632	282	569	285	818	574
CV%	9.0	5.0	9.5	6.3	9.4	6.5
Pressure Specification (PSI)	≤ 87					
Average Result	21.2	44.8	37.7	72.1	20.95	33.1
Std. Dev.	1.1	2.1	4.1	7.6	1.2	0.9
CV%	5.1	4.7	10.9	10.5	5.6	2.6

- Data from column manufacturing campaigns
- Within lot reproducibility is good and typically < 10%
- Lots produced 8-9 months apart demonstrate consistent performance
 - Note: pressure results higher as bed height increases

GoPure 1.2 cmD Columns

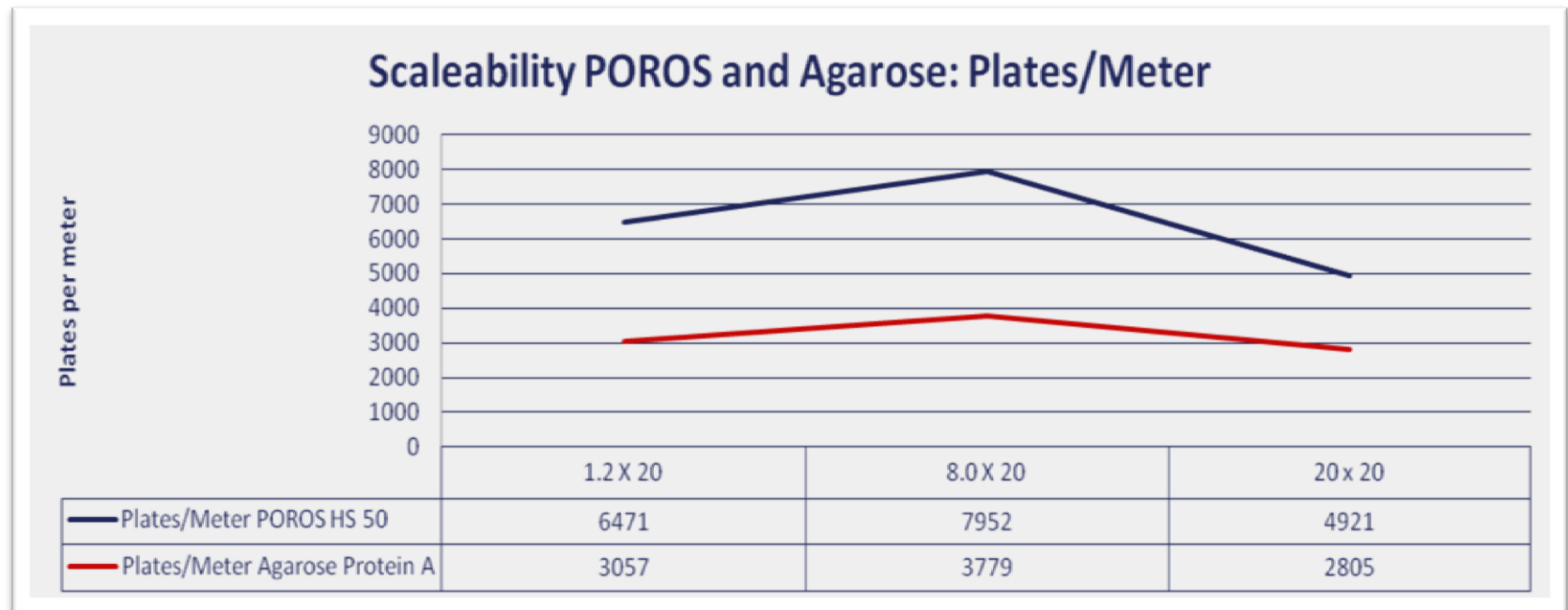
Scale down performance



Asymmetry specifications for all columns were 0.80 – 1.60.
The qualification test results, generated on different chromatography instruments, are consistent across all column diameters

GoPure 1.2 cmD Columns

Scale down performance



Efficiency specifications for POROS® GoPure columns are ≥ 4000 and Agarose Protein A GoPure columns ≥ 2000 plates per meter. Gopure 1.2 column performance is equivalent to larger diameter columns.

GoPure 1.2 cmD Columns

Self-pack column packing costs



The cost to pack a column or purchase a GoPure prepacked column are similar

GoPure™ Prepacked Columns

Validation study preparation made easy

- Time Savings
 - Spend your time executing value-add process validation activities
 - Equivalent cost to self-packed columns
- Flexibility
 - Any column length
 - Any resin
- High Performance Prepacked Columns
 - Standardized packing protocols
 - Reliable turnaround times
 - Reproducibility of column performance
 - Performance representative of larger diameter columns
 - Business process assures resin traceability from receipt to shipment
 - Global supply chain partner
 - Quality Management System: ISO 9001 and 13485



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