ReadyToProcess™ columns

User Manual



cytiva.com

Table of Contents

1 Introduction 4
1.1 About this manual 5
1.2 Important user information 6

2 Safety instructions 8
2.1 Safety precautions 9
2.2 Labels 12

3 Column description 14
3.1 General description 15
3.2 Illustration 20

4 Installation 21
4.1 Unpacking 22
4.2 Start using the column 24

5 Affinity chromatography resins 26
5.1 MabSelect PrismA and MabSelect PrismA X 27
5.2 MabSelect SuRe and MabSelect SuRe 70 30
5.3 MabSelect VL and Capto L 32
5.4 MabSelect VH3 34
5.5 MabSelect mild elution 36
5.6 rmp Protein A Sepharose 4 Fast Flow and Benzamidine Sepharose 4 Fast Flow 38
5.7 Additional affinity resins 40

6 Ion Exchange (IEX) chromatography resins 42
6.1 Capto S, Capto Q, and Capto DEAE resins 43
6.2 Capto SP ImpRes and Capto Q ImpRes resins 45
6.3 Capto S ImpAct resin 47
6.4 Sepharose Fast Flow IEX resins 49
6.5 Sepharose High Performance IEX resins 52

7 Multimodal chromatography resins 54
7.1 Capto adhere and Capto MMC resins 55
7.2 Capto adhere ImpRes and Capto MMC ImpRes resins 57
7.3 Capto Core 400 resin 59
7.4 Capto Core 700 resin 60

8 Hydrophobic Interaction Chromatography (HIC) resins 61
8.1 Capto Phenyl (high sub), Capto Butyl, Capto Octyl, and Capto PlasmidSelect 62
8.2 Capto Phenyl ImpRes and Capto Butyl ImpRes 63
8.3 Phenyl Sepharose 6 Fast Flow (low sub) and Phenyl Sepharose 6 Fast Flow (high sub) 65
8.4 Phenyl Sepharose High Performance, Butyl Sepharose High Performance, and PlasmidSelect Xtra 67
8.5 Butyl Sepharose 4 Fast Flow and Octyl Sepharose 4 Fast Flow 69

9 Operation 71
9.1 Handling and lifting of 450 and 600 mm i.d. columns 73
9.2 Connecting the column to the system 74
9.3 Clearance of storage solution and equilibration of the column 77
9.4 Regeneration of the column between purification cycles 79
9.5 Disconnect the column for storage 80
9.6 Storage 82
9.7 Disconnect the column prior to disposal 86
9.8 Evaluation of the packed bed (optional) 87

10 Troubleshooting 90

11 Reference information 92
11.1 Specifications 93
11.2 Flow conversion tables 100
11.3 Wetted parts 104
11.4 Chemical resistance 105
11.5 Recycling information 108
11.6 Regulatory information 109
11.6.1 Regulatory product documentation 110
11.6.2 Materials 111
11.7 Contact information 112
11.8 Ordering information 113

1 Introduction

About this chapter

This chapter contains important user information, descriptions of safety notices, and intended use of the ReadyToProcess™ columns.

In this chapter

Section		See page
1.1	About this manual	5
1.2	Important user information	6

1.1 About this manual

Purpose of this manual

The *User Manual* provides you with a general introduction and guide to ReadyToProcess column operation.

Typographical conventions

The text on a graphical user interface is identified in this manual by ***bold italic*** text.

The text on the label of a hardware item is identified in this manual by **bold** text.

Tip: *The text can include clickable hyperlinks to reference information.*

1.2 Important user information

Read this before using ReadyToProcess columns

All users must read this entire manual to fully understand the safe use of ReadyToProcess columns.

Intended use of ReadyToProcess columns

ReadyToProcess columns are designed for purification of biomolecules and are suitable for the production of material for clinical phase I and phase II studies. Depending on the scale of operations they can be used for full-scale manufacturing and preclinical studies.

ReadyToProcess columns are recommended for upflow mode and primarily intended for use together with ÄKTA ready™ chromatography systems. The ReadyToProcess columns can also be used with the standard systems ÄKTA process™ and ÄKTA pilot™.



WARNING

The ReadyToProcess columns must not be used for any other purpose than the intended use described in the User Manual.



WARNING

The columns are **not approved** for work in a potentially explosive atmosphere.

Disposal

When the column has been used it shall be disposed of as described in *Section 11.5 Recycling information, on page 108*. The ReadyToProcess columns cannot be repacked.

Definitions

This user documentation contains safety notices (WARNING, CAUTION, and NOTICE) concerning the safe use of the product. See definitions below.



WARNING

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.



CAUTION

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.



NOTICE

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

Notes and tips

Note: *A note is used to indicate information that is important for trouble-free and optimal use of the product.*

Tip: *A tip contains useful information that can improve or optimize your procedures.*

2 Safety instructions

About this chapter

This chapter describes safety precautions and the column label.

In this chapter

Section		See page
2.1	Safety precautions	9
2.2	Labels	12

2.1 Safety precautions

General precautions

The columns must be used in accordance with the safety instructions and technical specifications given in this User Manual to avoid personal injury or possible damage to equipment.

This User Manual does not guarantee user safety – it is the responsibility of the user's employer to ensure safe operation and provide appropriate training.

Information given in this User Manual is a suggested best working practice and shall in no way take precedence over individual responsibilities or local regulations. Great effort has been made to design and manufacture the various parts of the equipment so that it will comply with all applicable safety aspects for this type of equipment.

During the operation and during other work with a column, it is always each individual's responsibility to consider:

- their own and others' personal safety.
- the safety of the equipment through correct use in accordance with the descriptions and instructions given in this User Manual.

Flammable liquids and explosive environment



WARNING

Explosion hazard. The columns are **not classified** for work in a potentially explosive atmosphere.

Personal protection



WARNING

Hazardous substances and biological agents. When using hazardous chemical or biological agents, take all suitable protective measures, such as wearing protective clothing, glasses and gloves resistant to the substances used. Follow local and national regulations for safe operation and maintenance of this product.

Installation and moving



WARNING

Never exceed the column pressure specifications. To prevent rupture or injury, appropriate pressure safety monitoring equipment must be used, such as pressure alarms, pressure relief valves or rupture discs.



WARNING

Thoroughly rinse the column before disconnecting it from a system to make sure that there no hazardous chemicals (for example halogen-containing salt buffers) in the column prior to disposal.



WARNING

Heavy object. To avoid possible injury or damage, place the column on an even surface where it cannot be unbalanced and fall.



CAUTION

Heavy object. Appropriate transportation and lifting equipment (for example carts, pallet jacks, or telphers) must be used when handling larger columns. All lifting must be performed in accordance with local regulations.



CAUTION

Heavy object. The 450 and 600 mm i.d. columns are heavy. Take care when moving the columns to prevent squeezing or crushing injuries during movement. At least two, but preferably three or more, people are recommended when moving the columns.

Column operation



WARNING

Do not operate the product in any other way than as described in the user documentation.



WARNING

Never exceed the column pressure specifications. To prevent rupture or injury, appropriate pressure safety monitoring equipment must be used, such as pressure alarms, pressure relief valves or rupture discs.



WARNING

The working pressure of the column must never exceed the operating pressure specifications of the column, otherwise there is a risk of personal injury and damage to the column. Use pressure safety equipment, such as a pressure relief valve or rupture disc, to make sure that the maximum operating pressure of the column is not exceeded.

When rupture discs are used, make sure that these are positioned so that venting after rupture is directed to waste and not towards an area where personnel could be endangered.



WARNING

Pressure may remain in the column and tubing for an extended period after shutdown. Make sure the column and tubing is depressurized before opening or disconnecting.



WARNING

Thoroughly rinse the column before disconnecting it from a system to make sure that there no hazardous chemicals (for example halogen-containing salt buffers) in the column prior to disposal.



WARNING

Remove any NaOH residue from the surface of the column.

Note: *Unless otherwise stated, percentage solutions refer to volume by volume (v/v).*

2.2 Labels

Column label

The column label contains the product name and other important information that is specific to each column.

An example for columns up to 450 mm i.d. is described in the table below.

Label text	Description
29212474	Product code for the column.
32 L (450/200)	Column volume (32 L), inner diameter (450 mm) / bed height (200 mm).
Lot	Lot number. Refers to a column produced at a specific time. The lot number and identification number (Id No.) ensure that the ReadyToProcess column is fully traceable to the production source.
Expiry	Estimated expiry date.
Id No.	Identifies the individual column. The lot number and Id No. ensure that the ReadyToProcess column is fully traceable to the production source.
Bar code	The bar code (GS1-128, a total of 30 digits) contains an application identifier1 (90), the code number (digits 3 to 10), a second application identifier (10), lot number (digits 13 to 20), a third application identifier (21) and the Id No. (digits 23 to 30).
Store at	Recommended storage temperature when the column is not in use.
Max Operating Pressure	Shows the maximum operating pressure for the ReadyToProcess column itself and is noted here due to safety regulations. Note that different resins have different maximum operating pressures to ensure the integrity of the packed bed.
Max Operating Temperature	Shows the maximum operating temperature for the ReadyToProcess column.
	If the resin is flammable, the word Warning and a "flammable" pictogram is placed on the label with the following text: Flammable liquid and vapour. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Wear protective gloves. Store in a well ventilated place. Keep cool.

Pressure vessels above 200 bar liter are CE marked according to the Pressure Equipment Directive. Columns larger than or equal to 50 L therefore have labels as shown in the table below.

Label text	Description
29376118	Product code for the column.
57 L (600/200)	Column volume (57 L), inner diameter (600 mm) / bed height (200 mm).
Lot	Lot number. Refers to a column produced at a specific time. The lot number and identification number (Id No.) ensure that the ReadyToProcess column is fully traceable to the production source.
Expiry	Estimated expiry date. (YYYY-MM)
Id No.	Identifies the individual column. The lot number and Id No. ensure that the ReadyToProcess column is fully traceable to the production source.
Manf.	Manufacturing date. (YYYY-MM)
Bar code	The bar code (GS1-128, a total of 30 digits) contains an application identifier1 (90), the code number (digits 3 to 10), a second application identifier (10), lot number (digits 13 to 20), a third application identifier (21) and the Id No. (digits 23 to 30).
Store at	Recommended storage temperature when the column is not in use.
Operating Pressure	Shows the maximum operating pressure for the ReadyToProcess column. ***Note:*** *Different resins have different maximum operating pressure drops to ensure the integrity of the packed bed.*
Operating Temperature	Shows the operating temperature interval for the ReadyToProcess column.
	For flammable resins, the word Warning and a "flammable" pictogram is on the label together with the text: *Flammable liquid and vapor. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Keep container tightly closed. Wear protective gloves. Store in a well ventilated place. Keep cool.*
CE	The column complies with applicable European directives. CE marking is only applicable for columns larger than or equal to 50 L columns.

3 Column description

About this chapter

This chapter provides a description of the ReadyToProcess column and an illustration of the main parts.

In this chapter

Section		See page
3.1	General description	15
3.2	Illustration	20

3.1 General description

ReadyToProcess column platform

ReadyToProcess columns are part of the Cytiva ReadyToProcess platform, including chromatography and filtration products as well as other downstream solutions.

ReadyToProcess columns are supplied as complete units that connect directly to ÄKTA ready or ÄKTA ready XL with the available flow kits. The columns can also be used with standard chromatography systems, such as ÄKTA process. The smaller inner diameter (i.d.) columns, 80 and 126 mm, can also be used with ÄKTA pilot systems, but due to flow limitations, ÄKTA pilot systems cannot deliver more than 380 cm/h for an 126 mm i.d. column. The table below matches systems with columns.

Note: *ReadyToProcess columns are labeled* **inlet** *and* **outlet** *for running in the recommended upflow mode. However, the column can be run in downflow mode with retained performance by exchanging the* **inlet** *and the* **outlet** *connections when setting up the column in the chromatography system. This leads to a longer flowpath after the column.*

System	Max. flow rate for system (L/h)	Inner diameter (mm)	Flow rate (L/h) at flow velocities of:		
			100 cm/h	300 cm/h	500 cm/h
ÄKTA pilot	48	80	5	15	35
		126	13	37.5	N/A
ÄKTA ready with Low flow kit	175	80	5	15	35
		126	13	37.5	63
		178	25	75	125
		251	50	150	N/A
ÄKTA ready with High flow kit	10	251	10	50	250
		359	100	200	N/A
		450	160	480	N/A
		600	285	N/A	N/A
ÄKTA ready XL ¾″	1900	359	100	200	500
		450	160	480	800
		600	285	855	1425
ÄKTA ready XL 1″	3500	359	100	200	500
		450	160	480	800
		600	285	855	1425
ÄKTA process 6 mm	180	80	5	15	35
		126	13	37.5	63
		178	25	75	125
		251	50	150	N/A
ÄKTA process 10 mm	600	251	50	150	250
		359	100	200	500
		450	160	480	N/A
		600	285	N/A	N/A
ÄKTA process 1″	2000	359	100	200	500
		450	160	480	800
		600	285	855	1425

Prepacked columns

ReadyToProcess columns are prepacked, pre-qualified (by efficiency testing), and, if possible, pre-sanitized (see below) chromatography columns. The columns are available with a range of BioProcess™ resins, but can also be ordered packed with a range of other Cytiva resins selected by the customer. The following table lists some of the available column sizes. More bed heights are available.

Volume (L)	Inner diameter (mm)	Bed height (mm)	Label
0.8	80	150	(80/150)
1.0	80	200	(80/200)
1.3	80	250	(80/250)
1.9	126	150	(126/150)
2.5	126	200	(126/200)
3.1	126	250	(126/250)
3.7	178	150	(178/150)
5	178	200	(178/200)
6.2	178	250	(178/250)
7.4	251	150	(251/150)
10	251	200	(251/200)
12.4	251	250	(251/250)
15	359	150	(359/150)
20	359	200	(359/200)
24	450	150	(450/150)
25	359	250	(359/250)
32	450	200	(450/200)
40	450	250	(450/250)
42	600	150	(600/150)
57	600	200	(600/200)
71	600	250	(600/250)

Multiple cycles

ReadyToProcess columns can be used for multiple cycles. How many exactly, depends on the specific application and operating conditions:

- quality of the feed
- CIP efficiency
- properties of the liquids applied
- pressure drop over the column
- storage conditions

Bed integrity

In all separations with packed columns, bed integrity depends greatly on the running conditions. ReadyToProcess columns cannot be repacked. To minimize the risk that the bed integrity is affected after repeated cycles, consider extra precautionary measures for certain applications with prepacked columns, such as the use of:

- filtration prior to column load
- higher NaOH concentrations during CIP or before storage
- pre-filter cartridges for problem feeds

Packing factor

The packing factor of prepacked columns varies with the type of resin. The packing factor is a combination of mechanical compression and flow compression during packing. Typically, the factor varies between 1.1 and 1.2.

Customized columns

It is possible to customize ReadyToProcess columns for specific needs. The custom offering includes additional bed heights (100 to 250 mm) and/or resins not offered within the standard portfolio.

Column testing

ReadyToProcess columns are packed in an ISO 8 cleanroom class environment. Afterwards, the columns are efficiency-tested with a compatible test solution, then sanitized, and after that tested for endotoxin activity (< 0.25 EU/mL), total aerobic microbiological growth (CFU < 10/100 mL), as well as total combined yeast/mold growth (CFU < 10/100 mL). Values stated apply to sanitized columns. The columns are ready for immediate use and delivered with a reference sample of the resin lot packed in the column. The test results are presented in the *Certificate of Analysis*, which is available for downloading from *cytiva.com/certificates*.

Wetted parts

The wetted part materials are listed in *List of wetted materials, on page 104*. More information on the wetted parts materials is presented in the *Validation Guide* for ReadyToProcess columns available at *cytiva.com/rsf*.

Chemical resistance of column parts

ReadyToProcess columns and the chromatography resins are resistant to chemical agents used in protein recovery, including agents commonly contained in crude broth, buffer solutions for adsorption, elution and washing, and to solutions effective in cleaning and storage.

The chemical resistance of the outer surface of the column is listed in the table *Chemical resistance external surfaces, on page 105*, and the resistance of the wetted parts is listed in the table *Section 11.4 Chemical resistance, on page 105*. The concentrations and exposure times listed are typical for the intended use of the ReadyToProcess columns.

Note: *Chemical resistance data has been collected from several published sources, not from individual tests on column components. It must only be used as a guide.*

Note: *Chemical resistance external surfaces, on page 105, and Section 11.4 Chemical resistance, on page 105, list the chemical resistance of the column and not the chromatography resin. For the chemical resistance of the resin, refer to the Data file for the specific resin.*

The effects of a chemical will generally be more severe at higher temperatures. Note also that the combined effects of agents have not been taken into account in this table. In general, the ReadyToProcess columns are not compatible with long time exposure to organic solvents. An extractables study can be found in the *Validation Guide* for ReadyToProcess columns available at *cytiva.com/rsf*.

Non-sanitized (NS) ReadyToProcess columns

The ReadyToProcess NS columns are packed and qualified by efficiency testing but not sanitized. The ReadyToProcess NS columns are tested and supplied with the same type of regulatory product documentation as the ReadyToProcess columns.

The difference in documentation between ReadyToProcess columns and ReadyToProcess NS columns is the analytical specification limit for microbial contamination in NS columns. The Certificate of Analysis, showing packing performance as well as microbiology test results is available from *cytiva.com/certificates*.

NS column testing

Each ReadyToProcess NS column is packed in an ISO 8 cleanroom class environment and efficiency-tested. After efficiency testing and sampling the columns are ready for immediate use when delivered. The test results are presented in the Certificate of Analysis, which are available for downloading from *cytiva.com/certificates*.

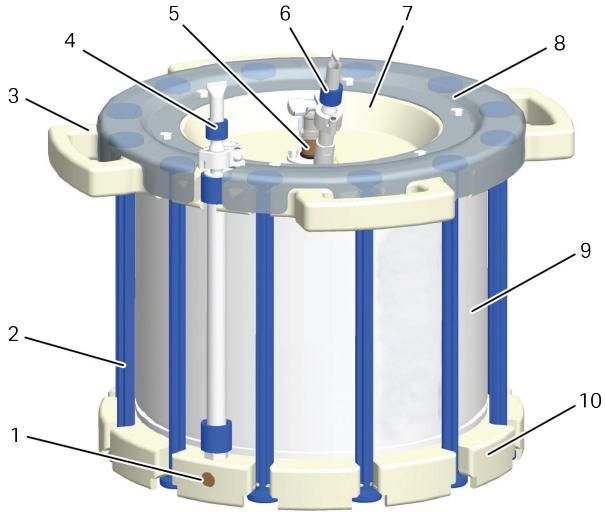
3.2 Illustration

ReadyToProcess column

The illustration below shows the exterior parts of a 20 L (359/200) column and the parts listed in table below are the same for all column sizes. On other columns, the nozzle design and the number of handles and tie rods might differ.

Heavier columns have four castor wheels to increase mobility. Two of the castor wheels have brakes.

The 450 and 600 mm i.d. columns are delivered with a pre-installed outlet tubing.



Part	Function
1	Plug at inlet tubing (not for customer use)
2	Tie rod
3	Handle
4	Inlet TC connection, marked **Bottom Inlet**
5	CPC or TC clamp sealing cap (on the packing nozzle)
6	Outlet TC connection, marked **Top Outlet**
7	Top lid
8	Protective rim
9	Column tube
10	Bottom lid

4 Installation

About this chapter

This chapter contains information about unpacking ReadyToProcess columns and removing the packaging, storage before use, and warnings before use.

In this chapter

Section		See page
4.1	Unpacking	22
4.2	Start using the column	24

4.1 Unpacking

Precautions



CAUTION

Heavy object. Appropriate transportation and lifting equipment (for example carts, pallet jacks, or telphers) must be used when handling larger columns. All lifting must be performed in accordance with local regulations.



CAUTION

Heavy object. The 450 and 600 mm i.d. columns are heavy. Take care when moving the columns to prevent squeezing or crushing injuries during movement. At least two, but preferably three or more, people are recommended when moving the columns.

Handling the column upon arrival

The 80 mm to 359 mm i.d. columns are delivered in two heat-sealed plastic bags inside a cardboard box. The procedure below applies to 80 mm to 359 mm i.d. columns after the cardboard packaging is opened.

The 450 and 600 mm i.d. columns are delivered in a box. Inside the box, columns are protected by a plastic dust cover sealed with a tie wrap. The 450 and 600 mm i.d. columns are delivered with an extra storage tube fixed in a tube support unit. The storage tube should be attached to the column during storage.

The 450 and 600 mm i.d. columns are delivered with separate Unpacking Instructions (29249825). These Unpacking Instructions are also available on the Cytiva website.

Follow the steps below to handle the column properly upon arrival.

Step	Action
1	Without opening the plastic bags, lift the column using the handles on the top lid and remove it from the cardboard box. Place the column on a cart, or a similar device. ***Note:*** *The large ReadyToProcess columns are packed with an expanded ethylene insert that is easily removed before the outer package is removed, leaving the column accessible on the pallet.*
2	Without removing the plastic bags, check the column for signs of damage. If any damage is found, document it carefully and contact Cytiva.

Step	Action
3	Move it to a suitable place for keeping until it is time for the column to be used. • See *Section 4.2 Start using the column, on page 24*. • See *Section 9.6 Storage, on page 82*, if the column is to be stored for more than a limited time before usage.
4	**NOTICE** To avoid contamination do not break the outer plastic bag or disturb the welded pieces of tubing mounted on the inlet and outlet TC connections of the column, see *Section 4.2 Start using the column, on page 24*. **NOTICE** The 450 and 600 mm i.d. columns have wheels for convenient handling. Make sure to clean the columns according to local procedures before moving them into production areas and follow the recommendations for chemical resistance. **NOTICE** The 450 and 600 mm i.d. columns are delivered with an extra storage tube fixed in a tube support unit. The storage tube should be attached to the column during storage.

4.2 Start using the column

Precautions



WARNING

Never exceed the column pressure specifications. To prevent rupture or injury, appropriate pressure safety monitoring equipment must be used, such as pressure alarms, pressure relief valves or rupture discs.



WARNING

Do not disconnect or release the CPC sealing cap, or remove the tie rods or the protective rim. Do not remove the welded tubing attached to the column inlet and outlet until the column is ready to be connected to a system for use.



WARNING

Heavy object. To avoid possible injury or damage, place the column on an even surface where it cannot be unbalanced and fall.



CAUTION

Do do not exceed recommended maximum pressure drop over the packed bed to avoid damage to the bed. The maximum pressure drop varies with chromatography resin used.



NOTICE

Do not turn, twist or break the inlet or outlet TC-connections. Handle connections with care.

Remove the packaging from the column

The 80 to 359 mm i.d. columns are supplied in double plastic bags and the 450 and 600 mm i.d. columns have a single plastic dustcover.

For 80 to 359 mm i.d. columns, remove the outer bag and move the column in the unbroken inner bag to the intended clean environment (for example a cleanroom) where the inner plastic bag is removed. The column can now be moved to the location of use, for example placed on an optional cart suitable for this purpose.

The 450 and 600 mm i.d. columns are delivered in a crate with separate unpacking instructions. For more information refer to *ReadyToProcess columns (i.d. 450 mm and 600 mm) Unpacking Instructions* (29249825). These Unpacking Instructions are also available on the Cytiva website.

Stability of packed bed for ReadyToProcess columns

To reduce risk for damaging the packed bed during operation of a ReadyToProcess column, the pressure drop over the packed bed must not exceed recommendations. Maximum pressure drop recommendation is found in *Chapter 5 Affinity chromatography resins, on page 26* to *Chapter 8 Hydrophobic Interaction Chromatography (HIC) resins , on page 61*. Resins based on a Sepharose™ High Performance (HP) matrix also have specific flow rate recommendations for removal of storage solutions, see the operations chapter *Chapter 9 Operation, on page 71*. These chapters also contain an estimate on the flow rate that can be expected at maximum pressure drop.

Note: *The Sepharose 4 Fast Flow resin is pressure sensitive and requires a lower flow rate than high-flow resins like Capto™ and MabSelect™. To speed up downstream processing, we recommend high-flow resins.*

5 Affinity chromatography resins

About this chapter

This chapter describes the affinity chromatography resins that can be used with ReadyToProcess columns.

In this chapter

Section		See page
5.1	MabSelect PrismA and MabSelect PrismA X	27
5.2	MabSelect SuRe and MabSelect SuRe 70	30
5.3	MabSelect VL and Capto L	32
5.4	MabSelect VH3	34
5.5	MabSelect mild elution	36
5.6	rmp Protein A Sepharose 4 Fast Flow and Benzamidine Sepharose 4 Fast Flow	38
5.7	Additional affinity resins	40

Introduction

Several affinity resins are available for ReadyToProcess columns. This chapter starts with a presentation of MabSelect PrismA™ and MabSelect PrismA X. This is followed by a section describing MabSelect SuRe™, MabSelect SuRe LX , and MabSelect SuRe 70. The next sections present MabSelect VL, MabSelect VH3, and MabSelect mild elution. In section 5.6, affinity resins on the Sepharose 4 Fast Flow base matrix are presented. More affinity resins that use different ligands and base matrices are available and their characteristics can be found in *Section 5.7 Additional affinity resins, on page 40*.

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

5.1 MabSelect PrismA and MabSelect PrismA X

Introduction

MabSelect PrismA is an affinity chromatography resin for the capture of monoclonal antibodies and Fc-containing recombinant proteins.

The protein A-derived MabSelect PrismA ligand is produced in *Escherichia coli*. Fermentation and subsequent purification is performed in the absence of animal products. The ligand has been specially engineered to create an affinity resin with enhanced alkali and protease stability. The resin is stable in concentrations up to 1.0 M NaOH. The specificity of binding to the Fc region of IgG is similar to that of conventional Protein A and provides excellent purification in one step. MabSelect PrismA has very high dynamic binding capacities at most commonly used residence times.

MabSelect PrismA X is an affinity chromatography resin for capturing high-titer monoclonal antibodies from large volumes of feed by packed bed chromatography.

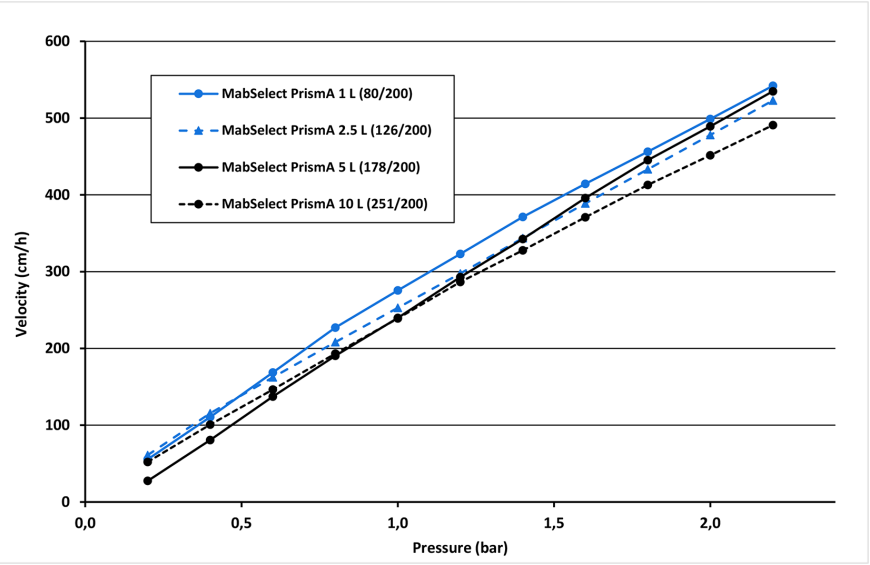
Key features of the MabSelect PrismA X resin include the following:

- cost-efficiency at low resin utilization, such as in clinical manufacturing
- high dynamic binding capacity; higher than 80 g/L at 6 min residence time and 74 g/L at 4 min residence time, in a well-packed column
- The alkaline-tolerant protein A-derived ligand allows for regular use of 0.5 to 1.0 M NaOH for cleaning-in-place (CIP)
- convenience for use in short bed height formats and suitable for rapid cycling chromatography (RCC) to further improve productivity in the protein A purification step

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

Pressure drop of MabSelect PrismA

The pressure drop over the packed bed depends on the liquid velocity applied, the viscosity and temperature of the liquid. A maximum pressure drop of 2.0 bar over the column shall not be exceeded to keep the integrity of the packed bed. Typically, a liquid velocity of 300 cm/h results in a pressure drop of less than 2.0 bar when using a 1 L (80/200) column with aqueous solutions at room temperature. The figure below shows examples of pressure-flow curves for 80, 126, 178, and 251 mm i.d. ReadyToProcess MabSelect PrismA columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	MabSelect PrismA	MabSelect PrismA X
Matrix	Rigid, highly cross-linked agarose	
Particle size, d_{50v}[1]	60 µm	50 µm
Ligand	Alkali-tolerant, protein A-derived (*E. coli)*	
pH stability, operational[2]	3 to 12	
Working temperature	4°C to 40°C	
Storage temperature	2°C to 8°C	
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)	
Approximate flow velocity at maximum pressure drop[3]	300 cm/h	220 cm/h
Storage solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.2 MabSelect SuRe and MabSelect SuRe 70

Introduction

MabSelect SuRe is a high-flow, alkali-tolerant, protein A-derived resin for the capture of monoclonal antibodies from large feed volumes.

The protein A-derived MabSelect SuRe ligand is produced in *Escherichia coli*. Fermentation and subsequent purification are performed in the absence of animal products. The protein A-derived ligand has been specially engineered to create an affinity resin with high alkali stability and high binding capacity for IgG. The resin is stable in concentrations up to 0.5 M NaOH. The specificity of binding to the Fc region of IgG is similar to that of conventional protein A and provides excellent purification in one step.

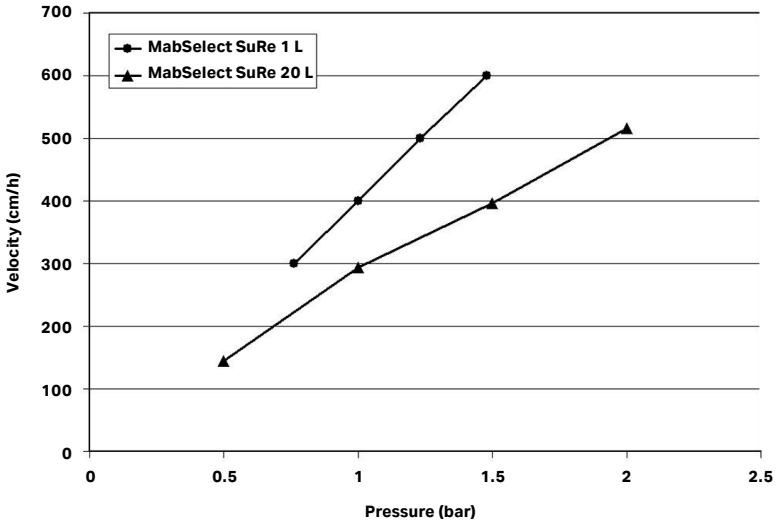
MabSelect SuRe 70 resin has high dynamic binding capacity, making it suitable for rapid resin cycling. The resin also allows 200 CIP cycles with 0.1 M NaOH and 100 CIP cycles with 0.5 M NaOH. The pressure-flow properties make the resin well-suited for running high-flow applications in short bed heights.

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

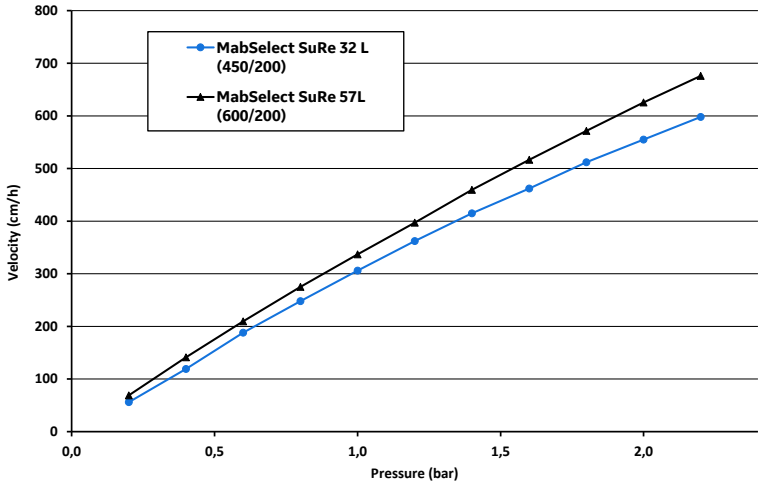
Pressure drop of MabSelect SuRe

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 2.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 500 cm/h results in a pressure drop of less than 2.0 bar when using a 20 L (359/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess MabSelect SuRe columns in operation with water at room temperature (20°C).



The following figure shows examples of pressure-flow curves for 450 mm and 600 mm i.d. ReadyToProcess MabSelect SuRe columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resins are summarized in the table below.

Characteristic	MabSelect SuRe	MabSelect SuRe LX	MabSelect SuRe 70
Matrix	Rigid, highly cross-linked agarose		
Particle size, d_{50v} [1]	85 µm		50 µm
Ligand	Alkali-tolerant, protein A-derived (*E. coli*)		
pH stability, operational [2]	3 to 12		
Working temperature	4°C to 40°C		
Storage temperature	2°C to 8°C		
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)		
Approximate flow velocity at maximum pressure drop [3]	500 cm/h		220 cm/h
Storage solution	20% ethanol		

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.3 MabSelect VL and Capto L

Introduction

MabSelect VL and Capto L resins are suited for diversified antibody processes involving the purification of mAb derived fragments and bispecific antibodies for clinical applications. The resins combine a rigid, high-flow agarose base matrix with protein L ligand.

MabSelect VL resin uses a new generation protein L ligand that is designed to have a higher dynamic binding capacity and higher alkali tolerance than Capto L resin.

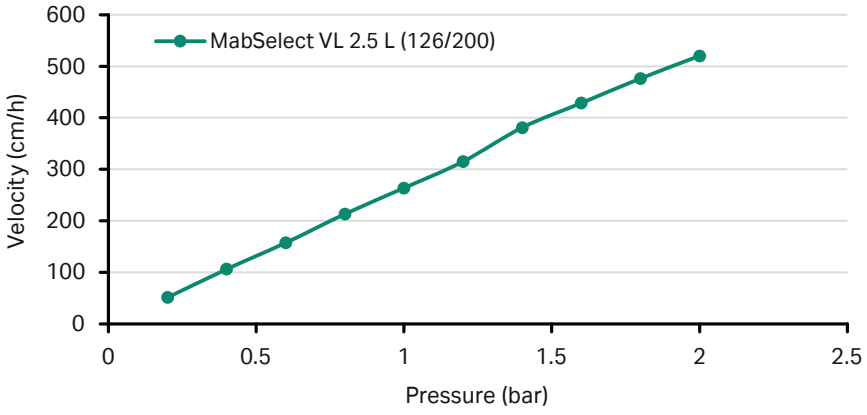
The ligand of the MabSelect VL resin is recombinantly produced in *Escherichia coli* and originates from the bacterium *Peptostreptococcus magnus*. Fermentation and subsequent purification are performed in the absence of animal derived products. The ligand has been specifically engineered to bind antigen-binding fragment (Fab) and mAb derived products containing the immunoglobulin G (IgG) kappa light chain.

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

Pressure drop of MabSelect VL

The pressure drop over the packed bed depends on the liquid velocity applied, the viscosity and temperature of the liquid. A maximum pressure drop of 2.0 bar over the column must not be exceeded to keep the integrity of the packed bed. Typically, a liquid velocity of 300 cm/h results in a pressure drop of less than 2.0 bar when using a 1 L (80/200) column with aqueous solutions at room temperature.

The figure below shows an example of a pressure-flow curve for a 126 mm i.d. ReadyToProcess MabSelect VL column in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	MabSelect VL	Capto L
Matrix	Rigid, highly cross-linked agarose	Highly cross-linked agarose
Particle size, d_{50v}[1]	~ 60 µm	85 µm
Ligand	Alkaline stabilized, protein L-derived (*E. coli)*	Recombinant protein L (*E. coli*)
pH stability, operational[2]	2 to 10	
Temperature stability	2°C to 40°C	4°C to 40°C
Storage temperature	2°C to 8°C	
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)	
Approximate flow velocity at maximum pressure drop[3]	300 cm/h	500 cm/h
Storage solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.4 MabSelect VH3

Introduction

MabSelect VH3 is an affinity chromatography resin for capturing antibodies and antibody fragments containing the variable heavy chain of the VH3 sequence family. The VH3 sequence family is the most common VH class for antibodies in commercialized biologics.

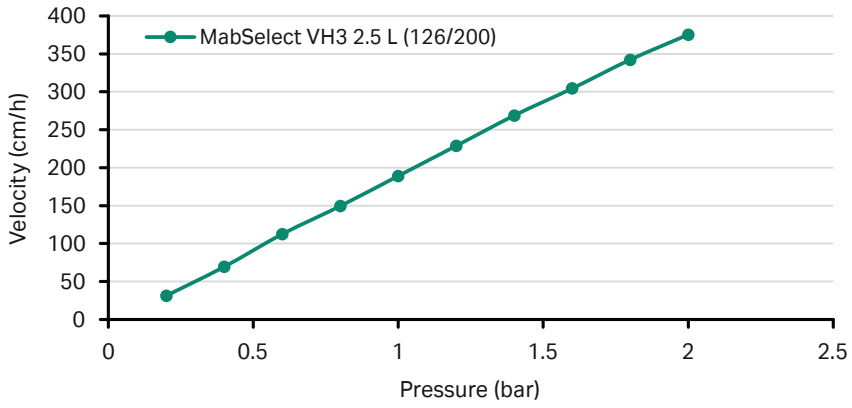
The MabSelect VH3 resin ligand is specifically engineered to create affinity only for the variable region of the heavy chain (VH3). Traditional protein A ligand resins have affinity for both the Fc region and the Fab VH3 region of human antibodies. With the MabSelect VH3 resin ligand, Fc interaction is knocked out and Fab VH3 interaction is enhanced.

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

Pressure drop

The pressure drop over the packed bed depends on the liquid velocity applied, the viscosity, and the temperature of the liquid. A maximum pressure drop of 2.0 bar over the column must not be exceeded to keep the integrity of the packed bed. Typically, a liquid velocity of 300 cm/h results in a pressure drop of less than 2.0 bar when using a 1 L (80/200) column with aqueous solutions at room temperature.

The figure below shows an example of a pressure-flow curve for a 126 mm i.d. ReadyToProcess MabSelect VH3 column in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	MabSelect VH3
Matrix	Rigid, highly cross-linked agarose
Particle size, d_{50v}[1]	~ 60 µm
Ligand	MabSelect VH3 (alkaline-stabilized, protein A-derived from *E. coli*), no interaction with the Fc region and enhanced interaction with the VH3 region
pH stability, operational[2]	3 to 12
Temperature stability	2°C to 40°C
Storage temperature	2°C to 8°C
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)
Approximate flow velocity at maximum pressure drop[3]	300 cm/h
Storage solution	20% ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.5 MabSelect mild elution

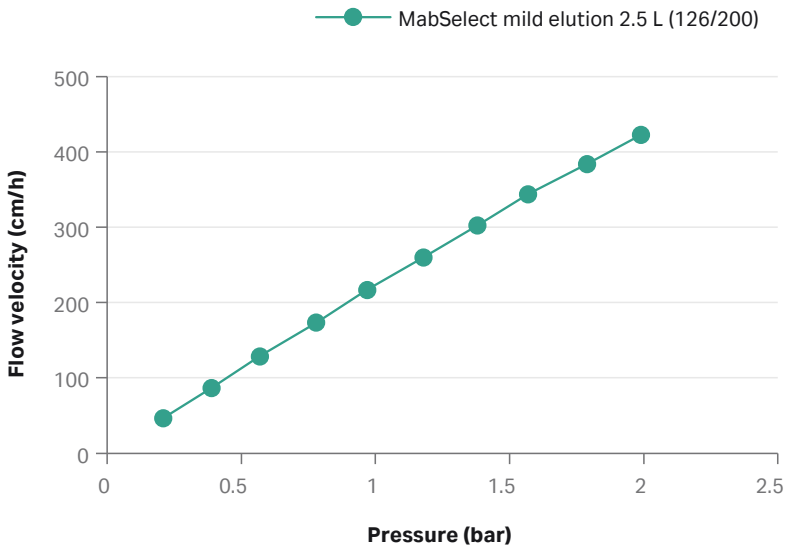
Introduction

MabSelect mild elution is a BioProcess affinity chromatography resin with an engineered protein A ligand that interacts only with the fragment crystallizable (Fc) region of human IgG antibodies. The resin allows for elution of bound antibodies in milder pH conditions than traditionally used in protein A chromatography. Acidic pH conditions often promote antibody aggregation. The resin combines high binding capacity with the ability to elute at higher pH values for more sensitive IgGs. This feature allows for high-productivity protein A capture chromatography for molecules that was previously unattainable.

For detailed information, refer to the applicable *Data file* or *Instructions* available on the Cytiva website.

Pressure drop of MabSelect mild elution

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and the temperature of the liquid. A maximum pressure drop of 2.0 bar over the column must not be exceeded to keep the integrity of the packed bed. Typically, a flow velocity of 300 cm/h results in a pressure drop of less than 2.0 bar when using a 2.5 L (126/200) column with aqueous solutions at room temperature. The figure below shows an example of a pressure-flow curve for a 126 mm i.d. ReadyToProcess MabSelect mild elution column in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	MabSelect mild elution resin
Matrix	Rigid, highly cross-linked agarose
Particle size, d_{50v}[1]	~ 60 µm
Ligand	MabSelect mild elution (alkaline-stabilized, protein A-derived from *E. coli*), no interaction with the VH3 domain
pH stability, operational[2]	3 to 12
Temperature stability	2°C to 40°C
Storage temperature	2°C to 8°C
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)
Approximate flow velocity at maximum pressure drop[3]	300 cm/h
Storage solution	20% (v/v) ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.6 rmp Protein A Sepharose 4 Fast Flow and Benzamidine Sepharose 4 Fast Flow

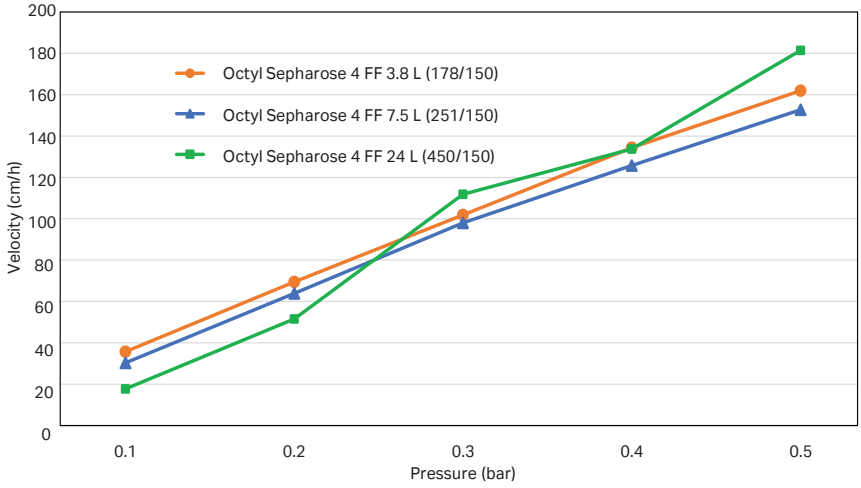
Introduction

This chapter presents rmp Protein A Sepharose 4 Fast Flow and Benzamidine Sepharose 4 Fast Flow. For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 0.5 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 80 cm/h results in a pressure drop of less than 0.5 bar when using a 20 L (359/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 3.8 L (178/150), 7.5 L (251/150), and 24 L (450/150) ReadyToProcess Sepharose 4 Fast Flow (FF) columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resins are summarized in the table below.

Characteristic	rmp Protein A Sepharose 4 Fast Flow	Benzamidine Sepharose 4 Fast Flow
Matrix	Cross-linked agarose, 4%, spherical	
Particle size, d_{50v} [1]	90 µm	
Ligand	Recombinant protein A (*E. coli*)	p-aminobenzamidine (pABA)
pH stability, operational[2]	3 to 10	2 to 8
Working temperature	4°C to 40°C	
Storage temperature	2°C to 8°C	
Maximum pressure drop over packed bed	0.05 MPa (0.5 bar, 7.2 psi)	
Approximate flow velocity at maximum pressure drop [3]	80 cm/h	
Storage solution	20% ethanol	20% ethanol + 0.2 M sodium acetate

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

5.7 Additional affinity resins

Introduction

There are additional base matrices with affinity ligands available in ReadyToProcess columns. This section presents the basic characteristics of the resins.

Characteristics

Some of the characteristics of the resins are summarized in the table below.

Characteristic	IMAC Sepharose Fast Flow	MabSelect	MabSelect Xtra™	KappaSelect	Lambda FabSelect
Matrix	Cross-linked 6% agarose	Highly cross-linked agarose, spherical			
Particle size, d_{50v}[1]	90 µm	85 µm	75 µm		
Ligand	Immobilized metal ion affinity chromatography (delivered unchanged)	Recombinant protein A (*E. coli*)		Recombinant protein (M_r 13 000) from *S. cerevisiae*. Affinity for the constant domain of the immunoglobulin kappa light chain	Recombinant protein (M_r 13 000) from *S. cerevisiae*. Affinity for the constant domain of the immunoglobulin lambda light chain
pH stability, operational[2]	3 to 12	3 to 10			
Working temperature	4°C to 40°C				
Storage temperature	4°C to 30°C	2°C to 8°C			
Maximum pressure drop over packed bed	0.12 MPa (1.2 bar, 17 psi)	0.20 MPa (2.0 bar, 29 psi)		0.30 MPa (3.0 bar, 44 psi)	
Approximate flow velocity at maximum pressure drop[3]	250 cm/h	500 cm/h		600 cm/h	
Storage solution	20% ethanol				

[1] Median particle size of the cumulative volume distribution.

[2] pH range where resin can be operated without significant change in function.

[3] Run in water, at room temperature and at 200 mm bed height.

Characteristic	Capto Chelating	VIIISelect	Alpha-1 Anti-trypsin Select	Capto DeVirs	Capto AVB	AVB Sepharose HP
Matrix	Highly cross-linked agarose				Highly cross-linked agarose, spherical	Cross-linked agarose
Particle size, d_{50v} [1]	75 µm				50 µm	34 µm
Ligand	Iminodiacetic acid	Recombinant protein (M_r 13 000) from *S. cerevisiae*. Binds to β domain deleted factor VIII molecules.	Alpha-1 anti-trypsin binding ligand	Dextran sulfate	Recombinant protein (M_r 14 000) from *S. cerevisiae*. Binds AAV of subclasses 1, 2, 3, and 5.	14 kD recombi-nant protein
pH stability, operational[2]	3 to 12	3 to 10	4 to 10	7 to 13	3 to 10	
Working temperature	4°C to 40°C					
Storage temperature	4°C to 30°C	2°C to 8°C				
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)	0.20 MPa (2.0 bar, 29 psi)	0.30 MPa (3.0 bar, 44 psi)		0.20 MPa (2.0 bar, 29 psi)	0.24 MPa (2.4 bar, 35 psi)
Approximate flow velocity at maximum pressure drop[3]	600 cm/h	500 cm/h	600 cm/h		220 cm/h	90 cm/h
Storage solution	20% ethanol					

[1] Median particle size of the cumulative volume distribution.

[2] pH range where resin can be operated without significant change in function.

[3] Run in water, at room temperature and at 200 mm bed height.

6 Ion Exchange (IEX) chromatography resins

About this chapter

This chapter describes the ion exchange chromatography resins that can be used with ReadyToProcess columns.

In this chapter

Section		See page
6.1	Capto S, Capto Q, and Capto DEAE resins	43
6.2	Capto SP ImpRes and Capto Q ImpRes resins	45
6.3	Capto S ImpAct resin	47
6.4	Sepharose Fast Flow IEX resins	49
6.5	Sepharose High Performance IEX resins	52

Introduction

Several IEX resins are available for ReadyToProcess columns. The IEX resins can be divided into three groups based on the type of base matrix: Capto, Sepharose Fast Flow (FF) and Sepharose High Performance (HP).

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

6.1 Capto S, Capto Q, and Capto DEAE resins

Ion exchangers

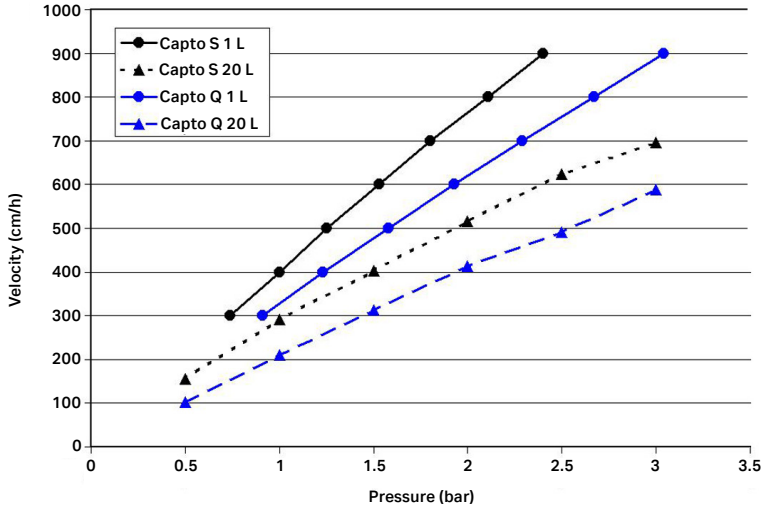
The below table summarizes the type of ion exchange for the specific resins.

Resin	Chemical functionality	Ion exchange
Capto S	Sulfonate	Strong cation exchanger
Capto DEAE	Diethylaminoethyl	Weak anion exchanger
Capto Q	Quaternary amine	Strong anion exchanger

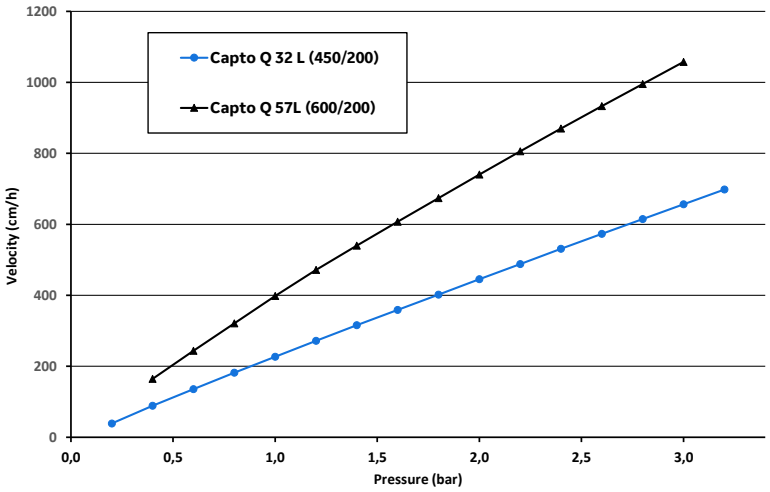
All of the resins have a surface extender for increased capacity and fast mass transfer, and are intended for capture and intermediate large-scale purification of proteins.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 3.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 700 cm/h results in a pressure drop of less than 3.0 bar when using a 20 L column (359/200) with aqueous solutions at room temperature. The actual flow velocity will depend on the resin and specific lot properties. The maximum pressure drop recommendation might be lower than the recommendation for the resin. This is to maintain the efficiency of the packed bed and minimize the risk of damaging it, since repacking is not possible. The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto S and Capto Q columns in operation with water at room temperature (20°C).



The following figure shows an example of a pressure-flow curve for a 57 L (600/200) ReadyToProcess Capto Q column in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Capto S, Capto DEAE, and Capto Q resins are summarized in the table below.

Characteristic	Capto S	Capto DEAE	Capto Q
Matrix	Highly cross-linked agarose with dextran surface extender		
Particle size, d_{50v} [1]	90 µm		
Ligand	Sulfonate, strong cation exchanger	Diethylaminoethyl, weak anion exchanger	Quaternary amine, strong anion exchanger
pH stability, operational [2]	4 to 12	2 to 9	2 to 12
Working temperature	4°C to 30°C	4°C to 40°C	4°C to 30°C
Storage temperature	4°C to 30°C		
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)		
Approximate flow velocity at maximum pressure drop [3]	700 cm/h		
Storage solution	20% ethanol, 0.2 M sodium acetate pH 5.5	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

6.2 Capto SP ImpRes and Capto Q ImpRes resins

Ion exchangers

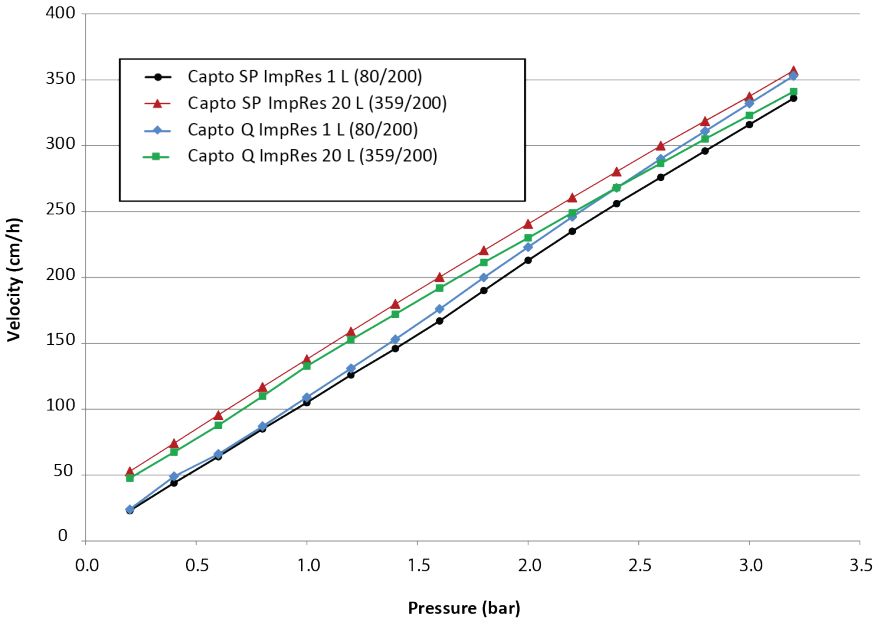
Capto SP ImpRes is a strong cation exchanger and Capto Q ImpRes is a strong anion exchanger. Both resins are designed for the high-throughput intermediate purification and polishing steps of a wide range of biomolecules. The resins are part of an expanded high-resolution platform based on the high-flow agarose Capto product line.

By combining the high-flow characteristics of Capto resin with a small particle size, Capto SP ImpRes and Capto Q ImpRes deliver excellent pressure-flow properties with impressive resolution. The ability to run at higher flow rates and higher bed heights also increases flexibility in process design.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity, the viscosity and temperature of the liquid. A maximum pressure drop of 3.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 300 cm/h results in a pressure drop of less than 3.0 bar when using a 2.5 L (126/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto SP ImpRes and Capto Q ImpRes columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Capto SP ImpRes and Capto Q ImpRes resins are summarized in the table below.

Characteristic	Capto SP ImpRes	Capto Q ImpRes
Matrix	High-flow agarose	
Particle size, d_{50v}[1]	40 µm	
Ligand	Sulfopropyl group, strong cation exchanger	Quaternary amine, strong anion exchanger
pH stability, operational[2]	4 to 12	2 to 12
Working temperature	4°C to 30°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.3 MPa (3.0 bar, 44 psi)	
Approximate flow velocity at maximum pressure drop[3]	300 cm/h	
Storage solution	20% ethanol, 0.2 M sodium acetate pH 5.5	20% ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

6.3 Capto S ImpAct resin

Ion exchanger

Capto S ImpAct is a strong cation exchange chromatography resin developed for intermediate purification and polishing of monoclonal antibodies (mAbs) and other biomolecules.

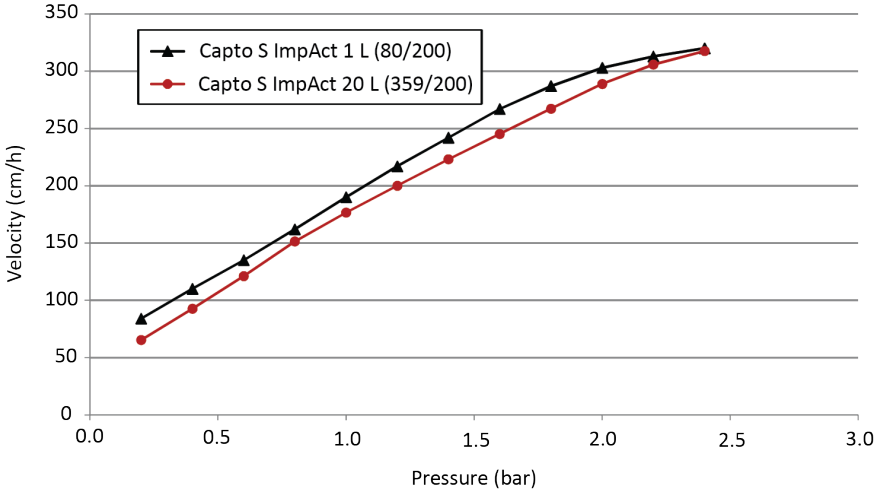
Capto S ImpAct is part of our platform of high-resolution resin based on the Capto product line. The polymeric ligand, in combination with the attributes of the base matrix, gives this cation exchanger a high binding capacity. Furthermore, the small bead size enables high-resolution purifications.

The high-flow characteristics of Capto resin allows for excellent pressure-flow properties. The exceptional binding capacity and resolution of Capto S ImpAct, combined with the ability to run at high flow rates and bed heights, increase productivity and flexibility in process design.

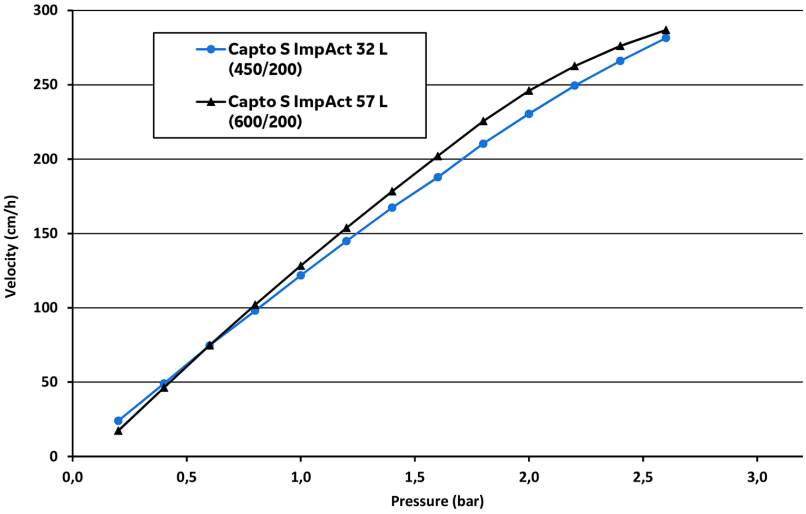
Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 2.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 220 cm/h results in a pressure drop of less than 2.0 bar when using a 2.5 L (126/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto S ImpAct columns in operation with water at room temperature (20°C).



The figure below shows examples of pressure-flow curves for 32 L (450/200) and 57 L (600/200) ReadyToProcess Capto S ImpAct columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Capto S ImpAct are summarized in the table below.

Characteristic	Capto S ImpAct
Matrix	High-flow agarose
Particle size, d_{50v}[1]	50 µm
Ligand	Sulfonate group, strong cation exchanger
pH stability, operational[2]	4 to 12
Working temperature	4°C to 30°C
Storage temperature	4°C to 30°C
Maximum pressure drop over packed bed	0.2 MPa (2.0 bar, 29 psi)
Approximate flow velocity at maximum pressure drop[3]	220 cm/h
Storage solution	20% ethanol, 0.2 M sodium acetate pH 5.5

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

6.4 Sepharose Fast Flow IEX resins

Ion exchangers

Sepharose Fast Flow (FF) IEX resins are available in five options: DEAE Sepharose FF, SP Sepharose FF, Q Sepharose FF, Q Sepharose XL, and CM Sepharose FF.

DEAE Sepharose FF is a weak anion exchanger, SP Sepharose FF is a strong cation exchanger, while Q Sepharose FF and Q Sepharose XL are strong anion exchangers.

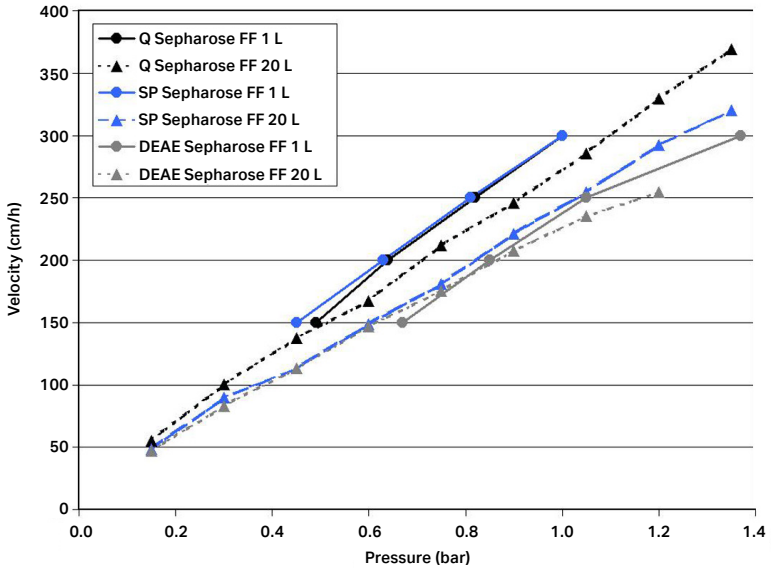
CM Sepharose FF is a weak cation exchanger used for preparative protein separations in both research and industrial applications.

Sepharose FF ion exchangers are suitable for initial purification of protein extracts, culture supernatants and other samples. Usually, conditions are chosen so that the components of interest bind to the ion exchanger while most contaminants pass through.

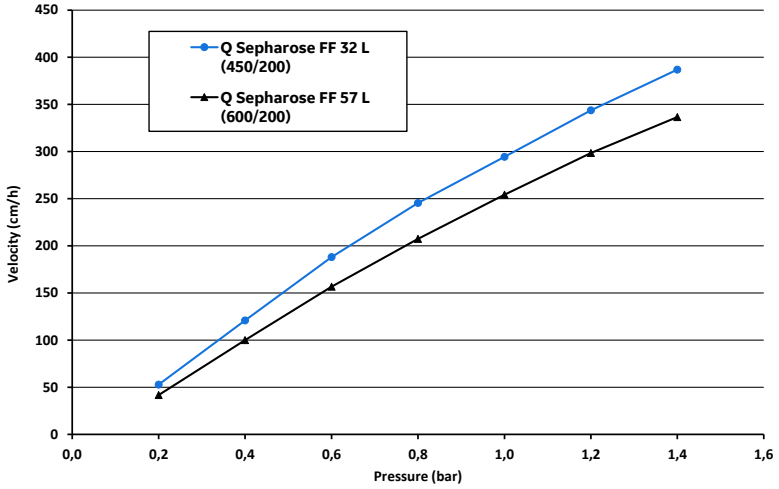
Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 1.2 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 250 cm/h results in a pressure drop of less than 1.2 bar when using a 20 L (359/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Sepharose Fast Flow IEX columns in operation with water at room temperature (20°C).



The following figure shows an example of pressure-flow curves for 32 L (450/200) and 57 L (600/200) ReadyToProcess Q Sepharose Fast Flow columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Sepharose Fast Flow IEX resins are summarized in the table below.

Characteristic	Q Sepharose XL	Q Sepharose Fast Flow	SP Sepharose Fast Flow	DEAE Sepharose Fast Flow	CM Sepharose Fast Flow
Matrix	Cross-linked 6% agarose with dextran extenders	Cross-linked 6% agarose			
Particle size, d_{50v}[1]	90 µm				
Ligand	Quaternary amine, strong anion exchanger		Sulfopropyl, strong cation exchanger	Diethylaminoethyl, weak anion exchanger	Carboxymethyl, weak cation exchanger
pH stability. operational[2]	2 to 12		4 to 13	2 to 9	3 to 13
Working temperature	4°C to 40°C				
Storage temperature	4°C to 30°C				
Maximum pressure drop over packed bed	0.12 MPa (1.2 bar, 17 psi)				
Approximate flow velocity at maximum pressure drop[3]	250 cm/h				
Storage solution	20% ethanol		20% ethanol containing 0.2 M sodium acetate, pH 5.5	20% ethanol	

[1] Median particle size of the cumulative volume distribution.

[2] pH range where resin can be operated without significant change in function.

[3] Run in water, at room temperature and at 200 mm bed height.

6.5 Sepharose High Performance IEX resins

Ion exchangers

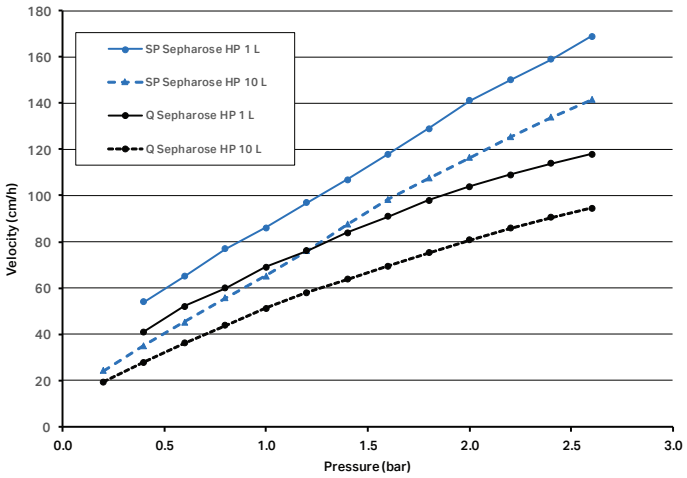
SP Sepharose High Performance is a strong cation exchange BioProcess resin and Q Sepharose High Performance is a strong anion exchange Bioprocess resin, both with high resolution designed for intermediate and polishing steps in downstream processing.

SP Sepharose High Performance and Q Sepharose High Performance are composed of cross-linked agarose beads with a mean diameter of 34 µm, modified with sulfopropyl (SP) strong cation exchange groups or quaternary amine (Q) strong anion exchange groups. They are designed for intermediate purification and polishing applications and to be used when resolution and capacity have priority. Both SP and Q Sepharose High Performance have high chemical stability and withstand effective CIP/sanitization protocols using sodium hydroxide.

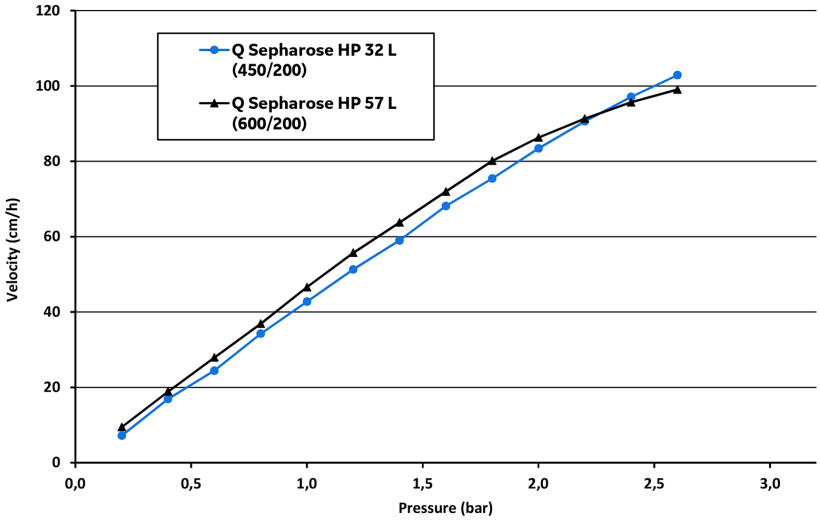
Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 2.4 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 90 cm/h results in a pressure drop of less than 2.4 bar when using a 2.5 L (126/200) column (not shown) with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 10 L (251/200) ReadyToProcess Sepharose High Performance (HP) IEX columns in operation with water at room temperature (20°C).



The following figure shows examples of pressure-flow curves for 32 L (450/200) and 57 L (600/200) ReadyToProcess Sepharose High Performance (HP) IEX columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of SP Sepharose HP and Q Sepharose HP resins are summarized in the table below.

Characteristic	SP Sepharose HP	Q Sepharose HP
Matrix	Cross-linked 6% agarose	
Particle size, d_{50v}[1]	34 µm	
Ligand	Sulfopropyl group, strong cation exchanger	Quaternary amine, strong anion exchanger
pH stability, operational[2]	4 to 13	2 to 12
Working temperature	4°C to 30°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.24 MPa (2.4 bar, 35 psi)	
Approximate flow velocity at maximum pressure drop[3]	90 cm/h	
Storage solution	20% ethanol, 0.2 M sodium acetate pH 5.5	20% ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

7 Multimodal chromatography resins

About this chapter

This chapter describes the multimodal chromatography resins that can be used with ReadyToProcess columns.

In this chapter

Section		See page
7.1	Capto adhere and Capto MMC resins	55
7.2	Capto adhere ImpRes and Capto MMC ImpRes resins	57
7.3	Capto Core 400 resin	59
7.4	Capto Core 700 resin	60

Introduction

The multimodal chromatography resins are IEX resins with multimodal functionality, that gives a different selectivity compared to traditional ion exchangers. Apart from ionic interactions, also hydrogen bonding and hydrophobic interactions are involved.

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

7.1 Capto adhere and Capto MMC resins

Ion exchangers

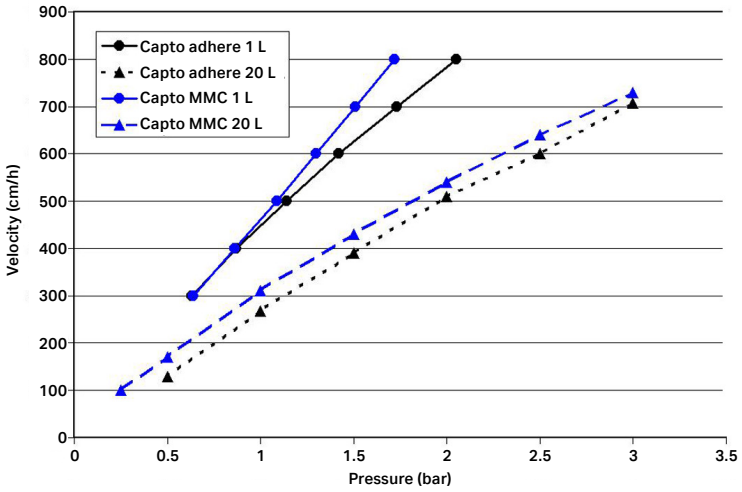
Capto adhere is a multimodal strong anion exchanger designed for post Protein A purification of monoclonal antibodies. Removal of leached Protein A, aggregates, host cell proteins, nucleic acids and viruses from monoclonal antibodies is performed in flow-through mode at which the antibodies pass directly through the column while the contaminants are adsorbed. For best performance of Capto adhere, screening and optimization of loading conditions are required.

Capto MMC is a multimodal weak cation exchanger that allows binding of proteins even at high ionic strength. This means that the resin can be used for direct load of clarified feedstocks, without prior dilution to reduce the conductivity of the starting material. The exceptional selectivity of Capto MMC can also be used to solve specific purification problems, at high or low ionic strength.

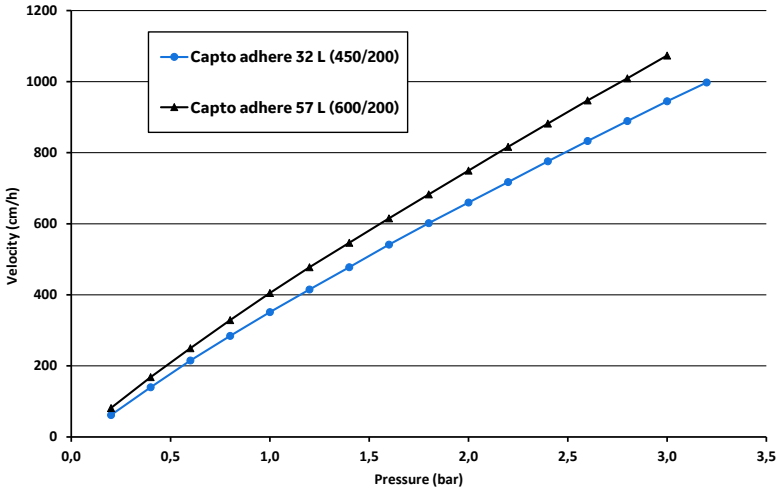
Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 3.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 600 cm/h results in a pressure drop of less than 3.0 bar when using a 20 L (359/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto adhere and Capto MMC columns in operation with water at room temperature (20°C).



The following figure shows examples of pressure-flow curves for 32 L (450/200) and 57 L (600/200) ReadyToProcess Capto adhere columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Capto adhere and Capto MMC resins are summarized in the table below.

Characteristic	Capto adhere	Capto MMC
Matrix	Highly cross-linked agarose	
Particle size, d_{50v}[1]	75 µm	
Ligand	N-benzyl-N-methylethanolamine, multimodal strong anion exchanger	N-benzoyl-homocysteine, multimodal weak cation exchanger
pH stability, operational[2]	3 to 12	
Working temperature	4°C to 30°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)	
Approximate flow velocity at maximum pressure drop[3]	600 cm/h	
Storage solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

7.2 Capto adhere ImpRes and Capto MMC ImpRes resins

Ion exchangers

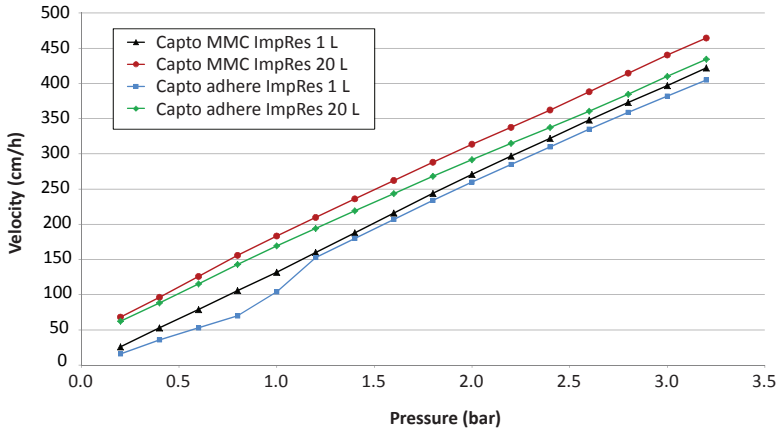
Capto adhere ImpRes is a strong anion exchange multimodal BioProcess chromatography resin, designed to allow effective monoclonal antibody polishing in the second or third step of a purification scheme downstream of the protein A capture step. Polishing can be performed in either bind and elute (binding) or flow-through (non-binding) modes.

Capto MMC ImpRes is a weak cation exchange multimodal BioProcess chromatography resin, designed to meet the demands of modern large-scale manufacturers, for high-resolution polishing of monoclonal antibodies and other biomolecules. The weak cation exchange multimodal ligand enables high selectivity in a broad pH/salt window compared with traditional ion exchangers, which allows the use of Capto MMC ImpRes in a variety of process conditions to solve challenging purification problems.

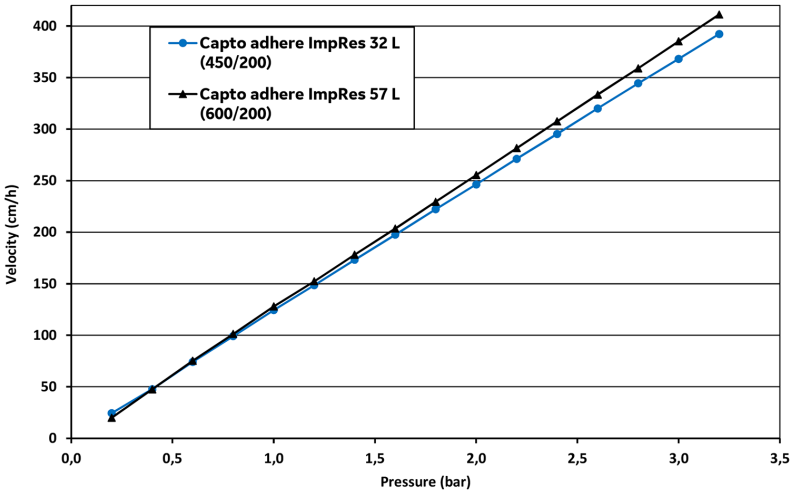
Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 3.0 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 300 cm/h results in a pressure drop of less than 3.0 bar when using the 2.5 L (126/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto adhere ImpRes and Capto MMC ImpRes columns in operation with water at room temperature (20°C).



The following figure shows examples of a pressure-flow curves for 32 L (359/200) and 57 L (600/200) ReadyToProcess Capto adhere ImpRes columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Capto adhere ImpRes and Capto MMC ImpRes resins are summarized in the table below.

Characteristic	Capto adhere ImpRes	Capto MMC ImpRes
Matrix	High-flow agarose	
Particle size, d_{50v}[1]	40 µm	
Ligand	Multimodal strong anion exchanger	Multimodal weak cation exchanger
pH stability, operational[2]	3 to 12	3 to 12
Working temperature	4°C to 30°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.3 MPa (3.0 bar, 44 psi)	
Approximate flow velocity at maximum pressure drop[3]	300 cm/h	
Storage solution	20% ethanol	20% ethanol, 0.2 M sodium acetate pH 5.5

[1] Media particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

7.3 Capto Core 400 resin

Introduction

Novel core bead technology and multimodal ligand give Capto Core 400 dual functionality, size exclusion and binding chromatography, in one chromatography resin. It significantly improves productivity enabled by up to 100-fold higher sample load and significantly higher flow rates compared with size exclusion chromatography. Capto Core 400 beads with a ligand-activated core and an inactive shell allows efficient capture of impurities, while target molecules are collected in the flowthrough.

The shell excludes large molecules (average cut-off: M_r ~ 400 000) from entering the core through the pores of the shell. These larger molecules are collected in the column flowthrough while smaller impurities bind to the internalized ligands. The multimodal ligand binds with most impurities over a wide range of pH and salt concentrations. Impurities are removed from the beads by cleaning-in-place (CIP) using NaOH and, in most cases, a solvent.

Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	Capto Core 400
Matrix	Highly cross-linked agarose
Particle size, d_{50v} [1]	90 µm
Ligand	Octylamine
pH stability, operational[2]	3 to13
pH stability, CIP[3]	3 to 14
Working temperature	4°C to 30°C
Storage temperature	4°C to 30°C
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)
Approximate flow velocity at maximum pressure drop[4]	600 cm/h
Storage solution	20% ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] pH range where resin can be subjected to cleaning- or sanitization-in-place without significant change in function.
[4] Run in water, at room temperature and at 200 mm bed height.

7.4 Capto Core 700 resin

Introduction

Novel core bead technology and a multimodal, octylamine ligand give Capto Core 700 both size exclusion and binding properties. The beads capture of contaminants efficiently, while target molecules are collected in the flowthrough. Capto Core 700 significantly improves productivity and at higher flow rates when compared with standard size exclusion (gel filtration) methods.

The resin has ligand-activated core and inactive shell. The shell excludes large molecules (average cut-off: M_r ~ 700 000) from entering the core through the pores of the shell. These larger molecules are collected in the column flowthrough while smaller impurities bind to the internalized ligands. The multimodal ligand binds with most impurities over a wide range of pH and salt concentrations. Impurities are removed from the beads by cleaning-in-place (CIP) using NaOH and in most cases, a solvent.

Characteristics

Some of the characteristics of the resin are summarized in the table below.

Characteristic	Capto Core 700
Matrix	Highly cross-linked agarose
Particle size, d_{50v}[1]	90 µm
Ligand	Octylamine
pH, operational[2]	3 to12
Working temperature	4°C to 30°C
Storage temperature	4°C to 30°C
Maximum pressure drop over packed bed	0.20 MPa (2.0 bar, 29 psi)
Approximate flow velocity at maximum pressure drop[3]	500 cm/h
Storage solution	20% ethanol

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

8 Hydrophobic Interaction Chromatography (HIC) resins

About this chapter

This chapter describes the Hydrophobic Interaction Chromatography (HIC) chromatography resins that can be used with ReadyToProcess columns.

In this chapter

Section		See page
8.1	Capto Phenyl (high sub), Capto Butyl, Capto Octyl, and Capto PlasmidSelect	62
8.2	Capto Phenyl ImpRes and Capto Butyl ImpRes	63
8.3	Phenyl Sepharose 6 Fast Flow (low sub) and Phenyl Sepharose 6 Fast Flow (high sub)	65
8.4	Phenyl Sepharose High Performance, Butyl Sepharose High Performance, and PlasmidSelect Xtra	67
8.5	Butyl Sepharose 4 Fast Flow and Octyl Sepharose 4 Fast Flow	69

Introduction

Several Hydrophobic Interaction Chromatography (HIC) resins are available for ReadyToProcess columns. The HIC resins can be divided into four groups based on the type of base matrix: Capto, Sepharose 6 Fast Flow (FF), Sepharose High Performance (HP), and Sepharose 4 Fast Flow (FF).

For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

8.1 Capto Phenyl (high sub), Capto Butyl, Capto Octyl, and Capto PlasmidSelect

Introduction

The resins Capto Phenyl (high sub), Capto Butyl and Capto Octyl are all designed for the intermediate stages of protein purification. All three resins combine high capacity, high flow rate, and low back pressure to reduce process cycle times.

These three resins are all based on the well-established Capto base matrix and with traditional HIC group ligands. Therefore they provide opportunities for improved productivity and straightforward process development.

Capto PlasmidSelect allows supercoiled covalently closed circular forms of plasmid DNA to be separated from open circular forms.

Capto PlasmidSelect is based on a rigid base matrix, delivering excellent pressure-flow properties to plasmid production.

Characteristics

Some of the characteristics of Capto Phenyl (high sub) and Capto Butyl HIC resins are summarized in the table below.

Characteristic	Capto Phenyl (high sub)	Capto Butyl	Capto Octyl	Capto PlasmidSelect
Matrix	Highly cross-linked agarose			
Particle size, d_{50v}[1]	75 µm			40 µm
Ligand	Phenyl	Butyl	Octyl	2-Mercaptopyridine
pH stability, operational[2]	3 to 13			
Working temperature	4°C to 40°C			
Storage temperature	4°C to 30°C			
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)			
Approximate flow velocity at maximum pressure drop[3]	600 cm/h			300 cm/h
Storage solution	20% ethanol			

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

8.2 Capto Phenyl ImpRes and Capto Butyl ImpRes

Introduction

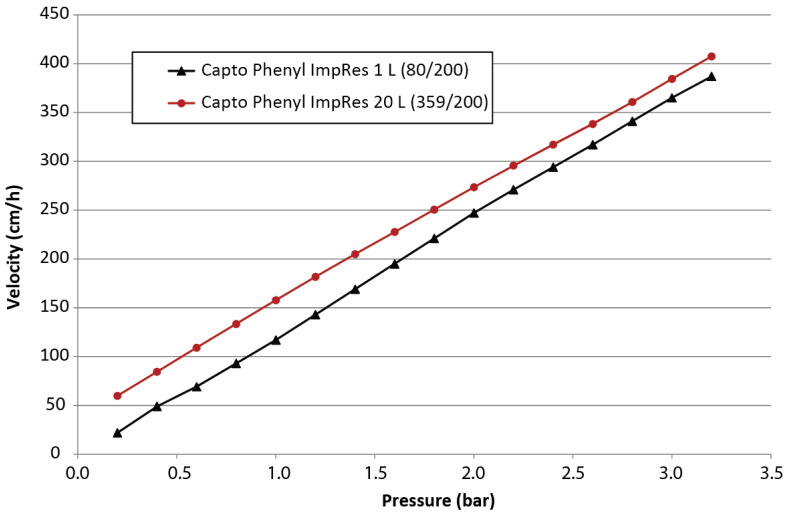
Capto Phenyl ImpRes and Capto Butyl ImpRes are BioProcess chromatography resins developed for large-scale purification of biopharmaceutical proteins. They are both HIC resin for the intermediate and polishing steps in a downstream purification process.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid.

The maximum pressure drop depends on the resin. For Capto ImpRes resins, it is 3.0 bar over the column. To ensure the integrity of the packed bed, this value must not be exceeded. Typically, a flow velocity of 300 cm/h results in a pressure drop of less than 3.0 bar when using the column with aqueous solutions at room temperature.

The figures below show examples of pressure-flow curves for 1 L (80/200) and 20 L (359/200) ReadyToProcess Capto Phenyl ImpRes resin columns in operation with water at room temperature (20°C).



For approximate data on pressure flow for different resins, see *Pressure-flow data, on page 99*.

Characteristics

Some of the characteristics of Capto ImpRes HIC resins are summarized in the table below.

Characteristics	Capto Phenyl ImpRes	Capto Butyl ImpRes
Matrix	Highly cross-linked agarose	
Particle size, d_{50v}[1]	~ 40 µm	
Ligand	Phenyl	Butyl
pH stability, operational[2]	3 to 13	
Working temperature	4°C to 40°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.30 MPa (3.0 bar, 44 psi)	
Approximate flow velocity at maximum pressure drop[3]	300 cm/h	
Storage Solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

8.3 Phenyl Sepharose 6 Fast Flow (low sub) and Phenyl Sepharose 6 Fast Flow (high sub)

Introduction

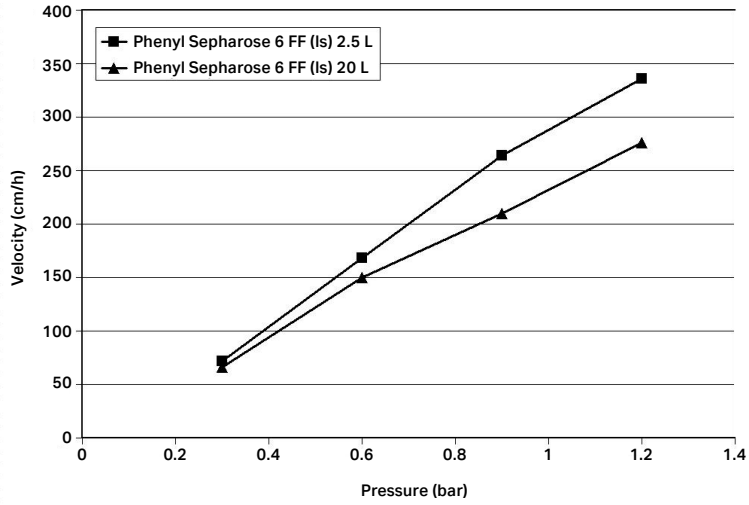
Sepharose 6 Fast Flow (FF) HIC resins are available in two options with different degree of ligand substitution: Phenyl Sepharose 6 Fast Flow (high sub) and Phenyl Sepharose 6 Fast Flow (low sub)

Sepharose 6 Fast Flow (FF) HIC resins are suitable for purification of protein extracts, culture supernatants and other samples. Usually, conditions are chosen so that the components of interest bind to the resin while most contaminants pass through.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. The maximum pressure drop depends on the resin, for Phenyl Sepharose 6 Fast Flow (low sub) and Phenyl Sepharose 6 Fast Flow (high sub) it is 1.2 bar. To ensure the integrity of the packed bed, this value must not be exceeded. Typically, a flow velocity of 250 cm/h results in a pressure drop of less than 1.2 bar when using the column with aqueous solutions at room temperature.

The figures below show examples of pressure-flow curves for 2.5 L (126/200) and 20 L (359/200) ReadyToProcess Phenyl Sepharose 6 Fast Flow (low sub) resin columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Sepharose 6 Fast Flow HIC resins are summarized in the table below.

Characteristics	Phenyl Sepharose 6 Fast Flow (low sub)	Phenyl Sepharose 6 Fast Flow (high sub)
Matrix	Cross-linked 6% agarose	
Average particle size, d_{50v}[1]	90 µm	
Ligand	Phenyl	
pH stability, operational[2]	3 to 13	
Working temperature	4°C to 40°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.12 MPa (1.2 bar, 17 psi)	
Approximate flow velocity at maximum pressure drop[3]	250 cm/h	
Storage solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

8.4 Phenyl Sepharose High Performance, Butyl Sepharose High Performance, and PlasmidSelect Xtra

Introduction

Phenyl Sepharose High Performance is an aromatic hydrophobic interaction chromatography (HIC) resin, and Butyl Sepharose High Performance is an aliphatic hydrophobic interaction chromatography (HIC) resin. Both resins are designed for intermediate and polishing step purification steps when high resolution is the priority.

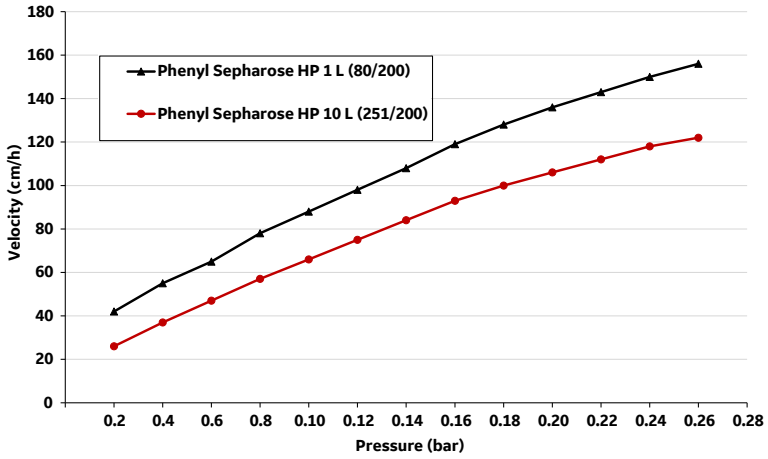
PlasmidSelect Xtra is a thiophilic aromatic adsorption chromatography resin with a selectivity that allows supercoiled covalently closed circular forms of plasmid DNA to be separated from open circular forms.

Note: *Sepharose High Performance is not available in ReadyToProcess columns with an inner diameter of 359 mm.*

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. The maximum pressure drop depends on the resin, for Sepharose High Performance it is 2.4 bar. To ensure the integrity of the packed bed this value must not be exceeded. Typically, a flow velocity of 90 cm/h results in a pressure drop of less than 2.4 bar when using the column with aqueous solutions at room temperature.

The figures below show examples of pressure-flow curves for 1 L (80/200) and 10 L (251/200) ReadyToProcess Phenyl Sepharose High Performance resin columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of Sepharose High Performance HIC resins are summarized in the table below.

Characteristic	Phenyl Sepharose High Performance	Butyl Sepharose High Performance	PlasmidSelect Xtra
Matrix	Cross-linked 6% agarose		
Particle size, d_{50v} [1]	34 µm		
Ligand	Phenyl	Butyl	2-Mercaptopyridine
pH stability, operational[2]	3 to 13		3 to 11
Working temperature	4°C to 40°C		
Storage temperature	4°C to 30°C		
Maximum pressure drop over packed bed	0.24 MPa (2.4 bar, 35 psi)		
Approximate flow velocity at maximum pressure drop[3]	90 cm/h		
Storage solution	20% ethanol		

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

8.5 Butyl Sepharose 4 Fast Flow and Octyl Sepharose 4 Fast Flow

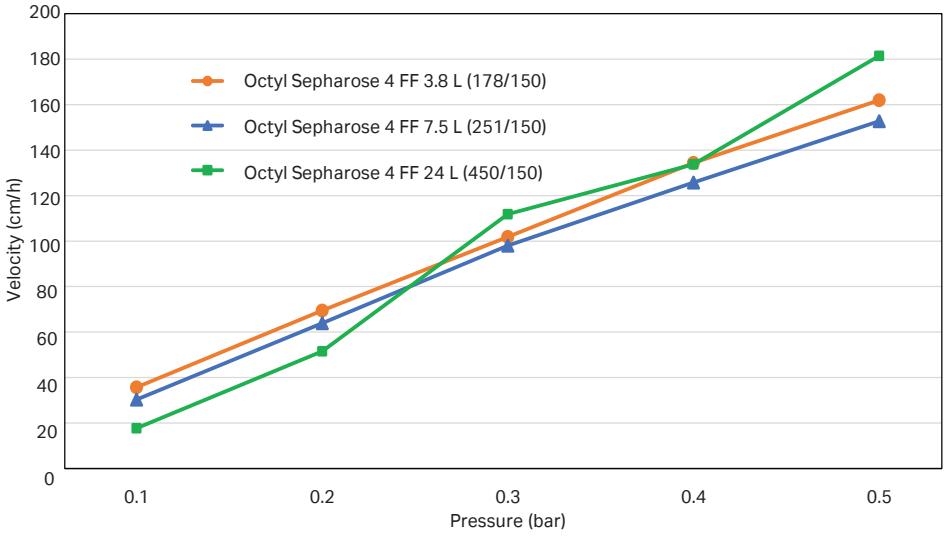
Introduction

This chapter presents Butyl Sepharose 4 Fast Flow and Octyl Sepharose 4 Fast Flow. For detailed information, refer to the applicable *Data files* or *Instructions* available on the Cytiva website.

Pressure drop

The pressure drop over the packed bed depends on the flow velocity applied, as well as the viscosity and temperature of the liquid. A maximum pressure drop of 0.5 bar over the column must not be exceeded in order to ensure integrity of the packed bed. Typically, a flow velocity of 80 cm/h results in a pressure drop of less than 0.5 bar when using a 20 L (359/200) column with aqueous solutions at room temperature.

The figure below shows examples of pressure-flow curves for 3.8 L (178/150), 7.5 L (251/150), and 24 L (450/150) ReadyToProcess Sepharose 4 Fast Flow (FF) columns in operation with water at room temperature (20°C).



Characteristics

Some of the characteristics of the resins are summarized in the table below.

Characteristic	Butyl Sepharose 4 Fast Flow	Octyl Sepharose 4 Fast Flow
Matrix	Cross-linked agarose, 4%, spherical	
Particle size, d_{50v} [1]	90 µm	
Ligand	Butyl	Octyl
pH stability, operational[2]	3 to 13	
Working temperature	4°C to 40°C	
Storage temperature	4°C to 30°C	
Maximum pressure drop over packed bed	0.05 MPa (0.5 bar, 7.2 psi)	
Approximate flow velocity at maximum pressure drop [3]	80 cm/h	
Storage solution	20% ethanol	

[1] Median particle size of the cumulative volume distribution.
[2] pH range where resin can be operated without significant change in function.
[3] Run in water, at room temperature and at 200 mm bed height.

9 Operation

About this chapter

This chapter provides the information required to operate ReadyToProcess column in a safe way.

In this chapter

Section		See page
9.1	Handling and lifting of 450 and 600 mm i.d. columns	73
9.2	Connecting the column to the system	74
9.3	Clearance of storage solution and equilibration of the column	77
9.4	Regeneration of the column between purification cycles	79
9.5	Disconnect the column for storage	80
9.6	Storage	82
9.7	Disconnect the column prior to disposal	86
9.8	Evaluation of the packed bed (optional)	87

Precautions



WARNING

Never exceed the column pressure specifications. To prevent rupture or injury, appropriate pressure safety monitoring equipment must be used, such as pressure alarms, pressure relief valves or rupture discs.



WARNING

Pressure may remain in the column and tubing for an extended period after shutdown. Make sure the column and tubing is depressurized before opening or disconnecting.



CAUTION

Do not exceed recommended maximum pressure drop over the packed bed to avoid damage to the bed. The maximum pressure drop varies with chromatography resin used.

9.1 Handling and lifting of 450 and 600 mm i.d. columns

Handles and castors

The larger columns have both handles and castors for handling and lifting. Castors facilitate moving the columns. If a castor loosens due to vibrations during handling or lifting it can be reassembled easily.

Lifting scenarios

The columns can be lifted from below or from above.



CAUTION

Heavy object. Appropriate transportation and lifting equipment (for example carts, pallet jacks, or telphers) must be used when handling larger columns. All lifting must be performed in accordance with local regulations.

To lift from below:

- Use a pallet jack or a forklift placed under the column or under the pallet with the column on it.

Note: *Make sure that the column does not slide off.*

To lift from above:

- Use a telpher with straps attached to the opposing column handles, see *Section 3.2 Illustration, on page 20*.

Note: *Do not apply force to the blue tie-rods.*

9.2 Connecting the column to the system

Introduction

All ReadyToProcess columns have heat-sealed sanitization tubes installed on the inlet and the outlet of the column.

Columns with an inner diameter of 80-359 mm have a reinforced inlet tube attached to the bottom lid of the column, and a short polypropylene outlet on top of the top lid.

450 and 600 mm i.d. ReadyToProcess columns have reinforced tubes on both inlet and outlet. They also have an additional storage tube connected to the outlet tube on top of the column to act as holder of extra storage solution during storage.

Note: *The extra storage tube is labeled and must be removed before connecting the column to a chromatography system.*

Note: *Save the storage tube and the tube support unit for future storage purposes.*

Compatible systems

ReadyToProcess columns can be used with ÄKTA ready, ÄKTA ready XL, or standard chromatography systems, such as ÄKTA process or ÄKTA pilot. For more information about matching chromatography systems with different sizes of columns, see *ReadyToProcess column platform, on page 15*.

Rupture disc

The use of a rupture disc as an extra safety precaution is recommended when using 600 mm i.d. ReadyToProcess columns. Make sure that the rupture vent is directed towards a safe area and not towards personnel. Install the rupture disc before connecting the column. If the column is run in upflow mode, install the rupture disc on the inlet tube. If downflow mode is used, install the rupture disc on the column outlet.

Use the following accessories for installation of a rupture disc on 600 mm i.d. ReadyToProcess columns: T-Junction, 1 inch, 3 × 50 mm TC (28938170) and Rupture Disc 4.2 bar, TC 50, i.d. 1 inch (29013998).

Note: *Set the maximum operating pressure alarm on the chromatography system to 3.8 bar over the column to prevent the disc from rupturing due to pressure spikes.*

Connecting to the ÄKTA ready

The ÄKTA ready wizard describes the steps to connect the column to the ÄKTA ready.

Note: *There are two different tubing kits available for use with ÄKTA ready. Columns with an inner diameter of 251 mm or more require a kit with an outlet tubing diameter of 9.5 mm. Columns with an inner diameter smaller than 251 mm require a kit with an outlet tubing diameter of 6.4 mm.*

Note: *Remove the storage tube before connecting the column to the ÄKTA ready system.*

Connect the column for running in upflow mode.

Connect to ÄKTA ready XL

Note: *Connect and run the column in upflow mode.*

Perform the following steps to connect ReadyToProcess column to an ÄKTA ready XL system:

Step	Action
1	Open the TC connection for the column bottom inlet tube. Remove the welded tubing end and save it for later use.
2	Spray or dip the TC connector in 70% ethanol and connect the column bottom inlet tube to the column bottom connection on the ÄKTA ready XL system. ***Note:*** *Air in the tubing does not cause problems since the column runs in upflow mode.*
3	Open the TC connection on the column top outlet tube. Remove the welded tubing end and save it for later use.
4	Remove the additional storage tube before connecting the column to the system. The storage tube is filled with storage solution. Empty the tube of the solution before storing the storage tube. ***Note:*** *Keep the storage tube and the tube support unit for future storage of the column. The storage tube is marked with a label to assist identification.*
5	Spray or dip the TC connector in 70% ethanol and connect the column top inlet tube to the column top connection on the ÄKTA ready XL system.
6	Place the column in ***OpenBottom*** position and start a flow of 100 L/h with the wash buffer.
7	Release the air trapped in the column bottom inlet tube though the column bottom connection on the ÄKTA ready XL system.
8	Put the column in ***Column Upflow*** mode.
9	Release the trapped air from the column top outlet tube through the column top connection on the ÄKTA ready. Increase the flow but do not exceed the pressure drop recommended for the media in the column.
10	Return the flow to 100 L/h and run the column in the ***OpenTop*** position.
11	Check that any remaining air has left the tubing.
12	End the manual run and continue to remove storage solution.

Connect to standard systems

Perform the following steps to connect the ReadyToProcess column to a standard system:

Step	Action
1	Before connecting the column, prime the system tubing with the running buffer by using the system pump.
2	Open the top TC connection of the column marked **Top Outlet** and remove the welded tubing end (save the welded tubing end, which will be used later to seal the column before disposal). ***Note:*** *The ReadyToProcess columns with an inner diameter of 450 mm have a tube connected to the top outlet. Use this tube to connect the column to the ÄKTA ready system.* ***Note:*** *A storage tube is connected to the ReadyToProcess columns with an inner diameter of 450 mm and 600 mm at delivery and during storage. Remove the storage tube before operation.* ***Note:*** *ReadyToProcess columns with an inner diameter of 600 mm are not suitable for standard systems. Consult the table in ReadyToProcess column platform, on page 15 for suitable systems.*
3	After spraying the TC connector with, or dipping it in, for example 70% ethanol, connect the system "column outlet tubing" to the column **Top outlet**. (At this stage, air in the tubing does not cause a problem since the column will be run in upflow mode later on).
4	Before connecting the column **Bottom Inlet,** start the pump at a low flow velocity (for example 50 cm/h) with the system valves set to "column inline" and "upflow" to make sure that the system tubing is fully primed and ready to be connected to the column **Bottom Inlet**.
5	Open the column TC connector marked **Bottom Inlet** and remove the welded tubing end (save also this welded tubing end to be used for sealing the column before disposal). If there is air in the **Bottom Inlet** tubing on the column, use a squirt bottle and fill the tubing for example with running buffer or 20% ethanol.
6	After spraying both the TC connectors with, or dipping them in, for example 70% ethanol, connect the system "column inlet tubing" to the column **Bottom Inlet**.
7	Turn off the pump or proceed to remove the storage solution.

9.3 Clearance of storage solution and equilibration of the column

Introduction

The procedure to clear the column from storage solution is described in the ÄKTA ready wizard.

A ReadyToProcess column is delivered packed with chromatography resin in a storage solution consisting of 20% ethanol and, for some columns, 20% ethanol containing 0.2 M sodium acetate, pH 5.5.

The column needs to be washed to clear it from the storage solution before starting the purification process.

Note: *Since they are less effective and consequently will be more expensive to use, buffers containing high concentrations of salt are not recommended for removal of storage solutions.*

Washing the column

We recommend washing the column with 6 column volumes (CV) running buffer (low salt containing buffers) or H_2O at a constant flow velocity of 100 cm/h. Make sure not to exceed the maximum working pressure of a resin. It is recommended to use 30 cm/h when clearing and/or equilibrating Sepharose High Performance columns and Sepharose 4 Fast Flow.

By following the washing procedure, the resin is cleared from storage solution. The wash can, in many cases, be performed with the desired running buffer (low salt containing buffers), to save time (equilibration of the column).

Note: *Sepharose High Performance and Sepharose 4 Fast Flow resins are pressure sensitive and therefore it is recommended that clearance of storage solutions and equilibration are performed at 30 cm/h.*

Note: *Capto DEAE in ReadyToProcess columns require additional column washes to clear out storage solution. It is recommended to use one of the following processes:*

- *The same number of column washes (CV) of equilibration buffer after CIP and/or SIP as recommended for equilibration of this resin.*
- *Wash until the column effluent shows stable conductivity and pH values before starting the purification process.*

Temperature adjustment

The wash also adjusts the temperature of the column to the running temperature (important, for example, for ReadyToProcess MabSelect SuRe columns, which are recommended to be stored at +2°C to +8°C).

Note: *It is not recommended to temperature-adjust the column only by moving it into a room temperature environment. Tests have shown that temperature adjustment of a 20 L (359/200) ReadyToProcess column by moving it into a room temperature environment can take several days.*

9.4 Regeneration of the column between purification cycles

Introduction

Regeneration is the removal of very tightly bound, precipitated or denatured substances from the purification process. If such contaminants are allowed to accumulate, they might affect the chromatographic properties of the column, reduce the capacity and, potentially, contaminate the product in subsequent runs. The number of cycles that can be run has to be investigated for each specific application and specific ReadyToProcess column.

If the fouling is severe it might block the column, increase the pressure drop over the column and as a consequence limit the applicable flow velocity.

Further details concerning regeneration of columns can be found in the Instructions for the different resins and the *Validation Guide* for ReadyToProcess columns available at *cytiva.com/rsf*.

9.5 Disconnect the column for storage

Precautions



WARNING

Thoroughly rinse the column before disconnecting it from a system to make sure that there no hazardous chemicals (for example halogen-containing salt buffers) in the column prior to disposal.



WARNING

Remove any NaOH residue from the surface of the column.

Disconnect the column

The steps below describe how to prepare the column for storage and how to disconnect it from the system.

Step	Action
1	Transfer the column over to storage solution by pumping 3 CV of storage solution through the column at a constant flow velocity of 100 cm/h or 30 cm/h. ***Note:*** *The storage solution is stated on the column label, for example 20% ethanol or 20% ethanol with 0.2 M sodium acetate, pH 5.5.* ***Note:*** *Do not exceed the maximum pressure drop of a resin. It is recommended to use 30 cm/h when equilibrating Sepharose High Performance and Sepharose 4 Fast Flow columns.*
2	Release any remaining pressure in the column by setting the system valves to "column inline" and opening a system outlet.
3	Disconnect the column from the system. **a.** For 80 to 359 mm i.d. columns: Seal the TC connectors using the welded tubing ends that were installed on the column at the delivery.

Step	Action
	b. For 450 and 600 mm i.d. columns: Reconnect the storage tube to the column using the tube support unit. Fill the tube with storage solution and seal the storage tube using the welded tubing ends that were installed on the storage tube at the delivery.
	Result:
	The column is now ready for storage. For more information regarding storage of the column, see *Section 9.6 Storage, on page 82*.

9.6 Storage

Precautions

NOTICE

Handle the column carefully to retain its performance.

Storage

Store the column according to the product label. The label shows the storage temperature and the storage solution. Store the column in a cool and dry place where it is not exposed to direct sunlight.

Columns with an inner diameter of 450 or 600 mm must be stored with the extra storage tube connected.

See below for instructions on how to reconnect the storage tube.

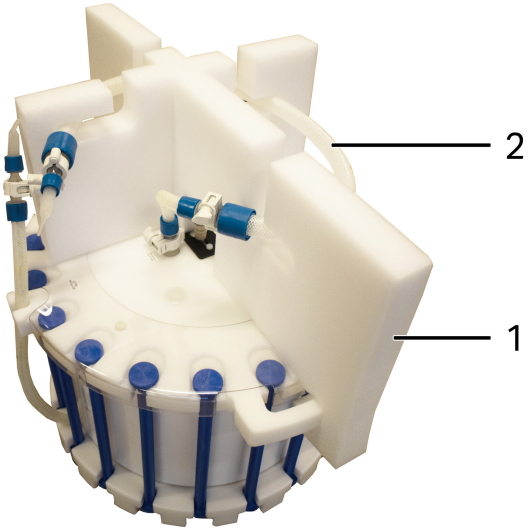
Storage tube

ReadyToProcess columns with an internal diameter of 450 and 600 mm are supplied with an extra storage tube fixated in a tube support unit. If the column is unpacked from the delivery crate, the tube support unit must be left on top of the column to secure the correct position of the storage tube.

The tube support unit and storage tube must be connected if the column is placed into long-term storage (more than 3 months). Connection of the tube support unit maintains the shelf-life of the column.

Illustration of storage tube support unit

The illustration below shows the column with the storage tube support unit installed.



Part	Function
1	Storage tube support unit
2	Storage tube

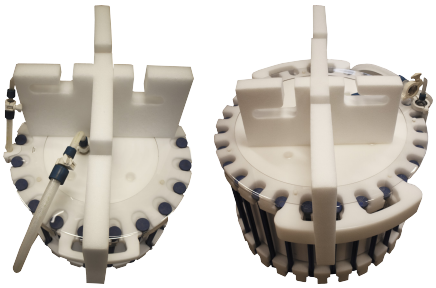
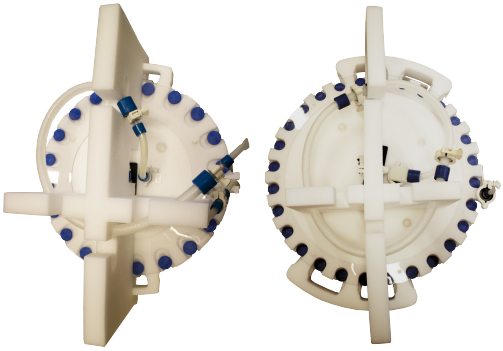
The purpose of this unit is to secure the outlet tube in such a way that the storage solution is striving to flow back towards the column top during long-term storage. If the column is to be placed without its packaging at the receiving site, leave the tube support unit on the column top to ensure shelf-life.

Note: *Retain the tube support unit for future use.*

Reinstall the storage tube and the tube support unit

Follow the below steps to reinstall the storage tube and the tube support unit to columns with an inner diameter of 450 and 600 mm.

Step	Action
1	**a.** Connect the storage tube to the outlet of the column and fill it with storage solution. For long-term storage we recommend 20% ethanol or 20% ethanol with 0.2 M sodium acetate, pH 5.5, when applicable. **b.** Seal the inlets and outlets with blind flanges to prevent evaporation.

Step	Action
2	**a.** Install the tube support unit that is delivered with the column. **b.** Place the tube support unit on top of the column lid. Place the unit across the center of the column and grip around the handles as shown in the illustration below. 
3	Bend the outlet tube (with the attached storage tube) slightly so that it can be placed into the tube support unit in an upward spiral. The goal is to secure the tube so that liquid flows down towards the column bed and air bubbles rise up and away from the column. 
4	Store the column with the storage tube installed according to the storage conditions indicated on the labels on the column. ***Note:*** *ReadyToProcess columns do not have any accessories. It is not possible to order only the support unit or the storage tube. If these parts are misplaced or discarded, make sure to secure the outlet tube in such a way that the storage solution within the tube strives back towards the column bed and not away from the outlet of the column. Make sure to inspect the column every 3 to 6 months. If the liquid level of storage solution is less than half the outlet tube, refill the tube.*

Storage solution

ReadyToProcess columns are supplied with 20%(v/v) ethanol as storage solution. (For some columns, the solution also contains 0.2 M sodium acetate, pH 5.5). Storage conditions are indicated on the labels on the column. This applies unless otherwise stated in the column documentation.

Before using the column

Before using the column, it must be equilibrated with a running buffer or equivalent as described in *Section 9.3 Clearance of storage solution and equilibration of the column, on page 77*. Columns stored in a cold room (for example ReadyToProcess MabSelect SuRe) will, at the same time as they are equilibrated to buffer, also be adjusted to the temperature of the buffer.

Storage after use

Use a solution that prevents microbial growth to store columns after use. For long-term storage we recommend 20%(v/v) ethanol or 20%(v/v) ethanol with 0.2 M sodium acetate, pH 5.5, when applicable. Seal the inlets and outlets with blind flanges to prevent evaporation.

Connect the storage tube and the tube support unit to the 450 and 600 mm i.d. columns for storage after use. For instructions on how to connect the storage tube and the tube support unit, see *Reinstall the storage tube and the tube support unit, on page 83*.

Columns can also be stored in 10 mM sodium hydroxide or 2%(w/w) benzyl alcohol for up to 12 months.



NOTICE

Do not store ReadyToProcess 450 and 600 columns in 10 mM sodium hydroxide or 2%(w/w) benzyl alcohol for more than 12 months at a maximum temperature of 24°C since the chemical resistance of the acrylic tube can change.

9.7 Disconnect the column prior to disposal

Precautions



WARNING

Thoroughly rinse the column before disconnecting it from a system to make sure that there no hazardous chemicals (for example halogen-containing salt buffers) in the column prior to disposal.



WARNING

Remove any NaOH residue from the surface of the column.

Disconnect the column

Follow the steps below to disconnect the column before disposal:

Step	Action
1	Using the system pump, empty the column of liquid by pumping air through it. Turn off the pump.
2	Use the system indicators to verify that all pressure is released.
3	Release any remaining pressure in the column by setting the system valves to "column inline" and opening a system outlet.
4	Disconnect the column from the system.
5	Seal the TC connectors using the welded tubing ends that were installed on the column at delivery. *Result:* The column is now ready for disposal.

Disposal

See *Section 11.5 Recycling information, on page 108* regarding disposal of the column.

9.8 Evaluation of the packed bed (optional)

Evaluation before delivery

The ReadyToProcess column has been efficiency tested with 20% ethanol as mobile phase at a flow velocity of 100 cm/h for all resins except Sepharose HP NS which has been tested at 30 cm/h at the production facility, using a system comparable with the ÄKTA ready system. Note that, apart from the system, test results also depend on factors such as flow velocity and type of mobile phase liquid used.

The stability of the packed ReadyToProcess column has been verified by transport testing. For more information, refer to the *Validation Guide* for ReadyToProcess columns available at *cytiva.com/rsf*.

Efficiency and A_s testing

A standard method of expressing the efficiency of a packed column is in terms of number of theoretical plates/meter (N/m), and the asymmetry factor, A_s. These values are easily determined by applying a tracer such as acetone (2% solution in 20% ethanol) to the column using 20% ethanol as eluent. The values are calculated as follows:

$N = 5.54 \times (V_R/w_h)^2$, assuming a Gaussian peak

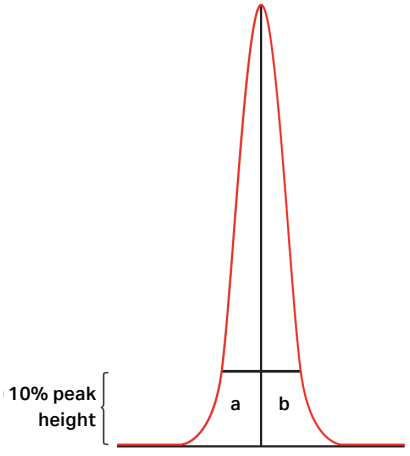
where

N = number of theoretical plates

V_R = peak retention (elution) volume or time

w_h = peak width at half height expressed in the same units as V_R

A typical test chromatogram showing asymmetry factor (A_s) value calculations is shown in the figure below.



Asymmetry factor As= b/a

where

a — is partial peak width, measured at 10% of the peak height for the leading part of the peak.

b — is partial peak width, measured at 10% of the peak height for the tailing part of the peak.

The calculated plate number varies depending on the test conditions and must therefore be used as a reference value only. Keep conditions and equipment constant so that results are comparable.

Changes in solute, solvent, eluent, sample volume, flow velocity (cm/h), liquid pathway, temperature, etc. influence the results. If an acceptance limit is defined in relation to column performance, the column plate number can be used as part of the acceptance criteria for column use.

More information

- For more information about efficiency testing, refer to the application note *Efficiency test of ReadyToProcess columns* available on the Cytiva website.

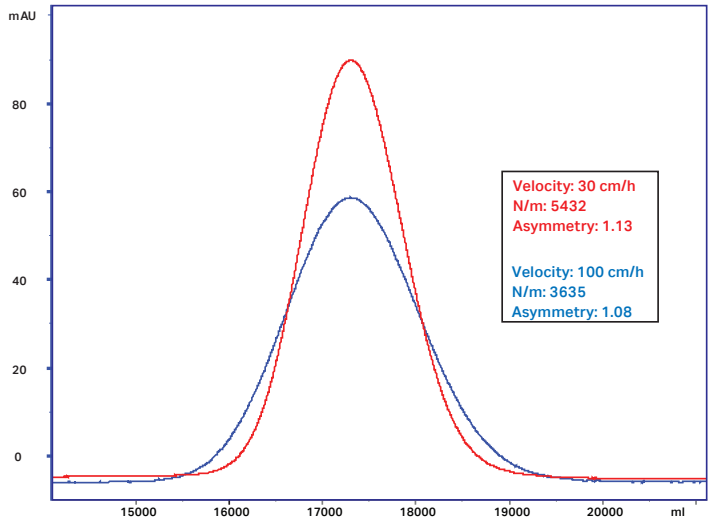
Efficiency-testing with a high flow velocity

Zone broadening in a chromatography column is related to hydrodynamic dispersion, molecular diffusion and mass transfer resistance. Because the extent of the hydrodynamic dispersion depends on column packing quality, a typical protocol for assessing the quality of column packing requires performing the quality test (efficiency test) at conditions where the contributions from mass transfer resistance and molecular diffusion can be minimized. These specific conditions depend on many factors including the type of mobile phase and tracer chosen for the efficiency test, the temperature at which the test is performed, and the type of chromatography resin, especially its particle size distribution.

Considering that Cytiva chromatography resins are manufactured to high quality standards and within a very tight technical specification, it can be expected that the contribution from intraparticle mass transfer resistance to the overall dispersion in the column is constant (and in effect scalable) for a given chromatography resin.

Similarly, the contribution related to molecular diffusion of the tracer is constant provided that specific test conditions, such as temperature, are constant. Therefore, the packing quality can be evaluated at conditions where mass transfer contribution is not optimized (that is, minimized). Consequently, performing efficiency tests at a higher velocity than the normally recommended range provides sufficient data to correctly assess column integrity if the other contributions to the overall dispersions are known.

The figure below shows efficiency tests of a ReadyToProcess 20 L (359/200) column at 30 and 100 cm/h flow velocity respectively, where N/m = theoretical plates per meter packed bed.



10 Troubleshooting

About this chapter

This chapter provides the information that users and service personnel need to identify and correct potential problems when operating ReadyToProcess columns.

If the suggested actions in this guide do not solve the problem, or if the problem is not covered by this guide, contact Cytiva for advice.

Column

Problem	Possible cause	Corrective action
Increased pressure drop and/or tailing peaks when running 450 or 600 mm i.d. columns	The 450 and 600 mm i.d. columns have sinter nets instead of mesh nets. This means that there is a higher risk of clogging since sinter nets have deeper pores than mesh nets.	Make sure to apply clean samples/feeds to the column. If a problem arises run alternate cycles of clean-in-place (CIP) protocols, initially in downflow but also upflow.
Air in the column	Air entered the column during installation or during the run.	Follow the steps in *Remove air from column bed, on page 91*.
High back pressure	The column is clogged during rerun.	• Perform regeneration of the column. • Filter the sample before applying it to the column.
Efficiency test results are not acceptable	Buffer and column do not have the same temperature.	Make sure that the column has the same temperature as the buffer and the ambient temperature where it is used. Perform the efficiency test again. For more information, see *Section 9.3 Clearance of storage solution and equilibration of the column, on page 77*.
Efficiency test result is not the same as on the certificate	The test is performed on a different instrument than the one used in production. Note that each test system and method used contributes to the test result and variance.	If the test result is within acceptance limits according to the certificate, the column is OK to use.

Note: *The storage tube must not be connected to the column during operation. If the storage tube is connected to the column during operation, it can negatively affect the efficiency test.*

Remove air from column bed

Follow the steps below to remove air from the column bed.

Step	Action
1	Install a fully opened flow restriction valve downstream on the column outlet.
2	Apply a low flow velocity (for example 30 cm/h) upflow through the column.
3	Restrict the flow through the outlet restrictor valve so that a back pressure of approximately 2 bar is applied over the column bed.
4	Run the column for 6 CV.
5	Evaluate the removal of the air by running an efficiency test on the column.

Note: *If air is still present, repeat the procedure above.*

11 Reference information

About this chapter

This chapter provides reference information regarding specifications, chemical resistance, wetted parts, flow conversions and ordering information.

In this chapter

Section		See page
11.1	Specifications	93
11.2	Flow conversion tables	100
11.3	Wetted parts	104
11.4	Chemical resistance	105
11.5	Recycling information	108
11.6	Regulatory information	109
11.7	Contact information	112
11.8	Ordering information	113

11.1 Specifications

General specifications

The table below shows general specifications of the 0.8 L to 3.1 L ReadyToProcess columns.

	0.8 L	1 L	1.3 L	1.9 L	2.5 L	3.1 L
Exact volume (L)	0.75	1.01	1.26	1.87	2.49	3.12
Inner diameter (mm)	80			126		
Inner cross section (cm^2)	50			124		
Packed bed height (mm)	150	200	250	150	200	250
Bed height tolerance (mm)	± 0.7					
Mechanical compression factor[1] (%)	≤ 15					
Outer height (mm)	419	469	519	432	482	532
Outer diameter incl. lid (mm)	155			210		
Packed column total weight (kg)	~ 3			~ 5	~ 6	~ 7
Inlet TC25 connector, tubing, i.d.	4.8 mm (3/16")					
Outlet TC25 connector, i.d. (mm)	4			6		
Ambient temperature[2] (°C)	4 to 30					
Liquid temperature[2] (°C)	4 to 40					
Shelf life[3] (months)	60					
Maximum liquid pressure[4]	0.40 MPa (4.0 bar, 58 psi)					

[1] The mechanical compression factor does not include flow compression, and varies depending on the resin and/or the size of the column.

[2] The temperature difference between the fluid running through the column and the ambient temperature in the room must never be greater than 20°C.

[3] A real-time study has been performed and data is presented within the *Validation Guide* for ReadyToProcess columns available at cytiva.com/rsf.

[4] For a packed column, restrictions regarding maximum pressure drop depend on the resin. The pressure drop between inlet and outlet of the ReadyToProcess column must never exceed the specified maximum pressure drop for the resin in the column.

The table below shows general specifications of the 3.7 L to 12.4 L ReadyToProcess columns.

	3.7 L	5 L	6.2 L	7.4 L	10 L	12.4 L
Exact volume (L)	3.73	4.98	6.22	7.42	9.90	12.37
Inner diameter (mm)	178			251		
Inner cross section (cm^2)	249			495		
Packed bed height (mm)	150	200	250	150	200	250
Bed height tolerance (mm)	± 0.9			± 0.7		
Mechanical compression factor[1] (%)	≤ 15					
Outer height (mm)	477	527	577	477	527	577
Outer diameter incl. lid (mm)	370			450		
Packed column total weight (kg)	~ 11	~ 13	~ 15	~ 20	~ 24	~ 27
Inlet TC25 connector, tubing i.d.	9.5 mm (3/8")					
Outlet TC25 connector, i.d. (mm)	7			10		
Ambient temperature[2] (°C)	4 to 30					
Liquid temperature[2] (°C)	4 to 40					
Shelf life[3] (months)	60					
Maximum liquid pressure[4]	0.40 MPa (4.0 bar, 58 psi)					

[1] The mechanical compression factor does not include flow compression, and varies depending on the resin and/or the size of the column.

[2] The temperature difference between the fluid running through the column and the ambient temperature in the room must never be greater than 20°C.

[3] A real-time study has been performed and data is presented within the *Validation Guide* for ReadyToProcess columns available at cytiva.com/rsf.

[4] For a packed column, restrictions regarding maximum pressure drop depend on the resin. The pressure drop between inlet and outlet of the ReadyToProcess column must never exceed the specified maximum pressure drop for the resin in the column.

The table below shows general specifications of the 15 L to 71 L ReadyToProcess columns.

	15 L	20 L	25 L	24 L	32 L	40 L	42 L	57 L	71 L
Exact volume (L)	15.18	20.24	25.31	23.32	31.81	39.76	42.41	56.55	70.69
Inner diameter (mm)	359			450			600		
Inner cross-section (cm^2)	1012			1590			2827		
Packed bed height (mm)	150	200	250	150	200	250	150	200	250
Bed height tolerance (mm)	± 1.0			± 2.7			± 2.4		
Mechanical compression factor[1] (%)	≤ 15								
Outer height (mm)	346	396	446	703.5[2]	753.5[2]	803.5[2]	798.5[2]	848.5[2]	898.5[2]
Outer diameter incl. lid (mm)	598			704			905		
Packed column total weight (kg)	~ 43	~ 49	~ 56	~ 97	~ 108	~ 119	~ 221	~ 236	~ 251
Inlet TC25 connector, tubing i.d.	12.7 mm (½")						N/A		
Inlet TC50 connector, tubing i.d.	N/A			N/A			19 mm (¾")		
Outlet TC25 connector, i.d. (mm)	12.0			11.4[3]			N/A		
Outlet TC50 connector, i.d. (mm)	N/A			N/A			17[4]		
Ambient temperature[5] (°C)	4 to 30								
Liquid temperature[5] (°C)	4 to 40			4 to 30					
Shelf life (months)	60[6]			48			36		
Maximum liquid pressure[7]	0.40 MPa (4.0 bar, 58 psi)								

1 The mechanical compression factor does not include flow compression, and varies depending on the resin and/or the size of the column.

2 This includes the storage tube support unit.

3 The i.d. noted here refers to the TC25 connector on the additional outlet tube. The TC25 outlet on the column itself has an inner diameter of 12.0 mm.

4 The i.d. noted here refers to the TC50 connector on the additional outlet tube. The TC50 outlet on the column itself has an inner diameter of 19 mm.

5 The temperature difference between the fluid running through the column and the ambient temperature in the room must never be greater than 20°C.

6 A real-time study has been performed and data is presented within the *Validation Guide* for ReadyToProcess columns available at cytiva.com/rsf.

7 For a packed column, restrictions regarding maximum pressure drop depend on the resin. The pressure drop between inlet and outlet of the ReadyToProcess column must never exceed the specified maximum pressure drop for the resin in the column.

Measurements of column packaging

The table below shows the external measurements of the column packaging. The same packaging is used for all bed heights between 150 mm and 250 mm for a certain inner diameter. The table below also shows the approximate weight for the three standard bed heights, 150, 200, and 250 mm. To convert inner diameter and bed height into volume, see *Prepacked columns, on page 16*.

	Column inner diameter (mm)						
	80	**126**	**178**	**251**	**359**	**450**	**600**
Length (mm)	300	300	500	570	730	930	1130
Width (mm)	300	300	500	570	730	870	1020
Height (mm)	584	584	625	745	750	1020	1100
Volume (L)	53	53	156	242	400	825	1268
Weight (kg) BH150[1]	4.1	6.2	24	29	60	146	292
Weight (kg) BH200[1]	4.4	6.8	25	31	65	156	311
Weight (kg) BH250[1]	4.7	7.4	26	34	70	166	329

[1] Weight of a package with specified column bed height (BH) (measurement in mm).

Storage solution and maximum operating pressure

The table below lists the storage solutions and the maximum allowed pressure drop over the packed bed. To prevent irreversible damage to the packed bed, the pressure drop over the column must not exceed these values regardless of column size.

Resin	Storage solution	Maximum pressure drop over packed bed		
		MPa	bar	psi
Affinity resins				
Blue Sepharose	20% EtOH + 0.2 M NaAc	0.12	1.2	17
Capto Blue	20% EtOH + 0.2 M NaAc	0.30	3.0	44
Capto L	20% EtOH	0.20	2.0	29
Chelating Sepharose	20% EtOH	0.12	1.2	17
KappaSelect	20% EtOH	0.30	3.0	44
LambdaFab Select	20% EtOH	0.30	3.0	44
MabSelect	20% EtOH	0.20	2.0	29
MabSelect PrismA	20% EtOH	0.20	2.0	29
MabSelect PrismA X	20% EtOH	0.20	2.0	29
MabSelect Sure	20% EtOH	0.20	2.0	29
MabSelect Sure LX	20% EtOH	0.20	2.0	29
MabSelect SuRe 70	20% EtOH	0.20	2.0	29
MabSelect VH3	20% EtOH	0.20	2.0	29
MabSelect mild elution	20% EtOH	0.20	2.0	29
MabSelect VL	20% EtOH	0.20	2.0	29
MabSelect Xtra	20% EtOH	0.20	2.0	29
Ion exchange resins				
Capto Q	20% EtOH	0.30	3.0	44
Capto Q ImpRes	20% EtOH	0.30	3.0	44
Capto S	20% EtOH + 0.2 M NaAc	0.30	3.0	44
Capto S ImpAct	20% EtOH + 0.2 M NaAc	0.20	2.0	29
Capto SP ImpRes	20% EtOH + 0.2 M NaAc	0.30	3.0	44
DEAE Sepharose FF	20% EtOH	0.12	1.2	17
Q Sepharose FF	20% EtOH	0.12	1.2	17
Q Sepharose HP	20% EtOH	0.24	2.4	35
Sepharose FF	20% EtOH	0.12	1.2	17
SP Sepharose FF	20% EtOH + 0.2 M NaAc	0.12	1.2	17
SP Sepharose HP	20% EtOH + 0.2 M NaAc	0.24	2.4	35

Resin	Storage solution	Maximum pressure drop over packed bed		
		MPa	bar	psi
Multimodal resins				
Capto adhere	20% EtOH	0.30	3.0	44
Capto adhere ImpRes	20% EtOH	0.30	3.0	44
Capto Core 400	20% EtOH	0.20	2.0	29
Capto Core 700	20% EtOH	0.20	2.0	29
Capto MMC	20% EtOH	0.30	3.0	44
Capto MMC ImpRes	20% EtOH + 0.2 M NaAc	0.30	3.0	44
Hydrophobic interaction resins				
Capto Butyl-S	20% EtOH	0.30	3.0	44
Capto Phenyl (high sub)	20% EtOH	0.30	3.0	44
Capto Phenyl ImpRes	20% EtOH	0.30	3.0	44
Phenyl Sepharose FF (high sub)	20% EtOH	0.12	1.2	17
Phenyl Sepharose FF (low sub)	20% EtOH	0.12	1.2	17
Phenyl Sepharose HP	20% EtOH	0.24	2.4	35

Pressure-flow data

The table below shows pressure-flow data for different resins and column sizes run at 200 cm/h with water. Sepharose HP NS resins are run at 100 cm/h. The data in the table is a guide. Always take precautions when running ReadyToProcess columns and check, for example, pressure limits and increase the flow velocity upwards in steps to prevent column damage due to high flow velocity values.

Resin	Flow velocity (cm/h)	Pressure (bar)			
		1 L (80/200)	20 L[1] (359/200)	32 L[1] (450/200)	57 L[1] (600/200)
Affinity resins					
MabSelect SuRe	200	0.5	0.6	0.6	0.6
MabSelect PrismA	200	0.7	-	-	-
Ion exchange resins					
Capto S	200	0.5	0.6	-	-
Capto Q	200	0.6	1.0	0.9	0.5
Capto SP ImpRes	200	1.6	1.6	-	-
Capto Q ImpRes	200	1.6	1.6	-	-
Capto S ImpAct	200	1.1	1.3	1.7	1.6
Q Sepharose Fast Flow	200	0.6	0.7	0.6	0.8
SP Sepharose Fast Flow	200	0.6	0.8	-	-
DEAE Sepharose Fast Flow	200	0.8	0.8	-	-
Q Sepharose HP	100	1.8	N/A	2.4	2.4
SP Sepharose HP	100	1.2	N/A	-	-
Multimodal resins					
Capto MMC	200	<0.5	0.6	-	-
Capto adhere	200	<0.5	0.8	0.6	0.5
Capto MMC ImpRes	200	1.5	1.2	-	-
Capto adhere ImpRes	200	1.5	1.3	1.6	1.6
Hydrophobic interaction resins					
Phenyl Sepharose Fast Flow	200	0.7	0.9	-	-
Phenyl Sepharose HP	100	1.3	N/A	-	-
Capto Phenyl ImpRes	200	1.6	1.4	-	-

[1] Not all pressure-flow data available at the time of print. More data added in future releases.

11.2 Flow conversion tables

The following tables show different measurements of flow and residence times for ReadyToProcess columns with an inner diameter of 80, 126, 178, 251, 359, 450, and 600 mm.

80 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	42	2.5	18	24	30
100	83	5.0	9	12	15
200	167	10.0	4.5	6	7.5
300	250	15.0	3.0	4	5.0
400	333	20.0	2.3	3	3.8
500	417	25.0	1.8	2.5	3.0

126 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	104	6.25	18	24	30
100	208	12.5	9	12	15
200	415	24.9	4.5	6	7.5
300	623	37.4	3.0	4	5.0
400	831	49.9	2.3	3	3.8
500	1038	62.3	1.8	2.5	3.0

178 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	208	12.5	18	24	30
100	417	25	9	12	15
200	833	50	4.5	6	7.5
300	1250	75	3.0	4	5.0
400	1667	100	2.3	3	3.8
500	2083	125	1.8	2.5	3.0

251 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	412	24.7	18	24	30
100	824	49.4	9	12	15
200	1649	98.9	4.5	6	7.5
300	2473	148.4	3.0	4	5.0
400	3297	197.8	2.3	3	3.8
500	4122	247.3	1.8	2.5	3.0

359 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	843	50.6	18	24	30
100	1686	101.2	9	12	15
200	3372	202.3	4.5	6	7.5
300	5059	303.5	3.0	4	5.0
400	6745	404.7	2.3	3	3.8
500	8431	505.9	1.8	2.5	3.0

450 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (mL/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	1333	80	18	24	30
100	2667	160	9	12	15
200	5333	320	4.5	6	7.5
300	8000	480	3.0	4	5.0
400	10 667	640	2.3	3	3.8
500	13 333	800	1.8	2.5	3.0

600 mm inner diameter columns

Flow velocity (cm/h)	Flow rate (L/min)	Flow rate (L/h)	Residence time (min)		
			BH 150 mm	BH 200 mm	BH 250 mm
50	2.4	143	18	24	30
100	4.8	285	9	12	15
200	9.5	570	4.5	6	7.5
300	14.3	855	3.0	4	5.0
400	19	1140	2.3	3	3.8
500	23.8	1425	1.8	2.5	3.0

11.3 Wetted parts

List of wetted materials

The table below lists the wetted materials used in ReadyToProcess columns. For information on material conformity, a list of the wetted parts, and schematic diagrams, refer to the *Validation Guide* for ReadyToProcess columns, available at cytiva.com/rsf.

Material	Column part
Polypropylene (PP)	(80–359 mm i.d columns): Column tube, connections, support nets, support screens, stream stoppers, lids, nets including molded net rings (450–600 mm i.d columns): Distributors, bottom inlet, top outlet, connections
Acrylic (PMMA)	Column tube for 450–600 mm i.d columns
Polyetheretherketone (PEEK)	Net holders, connectors and nozzle tube, (80–359 mm i.d columns) plug at inlet
Polyolefin (PO)	Hose (inlet tubing), outlet tubing, and storage tube on 450–600 mm i.d columns
Silicone	Welded tubing for inlet/outlet protection
Fluorocarbon rubber (FPM)	O-rings (80–600 mm i.d columns)
Ethylenepropylene-diene (EPDM)	TC gaskets and O-rings on 450–600 mm i.d columns The EPDM O-ring on 600 i.d. columns is parylene-coated.
Ultra High Molecular Weight Polyethylene (UHMWPE)	Snap ring 450 and snap ring 600, sinter mesh, 10 µm (450–600 mm i.d columns)
Polyethylene (PE)	Sinter mesh, 20 µm (450–600 mm i.d columns)

11.4 Chemical resistance

Chemical resistance external surfaces

The table below shows the chemical resistance of the external surfaces of 80 mm to 359 mm i.d. ReadyToProcess columns with exposure times up to 24 hours.

Chemical resistance of 80 mm to 359 mm i.d. columns	Concentration
Ethanol	70%(v/v)
2-propanol	70%(v/v)
Acetone	2%(v/v)

The table below shows the chemical resistance of the external surfaces of 450 mm and 600 mm i.d. columns with exposure times up to 24 hours.

Note: *450 mm and 600 mm i.d. ReadyToProcess columns have acrylic column tubes with lower chemical resistance than the polypropylene tubes used on the smaller columns.*

Chemical resistance of 450 and 600 mm i.d. columns	Concentration
Ethanol[1]	20%(v/v)
2-propanol[2]	30%(v/v)
Acetone	2%(v/v)

[1] Ethanol (maximum 20%(v/v)) is compatible with the acrylic tube material in 450 mm and 600 mm i.d. columns at < 30°C.
[2] 2-propanol (maximum 30%(v/v)) is compatible with the acrylic tube material in 450 mm and 600 mm i.d. columns at < 30°C.

Chemical resistance wetted parts

The table below shows the chemical resistance of the wetted parts of empty ReadyToProcess columns[1].

Chemical	Concentration[1]
Acetone	2%(v/v)
Acetic acid	1 M
Aqueous buffers, pH 2–12	< 0.3 M
Arginine	2 M

Chemical	Concentration[1]
Ammonium sulfate	4 M
Benzyl alcohol (long-term exposure)[2]	2%(w/w)
DTE/DTT (dithioerythritol/dithiothreitol)	100 mM
EDTA (ethylenediaminetetraacetic acid)	100 mM
Ethanol (longtime exposure)[3]	20%(v/v)
Ethylene glycol	50%(v/v)
Formaldehyde	0.1%
Glycerol	10%(v/v)
Glycine	2 M
Guanidine hydrochloride	6 M
Imidazole	1 M
Mercaptoethanol	20 mM
Phosphoric acid	0.1 M
Pluronic F-68	1%(v/v)
Polyethylene glycol, PEG 500	5%(v/v)
Polyethylene glycol, PEG 1000	1%(v/v)
Polyethylene glycol, PEG 5000	1%(v/v)
Potassium phosphate	1 M
1-propanol	5%(v/v)
2-propanol[4]	30%(v/v)
SDS	1%(w/v)
Sodium acetate	1 M
Sodium chloride	4 M
Sodium citrate	1 M
Sodium sulfate	1 M
Sodium hydroxide	1 M
Sodium hydroxide (long-term exposure)[5]	10 mM
Sorbitol	1 M
Sucrose	1 M

Chemical	Concentration[1]
Tween 20	1%(v/v)
Tween 80	1%(v/v)
Urea	8 M

[1] The column is intended to be used for a limited number of purification cycles, typically 5–10.
[2] Benzyl alcohol (maximum 2%(w/w)) is compatible with the acrylic tube material in 450 and 600 mm i.d. columns at < 24°C for up to 1 year. Take care when preparing solutions for both accuracy and allowing sufficient time for the benzyl alcohol to fully dissolve. Concentrations in excess of 2.2%(w/w) or at higher temperature will damage the acrylic.
[3] Ethanol (maximum 20%(v/v)) is compatible with the acrylic tube material in 450 and 600 mm i.d. columns at temperature < 30°C for long-term exposure.
[4] 2-propanol (maximum 30%(v/v)) is compatible with the acrylic tube material in 450 and 600 mm i.d. columns at temperature < 30°C.
[5] Long-term storage for 12 months in 10 mM sodium hydroxide < 30 is compatible with all available column sizes.

11.5 Recycling information

Introduction

This section contains information about the decommissioning of ReadyToProcess columns.

Disposal of the column

Make sure to always follow national and local regulations for handling and disposal. The columns are designed to be disposed of intact as combustible material.

Decontamination

The ReadyToProcess column must be decontaminated before decommissioning and all local regulations must be followed with regard to scrapping of the equipment.

11.6 Regulatory information

In this section

Section		See page
11.6.1	Regulatory product documentation	110
11.6.2	Materials	111

11.6.1 Regulatory product documentation

The columns are validated for performance criteria, stability, and sanitization design. They also use materials classified according to current regulatory guidelines specified on the materials. The documentation is divided into three parts:

- **Product documentation**: Product documentation is found in the online user manual. *Certificates of Analysis* showing packing performance as well as endotoxin and microbiology test results are available at *cytiva.com/certificates*.
- **Validation Guide**: The *Validation Guide* for ReadyToProcess columns contains product information, including stability and quality, a wetted parts list, as well as a brief description of the preparation. The *Validation Guide* is available at *cytiva.com/rsf*.
- **Regulatory Support File (RSF)**: *RSFs* for BioProcess chromatography resins are available at *cytiva.com/rsf*.

11.6.2 Materials

The polymeric materials used to manufacture ReadyToProcess columns are chosen for their biological and chemical compatibility with the samples, buffers, and solutions used during operation and during sanitization procedures. The materials for all wetted parts are selected to meet industry best practices for pharmaceutical and biopharmaceutical process equipment including bioreactivity compliance and animal origin information. The columns are designed to comply with hygienic requirements. For a list of the wetted parts, refer to the *Validation Guide* for ReadyToProcess columns available at *cytiva.com/rsf*.

11.7 Contact information

Contact information for support

To find local contact information for support and to send troubleshooting reports, visit *cytiva.com/contact*.

Legal manufacturer information

The table below summarizes the information about the legal manufacturer.

Contact information	Legal manufacturer
Name and address	Cytiva Sweden AB Björkgatan 30 SE 751 84 Uppsala Sweden
Telephone number	+ 46 771 400 600

11.8 Ordering information

ReadyToProcess columns

Standard ReadyToProcess columns are manufactured upon order. For standard columns, visit *cytiva.com*. Additional custom combinations of columns and resins are available upon request.

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