ReadyToProcess™ columns

PREPACKED CHROMATOGRAPHY COLUMNS

ReadyToProcess™ chromatography columns are validated high-performance bioprocessing columns that are supplied prepacked and ready for use. The columns are available with a range of BioProcess™ resins in different sizes (Fig 1). Standardized column formats allow short delivery lead times. ReadyToProcess columns are closed units and the design allows easy disposal after completed production, enabling flexibility in operations.

Reliable supply, predictable performance:

- Standardized column formats allow reduced column cost and short delivery lead times
- Robust column design and validated automated packing methods enable consistent column performance
- Cost-savings by eliminating the need for column preparation, packing, and validation procedures
- Customer safety stock possibility for security of supply

Security of supply

ReadyToProcess columns are covered by an extensive security of supply program for chromatography resins. As a supplier of both chromatography resins and prepacked columns, we take responsibility for the complete supply chain, from chromatography resin production to the final prepacked ReadyToProcess columns. Delivery lead times are shortened with efficient planning between bulk resin production and prepacked column production. We also work with supply chain sustainability for ReadyToProcess columns, which includes inventory management of empty column parts to minimize supply interruptions. We support the technical aspects of both resin and prepacked column as well as share expertise in various applications throughout the purification process. A business continuity plan is in place for the ReadyToProcess column production, which is located in Uppsala, Sweden, and the production site is ISO certified for business continuity. Our business continuity plan follows international standards and is complemented with a strategic reserve of chromatography resins to mitigate supply chain risks.

Fig 1. ReadyToProcess columns are easily connected to a chromatography system and can be disposed after completed production.

Standardized column format

Standardization of the ReadyToProcess column format means that each column is validated against its defined specifications. A validated column design and robust packing methods enable production with high lot-to-lot consistency.

Prepacked columns offer speed and flexibility

ReadyToProcess columns make several steps such as column preparation, packing, and qualification redundant, and significant time savings can be achieved in downstream processing.

Disposable ReadyToProcess columns offer the possibility of working in a flexible mode in early clinical phases to medium manufacturing scale (processing of up to 2000 L bioreactor harvests), while keeping a conventional column option for larger-scale manufacturing open. The chromatography resins used in ReadyToProcess columns have a long track-record of use in full-scale manufacturing including conventional, large-scale chromatography, where columns can be used for tens or hundreds of cycles. The transition from the ReadyToProcess format to full-scale manufacturing, 80 to 600 mm i.d., is therefore straightforward.

Available in sizes from 80 to 600 mm i.d., ReadyToProcess columns are well-suited for use with the single-use Xcellerex™ bioreactor systems with working volumes ranging from 10 to 2000 L, for design of a disposable process from upstream to downstream (Fig 2).

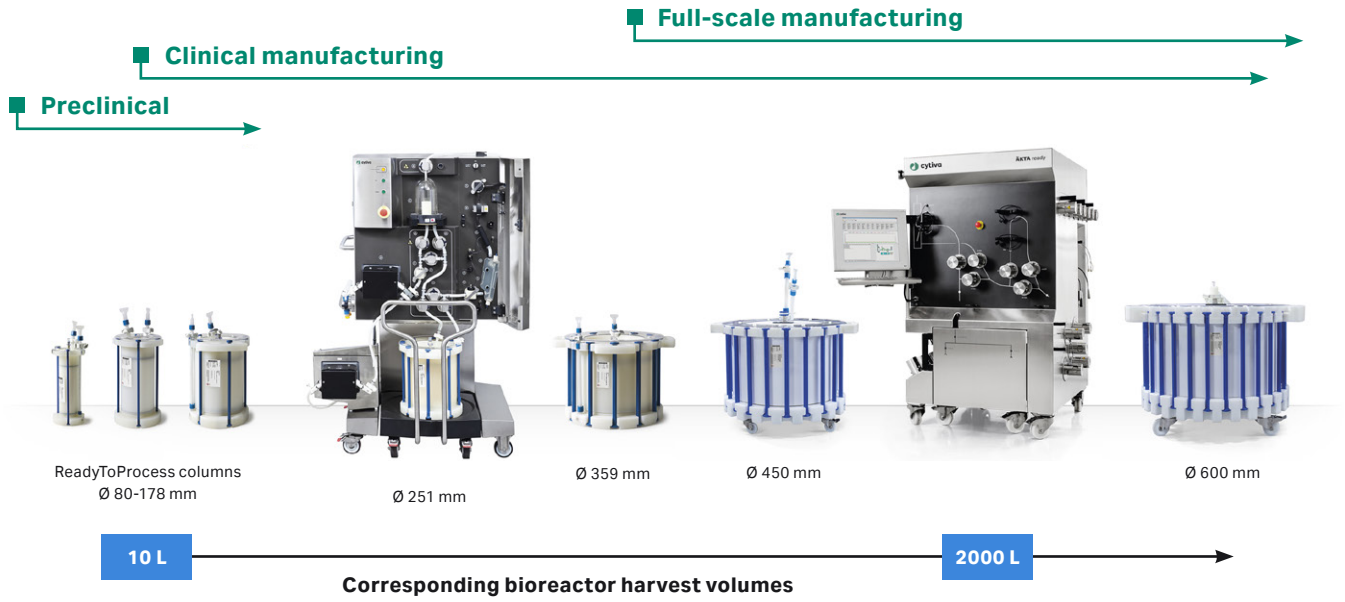


Fig 2. ReadyToProcess columns can be used with ÄKTA ready™ and ÄKTA ready XL chromatography systems. Consistency in column geometry allows for convenient scaling of ReadyToProcess columns from 80 to 600 mm i.d.

Many BioProcess resins are available in the ReadyToProcess format, such as MabSelect PrismA™, Capto™ S ImpAct, and Capto Q resins. The full offering is listed in the product list CY1797. Additional chromatography resins can be available in the ReadyToProcess column format upon request.

ReadyToProcess columns are available with bed heights of 150, 200, and 250 mm as standard for short delivery time. Other bed heights can be available through our customized offerings. Please contact your local sales representative for more information.

ReadyToProcess column characteristics

ReadyToProcess columns are packed using a pack-in-place method that combines the benefits of the packing methods for the AxiChrom™ and Chromaflow™ columns. The packing process is developed and optimized for each chromatography resin and is controlled through a specific packing system that automatically controls the pressure specific for the particular resin. For packing, the resin is supplied to the column through a packing valve. Packing is followed by mechanical compression of the resin.

ReadyToProcess columns have fixed bed heights, enabling optimization of contact time, flow rates, and capacity of modern chromatography resins. ReadyToProcess columns are designed for low hold-up volume when operated in up-flow mode but can be operated in down-flow mode if desired (Fig 3). Pressure/flow curves for operation with water at room temperature (20°C) are shown in Figure 4 for ReadyToProcess Capto adhere, MabSelect SuRe™, Phenyl Sepharose™ 6 FF, Capto S ImpAct, Capto MMC ImpRes, SP Sepharose HP, Capto Q, Q Sepharose FF columns, and MabSelect PrismA resins. Additional pressure/flow curves are found in the *ReadyToProcess column User Manual* (28925644)

The polymeric materials used for manufacturing of ReadyToProcess columns have been chosen for their biological and chemical compatibility with the samples, buffers, and solutions used during operation and sanitization procedures. Extractable studies and risk assessment have been performed (see details under *Column validation*). The materials are selected to meet industry best practices for pharmaceutical and biopharmaceutical process equipment including bioreactivity compliance. The materials are animal-derived component-free or have been produced under manufacturing conditions complying with EMEA/410/01. The columns are designed to comply with hygienic requirements. Materials used in wetted column parts are listed in Table 1.

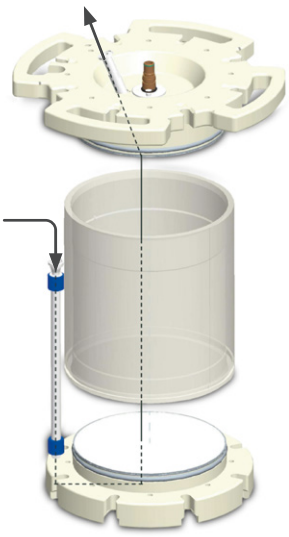


Fig 3. ReadyToProcess column with assembled parts. Arrows show flow direction.

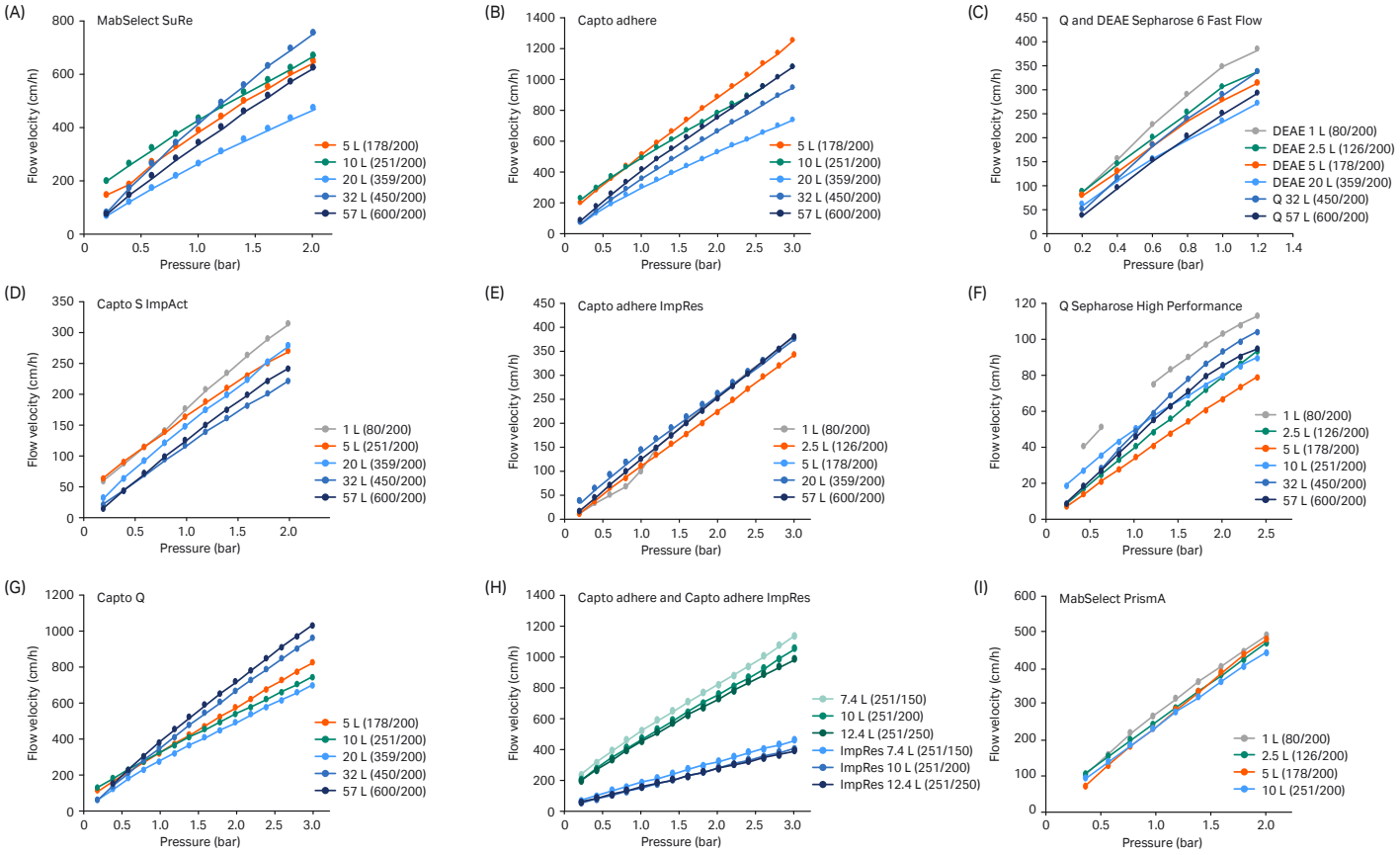


Fig 4. Examples of pressure/flow curves for ReadyToProcess columns prepacked with (A) MabSelect SuRe, (B) Capto adhere, (C) Q and DEAE Sepharose 6 Fast Flow, (D) Capto S ImpAct, (E) Capto adhere ImpRes, (F) Q Sepharose High Performance, (G) Capto Q, (H) Capto adhere and Capto adhere ImpRes, and (I) MabSelect PrismA

Table 1. Materials used in wetted parts of ReadyToProcess columns (see *User manual* 28925644 for details)

Material	Column part
Polypropylene (PP)	
All columns:	Column tube *
80–359 i.d. columns:	Lids, Nets, Support nets, Support screens, Stream stoppers
450–600 i.d. columns:	Distributors, Bottom Inlet, Top outlet
Acrylic (PMMA)	
450–600 i.d. columns:	Column tube
Polyetheretherketone (PEEK)	
All columns:	Net holders, Nozzle tube
80–359 i.d. columns:	Plug at inlet tubing
Polyolefin (PO)	
All columns:	Hose
TPE (thermoplastic elastomer)	
All columns:	Welded tubing for inlet/outlet protection
Fluorocarbon rubber (FPM)	
All columns:	O-rings
Ethylenepropylenediene (EPDM)	
All columns:	TC-gaskets
450–600 i.d. columns:	O-rings, O-rings to 600 i.d. column are parylene coated
Ultra-high molecular weight polyethylene (UHMWPE)	
450–600 i.d. columns:	Snap ring, Sinter mesh, 10 µm
Polyethylene (PE)	
450–600 i.d. columns:	Sinter mesh, 20 µm

* For the 80 to 359 i.d. columns, the inner, wetted surface of the column tube is PP

The most important characteristics of the ReadyToProcess columns are listed in Table 2. On delivery, ReadyToProcess columns are ready for immediate use. The columns are packed in cleanroom environment (class ISO 8) using validated packing protocols. As a part of the production procedure, each individual ReadyToProcess column is qualified by efficiency testing towards its validated specifications, that is, by analysis of number of theoretical plates per meter packed bed (N/m) and asymmetry factor (A_s). Acceptance limits have been established for efficiency testing at a flow velocity of 100 cm/h (except for Sepharose High Performance, which is tested at 30 cm/h) and the analytic results are specified in the Certificate of Analysis (CoA) accompanying each column. After qualification, the columns are sanitized where applicable (some chromatography resins are not compatible with the sanitization solution) and equilibrated with storage solutions. Every column delivery is accompanied with a reference side sample of the same resin lot as packed in the column (approximately 50 mL sedimented resin).

For the 600 mm i.d. columns, up to three resin lots per column can be combined to reach sufficient volumes to meet production lead times. The sample provided comprises the combined lots, and the CoA will include the lots' volumetric ratio and lot numbers.

Table 2. Characteristics of ReadyToProcess columns

	0.8 L	1 L	1.3 L	1.9 L	2.5 L	3.1 L	3.7 L	5 L	6.2 L	7.4 L	10 L	12.4 L	15 L	20 L	24 L**	25 L	32 L	40 L**	42 L**	57 L	71 L**
Column volume (L)	0.75	1.01	1.26	1.87	2.49	3.12	3.73	4.98	6.22	7.42	9.90	12.37	15.18	20.24	23.32	25.31	31.81	39.75	42.41	56.55	70.69
Inner diameter (mm)	80	80	80	126	126	126	178	178	178	251	251	251	359	359	450	359	450	450	600	600	600
Inner cross section (cm^2)	50	50	50	124	124	124	249	249	249	495	495	495	1012	1012	1590	1012	1590	1590	2827	2627	2827
Packed bed height (mm)	150	200	250	150	200	250	150	200	250	150	200	250	150	200	150	250	200	250	150	200	250
Net size (µm)*	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	14/25	10/20	14/25	10/20	10/20	10/20	10/20	10/20
Outer height (mm)	419	469	519	432	482	532	477	527	577	477	527	577	477	527	750†	577	629†	830†	740†	790†	840†
Outer diameter incl. lid (mm)	155	155	155	210	210	210	370	370	370	450	450	450	598	598	704	598	704	704	905	905	905
Packed column weight (kg)	~ 3	~ 3	~ 3	~ 5	~ 6	~ 7	~ 11	~ 13	~ 15	~ 20	~ 24	~ 27	~ 43	~ 49	~ 97	~ 56	~ 108	~ 119	~ 221	~ 236	~ 251
Inlet TC25 connectors, tubing i.d. (mm [inch])	4.8 (0.19)	4.8 (0.19)	4.8 (0.19)	4.8 (0.19)	4.8 (0.19)	4.8 (0.19)	9.5 (0.375)	9.5 (0.375)	9.5 (0.375)	9.5 (0.375)	9.5 (0.375)	9.5 (0.375)	12.7 (0.5)	12.7 (0.5)	12.7 (0.5)	12.7 (0.5)	12.7 (0.5)	12.7 (0.5)	19¶ (0.75)	19.0¶ (0.75)	19¶ (0.75)
Outlet TC25 connectors, tubing i.d. (mm)	4	4	4	6	6	6	7	7	7	10	10	10	12	12	12	12	12	12	17¶	17¶	17¶
Ambient temperature (°C)‡	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30	4–30
Liquid temperature (°C)‡	4–30	4–40	4–30	4–40	4–40	4–40	4–40	4–40	4–40	4–40	4–40	4–40	4–40	4–40	4–30	4–40	4–30	4–30	4–30	4–30	4–30
Maximum pressure, empty column, MPa (bar, psi)§	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)	0.4 (4.0, 58.0)
Estimated shelf life (months)	60	60	60	60	60	60	60	60	60	60	60	60	60	60	48	60	48	48	36	36	36

* Net mesh 25/20 µm for beads with a mean particle size of the cumulative volume distribution ($d_{50,volume}$) ≥ 75 µm and net mesh 14/10 µm for beads with a $d_{50,volume}$ ≤ 50 µm

† This includes the foam insert that positions the storage tube.

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

§ The maximum pressure for an empty ReadyToProcess column is 4.0 bar (58 psi, 0.40 MPa). For a packed column, restrictions regarding maximum pressure drop depend on the chromatography resin. The pressure drop between inlet and outlet of the ReadyToProcess column should never exceed the specified maximum pressure drop for the resin in the column. See User manual (28925644) for details.

¶ Connector is TC50

**Custom columns made to order

Column validation

Sanitization

Although most ReadyToProcess columns are delivered presanitized, the column design allows for easy sanitization. The sanitization procedure reduces both endotoxins and microorganisms. Each sanitized column is sampled for endotoxin analysis (acceptance limit < 0.25 EU/mL) and microbial growth to determine the total aerobic microbial count (colony forming units <10 CFU/100 mL) and the total combined yeast and mold count (colony forming units <10 CFU/100 mL). The results, including results from efficiency testing as well as endotoxin and microbial analyses, are presented in the CoA. As a last step, the column is equilibrated in 20% ethanol (20% ethanol with 0.2 M sodium acetate, pH 5.5 when applicable). The data is included in the validation guide (*see Related literature*).

All resins are not sodium hydroxide-stable, such as some of the affinity chromatography resins. Hence, columns containing such resins are delivered non-sanitized. Microbial analyses to determine the total aerobic microbial count (colony forming units <100 CFU/100 mL) and the total combined yeast and mold count (colony forming units <100 CFU/100 mL) are included in the CoA. Non-sanitized columns have NS included in the end of the product description. For more information, please refer to the validation guide for ReadyToProcess columns.

Transport simulation

Tests performed during transport simulations were either a program consisting of vertical impact by dropping test (SS-ISO 2248), compression test (ISO 12048), vibration test (SRETS packing-complete, filled transport packages and unit loads, vertical random vibration tests, level 3), and horizontal shock test (ISO 2244) or a program consisting of mechanical handling (drop test) according to ASTM 6179, compression test according to ASTM D 642 and vibration test according to ASTM D 4728 method A and ASTM D 999, Method A1. Transport simulation studies were performed at a certified testing facility.

For testing performed at a flow velocity of 30 cm/h, acceptance criteria for number of theoretical plates (N) per meter (m) packed bed were set to 3700 N/m for Capto Q, Capto S, and Phenyl Sepharose 6 FF (low sub) columns; 3900 N/m for MabSelect SuRe columns; and 4400 N/m for Capto adhere columns. The acceptance criterion for A_s was set to be within the range 0.8 to 1.8, both before and after testing. The results in Figure 5 show that the determined values for these parameters lie within set limits, demonstrating that ReadyToProcess columns are stable and robust and can be transported without effects on their performance. More information about transportation studies is included in the *ReadyToProcess Column Validation Guide*.

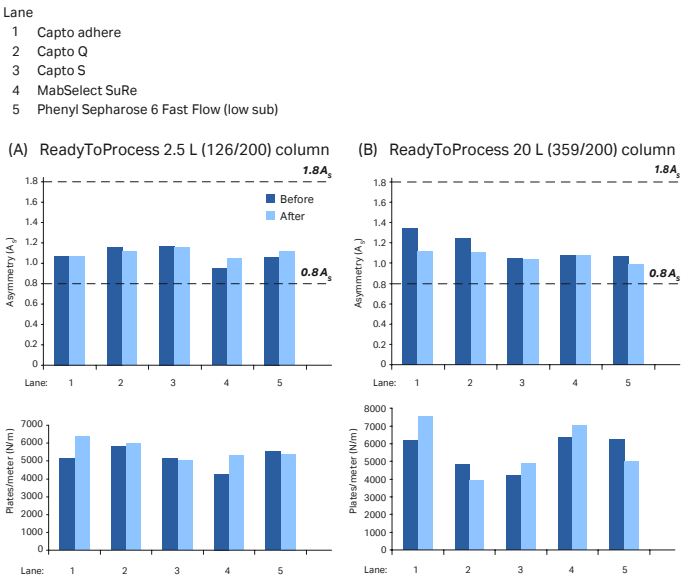


Fig 5. Test results after transport simulation on (A) ReadyToProcess 2.5 L (126/200) columns and (B) ReadyToProcess 20 L (359/200) columns show that both the number of theoretical plates (N/m) and the asymmetry factor (A_s) were within the predefined ranges.

Study on extractables and strategy for leachables

Studies on extractable compounds have been performed to identify potential compounds leachable from the assembled ReadyToProcess column hardware (unpacked). The results from identified and quantitated extractables were used to assess potential safety risks associated with the polymeric materials used in ReadyToProcess columns. Extractions were performed under conditions aligned with the BioPhorum Operations Group (BPOG) protocol that exceed worst-case process conditions regarding polarity of the solvents, pH, temperature, and contact time.

The studied extraction solutions were water, 0.1 M phosphoric acid, 0.5 M sodium hydroxide, 50% ethanol, 5 M sodium chloride, and 1% Polysorbate 80. Temperature was 40°C and contact time 24 h. Six assembled ReadyToProcess 1 L (80/200) columns were filled with respective extraction solution, closed, and agitated for 24 h at 40°C and 50 rpm before the solutions were analyzed for extractables with a set of analytical methods according to a test matrix. The concentrations of all detected compounds were below ppm level except triphenylphosphine oxide, which was at 3.3 ppm when extracted in 50% ethanol. An assembled ReadyToProcess 32 L (450/200) column was also tested with each solvent. A safety assessment of extractable compounds was performed to identify safety risk for the tested columns.

The chemical and toxicological information of extractable compounds used in the assessment did not indicate any toxicological concerns regarding the use of ReadyToProcess columns in typical biopharmaceutical manufacturing. As each purification process has specific process liquids and process conditions, it should be noted that it is always the responsibility of the user to evaluate extractables and leachables with respect to the actual process conditions and target product together with the relevant toxicological information.

BioProcess resin characteristics

BioProcess chromatography resins are specifically designed to meet the demands of industrial biotechnology, meaning that the resins are scalable from laboratory to manufacturing scale, are produced with validated manufacturing procedures, and can withstand standard cleaning-in-place (CIP) and sanitization-in-place (SIP) procedures.

All BioProcess resins are supported by our security of supply services as well as regulatory support files (RSF) and comprehensive documentation.

Characteristics of chromatography resins available in the ReadyToProcess column format are listed in corresponding resin data files. Detailed information about each resin is available from the respective data files (*see Ordering information*).

Regulatory product documentation

Each ReadyToProcess column is accompanied with an extensive documentation package to help customers register a manufacturing process containing a chromatography step including a ReadyToProcess column. The documentation is divided into four parts.

- **Product documentation**—a user manual, including a list of wetted parts and material conformance of the wetted parts, is provided. The product documentation contains a certificate of analysis showing packing performance as well as endotoxin and microbiology test results for the delivered column. The user manual can be downloaded from cytiva.com/instructions and the CoA can be downloaded from cytiva.com/certificates
- **Validation guides**—provide access to product information of the ReadyToProcess column including stability, validation, and quality as well as a brief description of the production process. The validation guide is available at cytiva.com/rsf
- **Regulatory support files (RSF)**—current files include additional information on each BioProcess chromatography resin. RSF are available at cytiva.com/rsf
- **CE certification**—columns > 50 L are CE certified according to Pressure Equipment Directive (PED). EU declaration of conformity and Operating Instructions are provided with the columns

Process scale-up studies

To show process scalability, a study was performed to verify that a protein separation experiment gives the same result regardless of column size or chromatography system used. A mixture of BSA and lactoferrin was applied to columns of different sizes: HiScale™ 16/20 column packed with 40 mL of Capto S chromatography resin; and 5 L (178/200), 32 L (450/200), and 57 L (600/200) ReadyToProcess Capto S columns and run in bind-and-elute mode on ÄKTA chromatography systems.

The elution peaks in the resulting chromatograms were compared. The results indicate that scale-up from HiScale 16/20 to the ReadyToProcess columns was possible and that the outcome was similar regardless of column or chromatography system used (Fig 6).

Scalability was also demonstrated for a monoclonal antibody (mAb) purification process. In this study, performance of ReadyToProcess columns was compared with the performance of the small-scale XK 16/40 column. The processes were run side-by-side using a generally applicable three-step mAb purification process including MabSelect SuRe, Capto Q, and Capto adhere resins. The ReadyToProcess columns exhibited similar performance to the XK 16/40 columns in all aspects studied, demonstrating that the purification process is directly scalable between the XK and ReadyToProcess formats. More detailed information can be found in *Purification of a monoclonal antibody using ReadyToProcess columns*, application note CY20575.

In a study of a separate mAb purification process, ReadyToProcess column performance was compared with the performance of conventional AxiChrom columns. MabSelect SuRe and Capto adhere resins were packed in the two different column formats. The results from the process run in ReadyToProcess columns were similar to the results obtained from the process run in AxiChrom columns (Table 3). Yield and impurity levels were almost identical over the process steps, demonstrating equivalent performance of the different column types. These results indicate that purification processes are also scalable between the ReadyToProcess and AxiChrom column formats. More detailed information can be found in *A flexible antibody purification process based on ReadyToProcess products*, application note CY13217.

Columns: HiScale 16/20
ReadyToProcess Capto S 5 L (178/200)
ReadyToProcess Capto S 32 L (450/200)
ReadyToProcess Capto S 71 L (600/200)

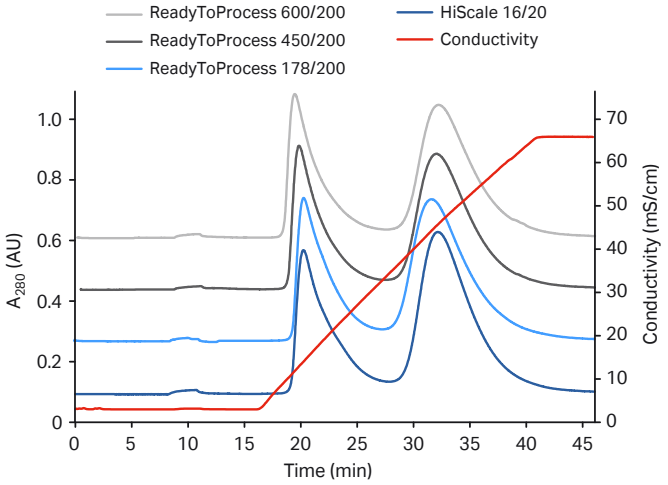
Sample: Mixture of BSA (M_r 66 000) and lactoferrin (M_r 90 000)

Equilibration buffer: 50 mM sodium acetate, pH 5.0

Elution buffer: 650 mM NaCl, pH 5.0

Gradient: 0% to 100% elution buffer in 10 CV

Systems: ÄKTA ready and ÄKTA ready XL with Low Flow Kit (for ReadyToProcess columns) and ÄKTA pure (for HiScale 16/20 column)



The height of the UV-curves has been normalized based on the height of the first peak.

Fig 6. Stacked chromatograms comparing gradient elution on three different ReadyToProcess columns compared with HiScale 16/20, all packed with Capto S. The chromatograms were obtained using ÄKTA ready systems (ÄKTA ready with Low Flow Kit, ÄKTA ready XL with Low Flow Kit) except for HiScale 16/20, which was run on an ÄKTA pure system. UV traces are normalized for peak height of first peak.

Table 3. Comparative evaluations of scaled-up processes with ReadyToProcess columns and conventional AxiChrom columns (yield is expressed as monomer yield for the Capto adhere step)

Process step	Yield (%)		Aggregate content (%)		Host cell protein (HCP) (ppm)		Protein A (ppm)	
	ReadyToProcess column	Conventional column	ReadyToProcess column	Conventional column	ReadyToProcess column	Conventional column	ReadyToProcess column	Conventional column
Fermentation			10	12	37 500	34 500	N/A*	N/A*
Harvest	100	100	10	12	37 500	34 500	N/A*	N/A*
Capture, MabSelect SuRe	96.0‡	96.2‡	10	12	19	24	8.8	1.9
UF/DF†	97.7	97.8	10	12	12	25	9.1	1.9
Polishing, Capto adhere	89.0	86.0	0.4	0.6	< LOQ§	< LOQ§	< LOQ§	< LOQ§
UF/DF† and sterile filtration	97.4	102¶	0.6	0.6	1.0	1.0	0.1	< LOQ§
Overall yield	81	81						

* N/A = not applicable

† UF/DF = ultrafiltration/diafiltration

‡ Average

§ LOQ = level of quantification (4.6 ng/mL for HCP, 3 ng/mL for ligand)

¶ Unit operations with > 100% in yield were calculated as 100%

Column performance in multiple runs

To investigate the effect of multiple runs on column performance, a ReadyToProcess MabSelect SuRe LX 1 L (80/200) column was evaluated over 50 process cycles using mAb-containing feedstock with CIP performed between cycles. Tests were performed every 10th cycle (Fig 7). The results show that column bed integrity, in terms of plates/m and AS, as well as mAb purity and recovery were maintained over 50 cycles, indicating the possibility of using prepacked ReadyToProcess columns for multiple runs, with a repeated CIP protocol included in each cycle.

Column: ReadyToProcess MabSelect SuRe LX 1 L (80/200)
Sample: mAb in Chinese hamster ovary (CHO) cell supernatant
Equilibration: 20 mM sodium phosphate, pH 7.0 + 500 mM NaCl
Elution: 50 mM sodium acetate, pH 3.5
System: ÄKTA ready gradient chromatography system

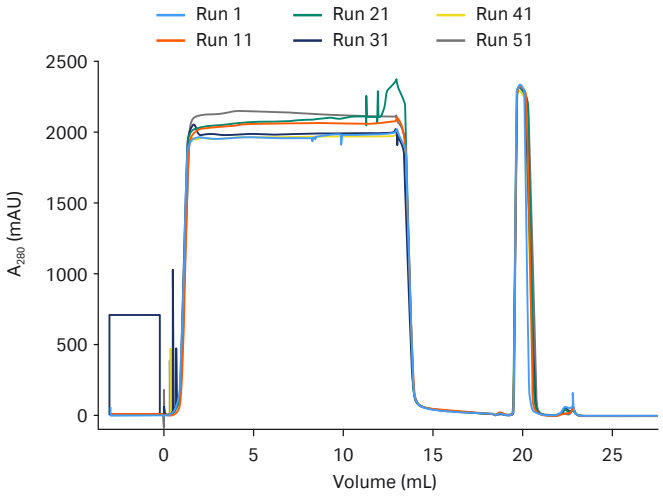


Fig 7. Overlay of chromatograms from Runs 1, 11, 21, 31, 41, 51 of repeated mAb capture cycles using the ReadyToProcess MabSelect SuRe LX 1 L column. Note, in run 21 and 31, the method was paused and restarted during sample load, causing spikes and a drifting UV curve.

Pressure safety

Along with pressure alarms in ÄKTA chromatography systems, an accessory is available for additional pressure safety for the RTP 600 column. The accessory comprises a pressure safety rupture and a T-junction to connect with the column. More information is found in the *Operating instruction: ReadyToProcess 600 column*.

Operation

Fast development of scalable methods

For efficient process development, high-throughput screening and optimization can be conducted in prefilled PreDictor™ 96-well filter plates or in prepacked PreDictor Robocolumn™ or HiScreen™ column formats. As the chromatography resins used in ReadyToProcess columns are also available in bulk, process development can also be achieved using the small-scale Tricorn™, XK, or HiScale columns. After optimization at laboratory scale, the process can be scaled up keeping the residence time constant for maintained capacity. Constant residence time between columns of different sizes can be achieved by increasing the column diameter and flow rate (L/min), while keeping the flow velocity (cm/h) and sample-to-bed volume ratio constant. Yield and clearance of critical impurities might change when column bed height or residence time is changed and should be validated using the final bed height.

Storage

ReadyToProcess columns are delivered prepacked with chromatography resin in a storage solution consisting of 20% ethanol. ReadyToProcess columns with resin coupled with the S- or SP-ligand as well as ReadyToProcess Capto MMC ImpRes are delivered in 20% ethanol, 0.2 M sodium acetate, pH 5.5. The columns should be cleared from storage solution in a wash step before starting the purification process. The wash will also adjust the temperature of the column to working temperature.

All columns, except ReadyToProcess affinity chromatography columns, are preferably stored at room temperature or colder (storage temperature range for these columns is 4°C to 30°C). ReadyToProcess affinity chromatography columns should be stored at 2°C to 8°C. Shelf life is maximum 5 yr or based on the shelf life of the packed chromatography resin. The shelf life is based on a real-time study at 30°C. The 5 yr shelf life is valid for 80 to 359 mm i.d. columns. The 450 mm i.d. columns have a shelf life of 4 yr, and the 600 mm i.d. columns have a shelf life of 3 yr. A real-time study is on-going for the 450 mm and 600 mm i.d. columns.

Equipment

ReadyToProcess columns are intended for use with the ÄKTA ready and ÄKTA ready XL single use chromatography systems, but can also be used with standard chromatography systems, such as the ÄKTA process™ CFG system. ReadyToProcess 1 L (80/200) and 2.5 L (126/200) columns can also be used with the ÄKTApilot™ and ÄKTA pilot™ 600 systems within a limited flow velocity range. Pressure alarm should be set to avoid exceeding the maximum recommended pressure drop for the packed column.

Ordering information

Available resin and dimensions

See document CY1797 for a list of available ReadyToProcess columns for affinity, ion exchange, hydrophobic interaction, multimodal, and size exclusion chromatography.

Related products

	Product code
T-junction 1", 3 × 50 mm TC	28938170
Rupture disc 4.2 bar, TC 50, ID 1"	29013998
ÄKTA ready RTP Column Trolley	28937588

Related literature

Product	Product code
Product list	CY1797
Validation guide: ReadyToProcess columns	29300614
Operating instructions: ReadyToProcess 600 columns	29340020
User manual: ReadyToProcess columns	28925644
Unpacking instructions	29249825
Case study	
Improve process economy by cycling of prepacked chromatography columns	CY15365
Application notes	
Efficiency test of ReadyToProcess columns	CY13256
Purification of a monoclonal antibody using ReadyToProcess columns	CY20575
ReadyToProcess increases facility capacity and shortens change-over time	CY13170
A flexible antibody purification process based on ReadyToProcess products	CY13217
Scale-up and process economy calculations of a dAb purification process using only ready-to-use products	CY13817
Evaluation of performance of a disposable mAb affinity chromatography column used over multiple process cycles	CY42596

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