Prepacked chromatography columns

**ReadyToProcess™ 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 off-the-shelf availability for 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 off-the-shelf availability for 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, GE Healthcare takes responsibility for the complete supply chain, from chromatography resin production to the final prepacked ReadyToProcess columns. Delivery lead times are shortened with a wide range of stock items and an efficient planning between bulk resin production and prepacked column production for non-stock items. GE Healthcare also works with supply chain sustainability for ReadyToProcess columns, which includes inventory management both at GE and at its suppliers of empty column parts to minimize supply interruptions. GE supports 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. GE’s business continuity plan follows international standards and is complemented with a strategic reserve of chromatography resins to mitigate supply chain risks.

**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 saving 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 is therefore straightforward. Available in sizes from 80 to 450 mm i.d., ReadyToProcess columns are well-suited for use with the single-use Xcellerex™ XDR bioreactor systems with working volumes ranging from 10 to 2000 L, for design of a disposable process from upstream to downstream (Fig 2).
Clinical manufacturing

Preclinical

Full-scale manufacturing

BioProcess resin groups currently available in the
ReadyToProcess format are MabSelect SuRe™, MabSelect™,
Capto™ S ImpAct, Capto ImpRes, Capto, Sepharose™ 6
Fast Flow, and Sepharose High Performance resins. The
full offering is listed in the Product sheet (29161435).
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. Other bed heights can be
available through GE’s 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 recommended for up-flow mode running condition but
can be run 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, and
Q Sepharose FF columns.

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 meet
the United States Pharmacopeia (USP) class VI requirements
according to USP <88> Biological Reactivity Tests, In Vivo and
FDA CFR 177. The materials are animal-derived component
free or has 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 2. ReadyToProcess columns can be used with AKTA™ ready and AKTA ready XL chromatography systems. Consistency in column geometry allows for convenient scaling of ReadyToProcess columns from 80 to 450 mm in i.d.

Fig 3. ReadyToProcess column with assembled parts and packing valve for resin. Arrows show flow direction.
Table 1. Materials used in wetted parts of ReadyToProcess columns (see User manual 28925644 for details)

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Material</th>
<th>Column part</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP</td>
<td>Polypropylene</td>
<td>Column tube* , lids, TC connections, support nets*, support screens*, stream stoppers, hose connections, welded tubing for inlet/outlet protection</td>
</tr>
<tr>
<td>PMMA</td>
<td>Polymethylmetakrylat</td>
<td>Column tube 32 L (450/200)</td>
</tr>
<tr>
<td>PEEK</td>
<td>Polyetheretherketone</td>
<td>Plug at inlet tubing, filter holder, resin packing valve</td>
</tr>
<tr>
<td>PO 2475</td>
<td>Polyolefin (TygonTM)</td>
<td>Hose (inlet tubing)</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>Ultra high molecular weight polyethylene</td>
<td>Sinter mesh 10 μm, 32 L (450/200)</td>
</tr>
<tr>
<td>FPM</td>
<td>Fluorocarbon rubber</td>
<td>O-rings</td>
</tr>
<tr>
<td>PE</td>
<td>Polyethylene</td>
<td>Sinter mesh 20 μm, 32 L (450/200)</td>
</tr>
<tr>
<td>EPDM</td>
<td>Ethylenepropylenenediene</td>
<td>TC gaskets</td>
</tr>
</tbody>
</table>

* For the 80 to 359 mm i.d. columns, the inner, wetted surface of the column tube, support nets, and support screens is made of polypropylene.

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). 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 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 (125 mL as a 50% slurry).
Table 2. Characteristics of ReadyToProcess columns

<table>
<thead>
<tr>
<th>Column volume (L)</th>
<th>0.8 L</th>
<th>1 L</th>
<th>1.3 L</th>
<th>1.9 L</th>
<th>2.5 L</th>
<th>3.1 L</th>
<th>3.7 L</th>
<th>5 L</th>
<th>6.2 L</th>
<th>7.4 L</th>
<th>10 L</th>
<th>12.4 L</th>
<th>15 L</th>
<th>20 L</th>
<th>25 L</th>
<th>32 L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Column volume (L)</td>
<td>0.75</td>
<td>1.01</td>
<td>1.26</td>
<td>1.87</td>
<td>2.49</td>
<td>3.12</td>
<td>3.73</td>
<td>4.98</td>
<td>6.22</td>
<td>7.42</td>
<td>9.90</td>
<td>12.37</td>
<td>15.18</td>
<td>20.24</td>
<td>25.31</td>
<td>31.81</td>
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<tr>
<td>Inner diameter (mm)</td>
<td>80</td>
<td>126</td>
<td>178</td>
<td>251</td>
<td>359</td>
<td>450</td>
<td>598</td>
<td>428</td>
<td>618</td>
<td>818</td>
<td>1128</td>
<td>1528</td>
<td>1928</td>
<td>2528</td>
<td>3228</td>
<td></td>
</tr>
<tr>
<td>Inner cross section (cm²)</td>
<td>50</td>
<td>124</td>
<td>249</td>
<td>495</td>
<td>1012</td>
<td>1590</td>
<td>2024</td>
<td>2531</td>
<td>3181</td>
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<tr>
<td>Packed bed height (mm)</td>
<td>150</td>
<td>200</td>
<td>250</td>
<td>150</td>
<td>200</td>
<td>250</td>
<td>150</td>
<td>200</td>
<td>250</td>
<td>150</td>
<td>200</td>
<td>250</td>
<td>150</td>
<td>200</td>
<td>250</td>
<td>200</td>
</tr>
<tr>
<td>Mechanical compression factor (%)†</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td>≤ 15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outer height (mm)</td>
<td>419</td>
<td>469</td>
<td>519</td>
<td>432</td>
<td>482</td>
<td>532</td>
<td>477</td>
<td>527</td>
<td>577</td>
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<td>577</td>
<td>477</td>
<td>527</td>
<td>577</td>
<td>629</td>
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<tr>
<td>Outer diameter incl. lid (mm)</td>
<td>155</td>
<td>210</td>
<td>370</td>
<td>450</td>
<td>598</td>
<td>704</td>
<td>598</td>
<td>704</td>
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<td>704</td>
<td>598</td>
<td>704</td>
<td>704</td>
<td>704</td>
</tr>
<tr>
<td>Packed column weight (kg)</td>
<td>~ 3</td>
<td>~ 5</td>
<td>~ 6</td>
<td>~ 7</td>
<td>~ 11</td>
<td>~ 13</td>
<td>~ 15</td>
<td>~ 20</td>
<td>~ 24</td>
<td>~ 27</td>
<td>~ 43</td>
<td>~ 49</td>
<td>~ 56</td>
<td>~ 108</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inlet TC25 connectors, tubing i.d. (mm [inch])</td>
<td>4.8 (0.19)</td>
<td>4.8 (0.19)</td>
<td>9.5 (0.375)</td>
<td>9.5 (0.375)</td>
<td>12.7 (0.5)</td>
<td>12.7 (0.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outlet TC25 connectors, tubing i.d. (mm)</td>
<td>4</td>
<td>6</td>
<td>7</td>
<td>10</td>
<td>12</td>
<td>12</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Maximum pressure empty column (bar)§</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Estimated shelf life (months)</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>36</td>
<td>36</td>
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<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

* Net mesh 25/20 μm for beads with a mean particle size of the cumulative volume distribution (<d>50,volume</d> ≥ 75 μm and net mesh 14/10 μm for beads with <d>50,volume</d> ≤ 50 μm.
† The mechanical compression factor does not include flow compression and varies depending on the resin and/or the size of the column.
‡ 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.

**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, including spore-forming organisms. Each sanitized column is sampled for endotoxin analysis (acceptance limit < 0.25 EU/mL) and microbial growth (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. For more information, please refer to the validation guide for the specific ReadyToProcess column.

**Transport simulation**

Tests performed during transport simulations were 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) according to a defined test program. 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 As 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.

* The ReadyToProcess 5 L (178/200) column size was only tested with Capto Q resin.
were within the predefined ranges.

Studies on extractable compounds have been performed to identify potential compounds leachable from the assembled ReadyToProcess column hardware (unpacked). The results from identified and quantified extractables were used to assess potential safety risks associated with the polymeric materials used in ReadyToProcess columns. Extractions were performed under conditions that exceed worst case process conditions regarding polarity/nonpolarity of the solvents, pH, temperature, and contact time. The studied extraction solutions were water for injection (WFI), phosphoric acid (pH 3), sodium hydroxide (pH 14), and ethanol (100%). Temperature was 40°C and contact time 24 h. Four assembled ReadyToProcess 2.5 L (126/200) columns were filled with respective extraction solution, closed, and agitated for 24 h at 40°C and 100 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 100% ethanol. In addition, a study on extractables was conducted on plastic materials exclusively used in the ReadyToProcess column. The results from the number of theoretical plates (N/m) and the asymmetry factor (Aₜ) 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 quantified extractables were used to assess potential safety risks associated with the polymeric materials used in ReadyToProcess columns. Extractions were performed under conditions that exceed worst case process conditions regarding polarity/nonpolarity of the solvents, pH, temperature, and contact time. The studied extraction solutions were water for injection (WFI), phosphoric acid (pH 3), sodium hydroxide (pH 14), and ethanol (100%). Temperature was 40°C and contact time 24 h. Four assembled ReadyToProcess 2.5 L (126/200) columns were filled with respective extraction solution, closed, and agitated for 24 h at 40°C and 100 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 100% ethanol. In addition, a study on extractables was conducted on plastic materials exclusively used in the ReadyToProcess column. The results from the number of theoretical plates (N/m) and the asymmetry factor (Aₜ) were within the predefined ranges.

**BioProcess resin characteristics**

BioProcess chromatography resins from GE Healthcare 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 GE’s 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 their respective data file (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 three parts.

- **Product documentation**—a user manual, including a list of wetted parts, is provided. Material conformance of wetted parts shows conformance with 21CFR177, USP Class VI, and animal-free origin (or EMEA/410/01) for each wetted part material as well as traceability of the material. 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 is distributed with each column and the CoA can be downloaded from gelifesciences.com/certificates.

- **Validation guides**—gives access to product information of the ReadyToProcess column including stability, validation, and quality as well as a brief description of the production process.

- **RSF**—current files include additional information on each BioProcess chromatography resin. RSF addenda and RSF are available at gelifesciences.com/rsf.
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. Columns used were XK 16/40; BPG 100; and 2.5 L (126/200), 10 L (251/200), and 20 L (359/200) ReadyToProcess columns, all packed with Capto S resin and run in bind-and-elute mode on an ÄKTA system.

Columns: XK 16/40 packed with Capto S to a bed height of 20 cm BPG 100 packed with 1.5 L Capto S to a bed height of 20 cm ReadyToProcess Capto S 2.5 L (126/200) ReadyToProcess Capto S 10 L (251/200) ReadyToProcess Capto S 20 L (359/200) Sample: Mixture of BSA (Mr 66 000) and lactoferrin (Mr 90 000) Equilibration: 50 mM sodium acetate, pH 5.0 Elution: Stepwise with 3 column volumes each of 50 mM sodium acetate + 0.3 M NaCl, pH 5.0 and 50 mM sodium acetate + 0.65 M NaCl, pH 5.0 Systems: ÄKTA chromatography systems

The elution peaks in the resulting chromatograms were compared. The results indicate that scale-up from XK 16/40 and BPG 100 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 application note 28919856.

In a study of a separate mAb purification processes, ReadyToProcess column performance was compared with the performance of conventional AxiChrom columns. A mAb purification processes comprising chromatography steps including MabSelect SuRe and Capto adhere resins packed in the two different column formats were compared. 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 application note 28940348.

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)

<table>
<thead>
<tr>
<th>Process step</th>
<th>Yield (%)</th>
<th>Aggregate content (%)</th>
<th>Host cell protein (HCP) (ppm)</th>
<th>Protein A (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ReadyToProcess column</td>
<td>Conventional column</td>
<td>ReadyToProcess column</td>
<td>Conventional column</td>
</tr>
<tr>
<td>Fermentation</td>
<td>100</td>
<td>100</td>
<td>37 500</td>
<td>34 500</td>
</tr>
<tr>
<td>Harvest</td>
<td>10</td>
<td>12</td>
<td>37 500</td>
<td>34 500</td>
</tr>
<tr>
<td>Capture, MabSelect SuRe</td>
<td>96.0†</td>
<td>96.2†</td>
<td>10</td>
<td>12</td>
</tr>
<tr>
<td>UF/DF†</td>
<td>97.7</td>
<td>97.8</td>
<td>12</td>
<td>25</td>
</tr>
<tr>
<td>Polishing, Capto adhere</td>
<td>89.0</td>
<td>86.0</td>
<td>0.4</td>
<td>0.6</td>
</tr>
<tr>
<td>UF/DF† and sterile filtration</td>
<td>97.4</td>
<td>102†</td>
<td>0.6</td>
<td>0.6</td>
</tr>
<tr>
<td>Overall yield</td>
<td>81</td>
<td>81</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 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 effects of multiple runs on column performance, ReadyToProcess MabSelect SuRe 2.5 L (126/200) columns were run five times consecutively with cell culture feed supernatant and with CIP performed between cycles (Fig 7). All chromatograms were largely identical, showing that multiple runs can be conducted with retained performance.

Column: ReadyToProcess MabSelect SuRe 2.5 L (126/200)
Sample: mAb in Chinese hamster ovary (CHO) cell supernatant
Equilibration: 0.02 M sodium phosphate + 0.15 M NaCl, pH 3.5
Elution: 0.01 M sodium phosphate + 0.01 M sodium citrate, pH 3.5
System: ÄKTAprocess™ chromatography system

Fig 7. Overlay of chromatograms from five parallel runs of a mAb purification step.

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 three years or based on the shelf life of the included chromatography resin. The shelf life is based on a real-time study for up to 48 months at 30°C. The three year shelf life is valid for 1 to 20 L (80 to 359 mm i.d.) columns. The 32 L (450/200) column has an estimated shelf life of two years.

Equipment

ReadyToProcess columns are intended for use with the ÄKTA ready product family, but can also be used with standard chromatography systems, such as the ÄKTAprocess 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 maximal recommended pressure drop for the packed column.
**Ordering information**

Stock items (for complete list of available standard ReadyToProcess columns, see Product sheet 29161435)

<table>
<thead>
<tr>
<th>Product</th>
<th>Column size</th>
<th>Product code</th>
</tr>
</thead>
<tbody>
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**Case study**

Improve process economy by cycling of prepacked chromatography columns

**Product code**

29260019

**Application notes**

Efficiency test of ReadyToProcess columns

Product code

28919821

Purification of a monoclonal antibody using ReadyToProcess columns

Product code

28919856

ReadyToProcess increases facility capacity and shortens change-over time

Product code

28946087

A flexible antibody purification process based on ReadyToProcess products

Product code

28940348

Scale-up and process economy calculations of a dAb purification process using only ready-to-use products

Product code

29227450

Evaluation of performance of a disposable mAb affinity chromatography column used over multiple process cycles

Product code

28919821

**Data files**

ÄKTA ready

Product code

28915986

ÄKTA ready XL

Product code

KA1755181217DF

MabSelect

Product code

18001165

MabSelect PrismA

Product code

KA553200917DF

MabSelect SuRe

Product code

11001165

MabSelect SuRe LX

Product code

28987062

Capto S ImpAct

Product code

29067018

Capto adhere ImpRes

Product code

29034497

Capto MMC ImpRes

Product code

29035674

Capto SP ImpRes, Capto Q ImpRes

Product code

28937637

Capto Phenyl ImpRes and Butyl ImpRes

Product code

29031925

Capto adhere

Product code

28907888

Capto MMC

Product code

11003545

Capto Q and Capto S

Product code

11002576

Sepharose Fast Flow ion exchangers

Product code

18102066

Phenyl Sepharose 6 Fast Flow (low sub), Phenyl Sepharose 6 Fast Flow (high sub)

Product code

18102053

Q Sepharose High Performance, SP Sepharose High Performance

Product code

18117288

Q Sepharose XL, SP Sepharose XL

Product code

18112382

**Related literature**

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