PreDictor™ RoboColumn® units

HIGH-THROUGHPUT PROCESS DEVELOPMENT

PreDictor™ RoboColumn® units are miniaturized chromatographic columns prepacked with BioProcess™ chromatography resins from Cytiva (Fig 1). The columns are available for several chromatographic techniques such as ion exchange chromatography (IEX), affinity chromatography (AC), multimodal chromatography (MM), and hydrophobic interaction chromatography (HIC).

PreDictor™ RoboColumn® units are part of the toolbox for high-throughput process development (HTPD). These miniaturized columns support HTPD by using a robotic liquid handling workstation, such as Freedom EVO from Tecan, for fully automated and parallel chromatographic separations. Perform HTPD work using PreDictor™ RoboColumn® units alone or as a complement to PreDictor™ 96-well filter plates (Fig 2).

- Miniaturized column format: facilitates screening of a wide range of parameters with small sample consumption
- Reduced experimental time: minimizes manual labor and saves times through automation and parallel screening
- Increased process understanding: high-throughput workflow allows investigation of enlarged experimental space for better process understanding
- Support workflows using HTPD bioreactors: enables parallel purification for product quality comparisons

Characteristics

PreDictor™ RoboColumn® units are convenient screening tools, available in different volumes (50, 200, and 600 µL), and prepacked with a wide range of BioProcess™ chromatography resins. The columns are compatible with solutions commonly used in the purification of biopharmaceuticals. Cover seals at the top and bottom of each column prevent it from drying out. PreDictor™ RoboColumn® units are supplied in rows of eight columns with the same chromatography resin and can be individually and easily arranged on an array plate containing 96 positions. For PreDictor™ RoboColumn® unit characteristics, see Table 1.

Fig 1. PreDictor™ RoboColumn® units are prepacked miniaturized columns for fully automated chromatographic separation.
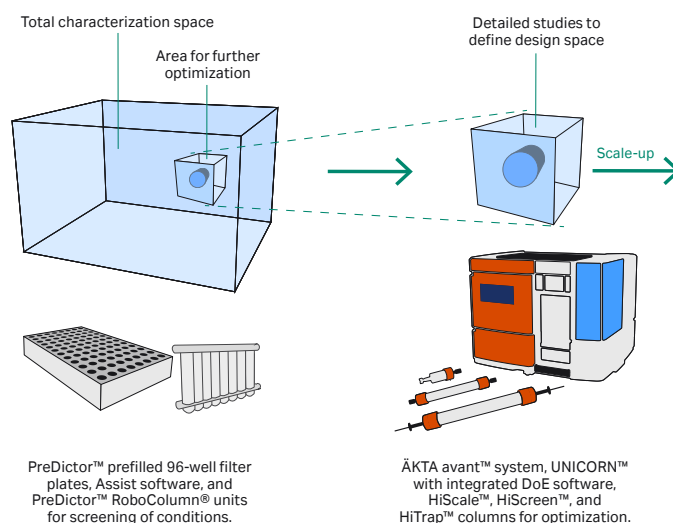

Fig 2. Conceptual visualization of a workflow for process development. Parallel screening by using PreDictor™ plates or PreDictor™ RoboColumn® units makes it possible to explore a large experimental space for optimal conditions. Once these have been identified, fine-tuning and verification are carried out on columns and ÄKTA™ systems. Finally, scale-up is done under conditions in which a robust production scale process can be operated.

cytiva

Table 1. PreDictor™ RoboColumn® unit* characteristics

Column

Column volume	50 µL	200 µL	600 µL
Bed height	2.5 mm	10.0 mm	30.0 mm
Column height	39 mm	39 mm	59 mm
Column i.d.	5 mm		
Column material	Polypropylene		
Filter material	Polypropylene		
Filter pore size	7 to 12 µm		
Chemical stability	Commonly used aqueous buffers, pH 1 to 14, organic solvents[†]		
Avoid	Halogenated organic solvents, hexane		
Storage solution	PreDictor™ RoboColumn® Capto™ S ImpAct, Capto S, Capto SP ImpRes, Capto MMC ImpRes, SP Sepharose™ FF, SP Sepharose HP: 20% ethanol + 0.2 M sodium acetate All other PreDictor™ RoboColumn®: 20% ethanol		
Recommended storage temperature	AIEX [‡], CIEX [‡], HIC, and MM: 4°C to 30°C AC: 2°C to 8°C		
Working temperature	4°C to 30°C		
Maximum working pressure[§]	Up to 8.0 bar		
Flow velocity	16 to 1000 cm/h		

Array plate

Plate size	128.3 × 14.0 × 86.0 mm (w × h × d)
Plate material	Polypropylene
Number of positions	96

* PreDictor™ RoboColumn® units are packed by Repligen GmbH.

[†] Note: The chemical stability of the packed chromatography resins has also been taken into consideration. For more information, please refer to www.cytiva.com/bioprocess to find specifications for each chromatography resin.

[‡] AIEX = anion exchange, CIEX = cation exchange.

[§] Note: Please refer to the pressure limit for each chromatography resin.

HTPD workflow

PreDictor™ RoboColumn® units can be used in a broad spectrum of applications, including parallel screening and optimization of chromatographic conditions as well as scale-down experiments. The columns are intended for automated workflows using a robotic liquid handling system such as Freedom EVO.

The HTPD workflow consists of the following steps:

1. Plan the experimental setup by using a systematic approach.
2. Perform the experiments, testing various experimental conditions in a parallel manner.
3. Analyze data using high-throughput analysis.
4. Evaluate data and analyze results.

Plan

The experimental setup should simultaneously test as many different conditions (factors) as possible. Preferentially, this is done using design of experiments (DoE), a statistical approach used to identify and define the factors having the greatest impact on the process or end product.

Using DoE, a maximum amount of information is obtained from a minimum number of experiments by varying the relevant factors simultaneously. The resulting DoE data (responses) are used to generate a statistical model that can predict the response to untested factor settings, which allows increased process understanding.

Before starting, the experimental objectives should be defined. Objectives may include:

Screening

- Which factors are most important (i.e., have a significant effect on the response)?
- What factor range should be explored?

Optimization

- What is the optimal combination of settings for the important factors?
- If there is more than one response, is it possible to find common factor settings that satisfy all responses, or is a compromise needed?

Robustness testing

- Is the process robust (i.e., unaffected typical process variations)?
- How much will the product characteristics vary due to process variations?

It is important to define the factors and responses that will be studied. The selection of analytical techniques for the responses will affect the amount of sample needed for each experiment. Running replicates is recommended for outlier analysis.

Perform

PreDictor™ RoboColumn® units are designed for automated parallel experiments, minimizing manual work. The columns are supplied as a row of eight, although columns can easily be arranged individually. This modular design allows increased flexibility in designing and setting up experiments.

Analyze

HTPD experiments usually include a large number of samples, so high-throughput analytical methods are preferred if available. In some cases, simple absorbance measurements (e.g., at 280 nm) might be sufficient during initial screening. During the initial screening phase, analyses should be limited to the most critical responses. Based on the results, selected conditions can thereafter be chosen for responses that require more advanced analytical methods.

Evaluate

Data is evaluated, for example, by using traditional methods for determining resolution or breakthrough capacity. Based on the results, further investigation by using HTPD might be relevant before moving to larger columns for verification and fine-tuning.

Applications

Screening of chromatographic conditions

PreDictor™ RoboColumn® units are miniaturized columns run in the same manner as conventional larger columns. These columns can be used to screen different parts of the chromatographic cycle such as binding studies (including dynamic binding capacities), elution studies, and wash studies. Figure 3 shows a screening experiment to determine which conditions give a high dynamic binding capacity (DBC). In Figure 4, binding capacity for conalbumin on Capto™ S resin is shown, using two different column formats (prepacked PreDictor™ RoboColumn® units and user-packed Tricorn™ column) and a prepacked 96-well plate format (PreDictor™ plate).

Figure 5 shows that PreDictor™ RoboColumn® units give highly reproducible data, demonstrated in two different sets of DBC experiments.
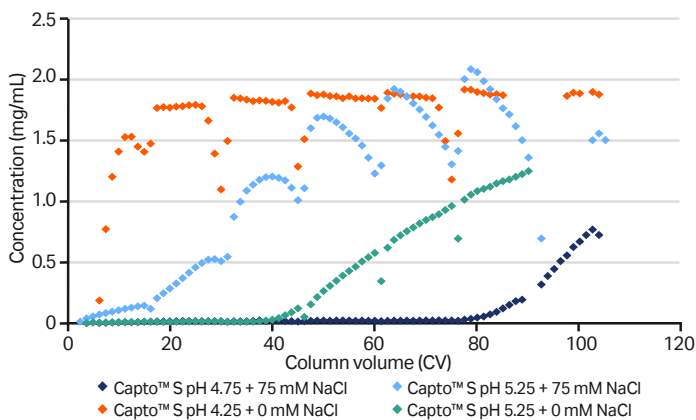
Fig 3. Breakthrough curves shown for conalbumin using PreDictor™ RoboColumn® Capto™ S units, column volume 200 µL at different pH values and NaCl concentrations. Each data point represents a small fraction (droplet) from the column run.
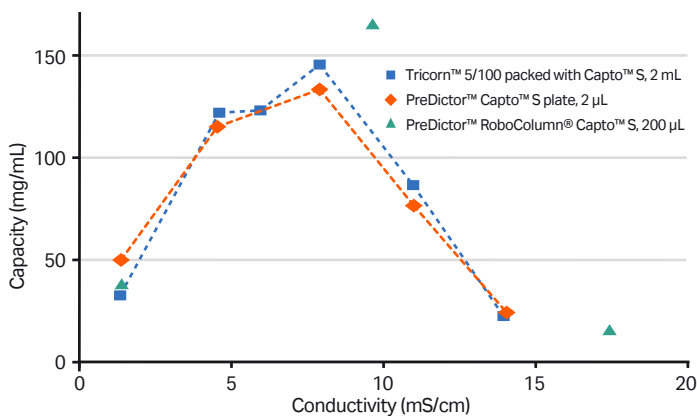
Fig 4. Binding capacity of Capto™ S resin for conalbumin at pH 4.75 shown for a 2 mL column (Tricorn™ 5/100), a 200 µL column (PreDictor™ RoboColumn®), and 2 µL in batch mode (PreDictor™ plate). Capacities are shown as dynamic binding capacities (DBC) at 10% breakthrough for the two column formats and as static binding capacity (SBC) for the PreDictor™ Capto™ S, 2 µL plate. Fewer measurement points were measured for the PreDictor™ RoboColumn® unit, however, the observed trend is similar.
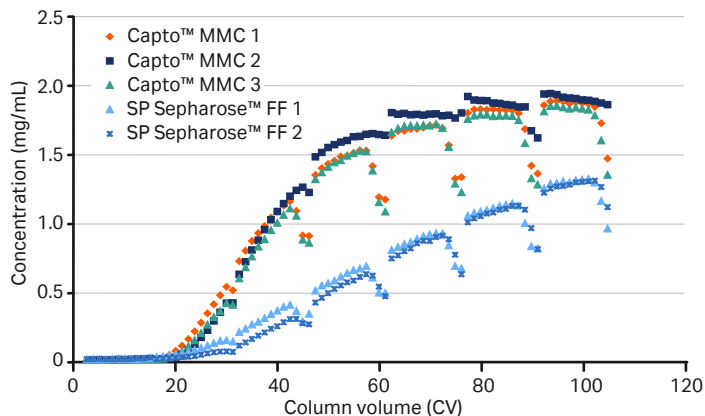
Fig 5. High reproducibility shown for breakthrough curves from two different experiments using PreDictor™ RoboColumn® units. One set of experiments is conalbumin on three different PreDictor™ RoboColumn® Capto™ MMC units at pH 5.25 with 150 mM NaCl. The second set of experiments is conalbumin on two PreDictor™ RoboColumn® SP Sepharose™ Fast Flow units, where breakthrough curves have been monitored at pH 4.75 with 75 mM NaCl.

Selectivity

In Figure 6, ribonuclease A, cytochrome c, and lysozyme were sequentially eluted using a step gradient consisting of NaCl at pH 7.2. A pseudochromatogram was plotted from the PreDictor™ RoboColumn® data (Fig 6A). The data from using the miniaturized columns is similar to the results from the corresponding experiment using Tricorn™ 5/100 column (2 mL) shown in Figure 6B.
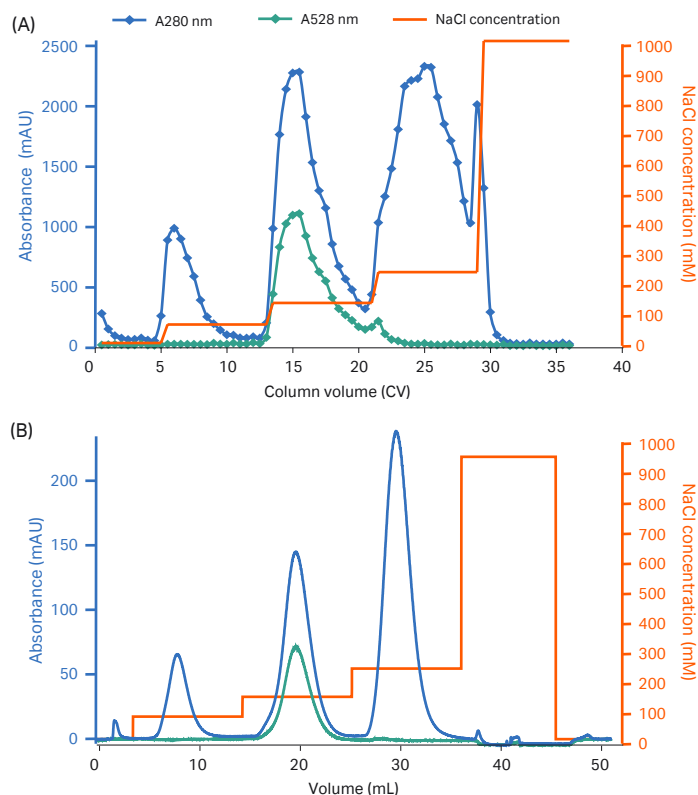
Fig 6. (A) Pseudochromatogram created by plotting absorbance and gradient versus column volume. Ribonuclease A, cytochrome c, and lysozyme were separated at pH 7.2 using PreDictor™ RoboColumn® Capto™ S units, 200 µL. The elution of cytochrome c is easily detected at 528 nm as indicated by the orange curve. The extra peak observed at 30 CV is due to the short elution step. (B) Chromatogram showing the separation of ribonuclease A, cytochrome c, and lysozyme at pH 7.2 using a Tricorn™ 5/100 column packed with Capto™ S resin. The elution of cytochrome c is easily detected at 528 nm as indicated by the orange curve. The blue curve is the absorbance at 280 nm and the red curve is the NaCl gradient.

Ordering information

List of selected PreDictor™ RoboColumn® products. For additional requests please contact your local sales representative.

Note: pack size = one row of eight columns

Products		Product code
Ion exchange chromatography (IEX)		
PreDictor™ RoboColumn® Capto™ S ImpAct	200 µL 600 µL	17371771 17371772
PreDictor™ RoboColumn® Capto™ Q	200 µL 600 µL	28986072 28986175
PreDictor™ RoboColumn® Capto™ S	200 µL 600 µL	28986081 28986176
PreDictor™ RoboColumn® Capto™ DEAE	200 µL 600 µL	28986082 28986177
PreDictor™ RoboColumn® Capto™ Q XP	200 µL 600 µL	29275366 29275367
PreDictor™ RoboColumn® Q Sepharose™ HP	200 µL 600 µL	28986103 28986192
PreDictor™ RoboColumn® SP Sepharose™ HP	200 µL 600 µL	28986104 28986193
PreDictor™ RoboColumn® Q Sepharose™ FF	200 µL 600 µL	28986086 28986180
PreDictor™ RoboColumn® SP Sepharose™ FF	200 µL 600 µL	28986087 28986181
PreDictor™ RoboColumn® CM Sepharose™	200 µL 600 µL	29275282 29275283
PreDictor™ RoboColumn® Capto™ Q ImpRes	200 µL 600 µL	28996918 28997391
PreDictor™ RoboColumn® Capto™ SP ImpRes	200 µL 600 µL	28997449 28997450
PreDictor™ RoboColumn® SOURCE™ 15 Q	200 µL 600 µL	29275272 29275273
PreDictor™ RoboColumn® SOURCE™ 15 S	200 µL 600 µL	29275274 29275275
PreDictor™ RoboColumn® SOURCE™ 30 Q	200 µL 600 µL	29275276 29275277
Multimodal chromatography (MM)		
PreDictor™ RoboColumn® Capto™ MMC ImpRes	200 µL 600 µL	17371640 17371641
PreDictor™ RoboColumn® Capto™ adhere ImpRes	200 µL 600 µL	17371540 17371541
PreDictor™ RoboColumn® Capto™ MMC	200 µL 600 µL	28986084 28986178
PreDictor™ RoboColumn® Capto™ adhere	200 µL 600 µL	28986085 28986179
PreDictor™ RoboColumn® Capto™ Core 700	200 µL 600 µL	29275362 29275363

Affinity chromatography (AC)		
PreDictor™ RoboColumn® MabSelect PrismA™	200 µL 600 µL	17549833 17549834
PreDictor™ RoboColumn® MabSelect SuRe™ pcc	200 µL 600 µL	29275296 17549141
PreDictor™ RoboColumn® MabSelect SuRe™ LX	50 µL 200 µL 600 µL	28986203 28997440 28997451
PreDictor™ RoboColumn® MabSelect SuRe™	50 µL 200 µL 600 µL	28986203 28986107 29093969
PreDictor™ RoboColumn® MabSelect Xtra™	50 µL 200 µL 600 µL	28986204 28986108 29275291
PreDictor™ RoboColumn® MabSelect™	50 µL 200 µL 600 µL	28986202 28986106 29201295
PreDictor™ RoboColumn® MabSelect™ VL	200 µL 600 µL	17542033 17542034
PreDictor™ RoboColumn® Capto™ L	200 µL 600 µL	29003420 29003421
PreDictor™ RoboColumn® Protein G Sepharose™ 4 FF	200 µL 600 µL	29275288 29275289
PreDictor™ RoboColumn® KappaSelect	200 µL 600 µL	29275294 29275295
PreDictor™ RoboColumn® AVB Sepharose™ HP	200 µL 600 µL	29275298 29275299
PreDictor™ RoboColumn® LambdaFabSelect	200 µL 600 µL	29275370 29275371
PreDictor™ RoboColumn® VII Select	200 µL 600 µL	29275278 29275279
PreDictor™ RoboColumn® Capto™ Chelatin	200 µL 600 µL	29275280 29275281
PreDictor™ RoboColumn® Capto™ Blue	200 µL 600 µL	29275364 29275365
PreDictor™ RoboColumn® IMAC Sepharose™ 6 FF	200 µL 600 µL	29275368 29275369
PreDictor™ RoboColumn® Capto™ DeVirS	200 µL 600 µL	29275292 29275293
PreDictor™ RoboColumn® Capto™ AVB	200 µL 600 µL	29714911 29714912
PreDictor™ RoboColumn® Ni Sepharose™ FF	200 µL 600 µL	29714913 29714914
PreDictor™ RoboColumn® Ni Sepharose™ Excel	200 µL 600 µL	29714915 29714916
PreDictor™ RoboColumn® Capto™ Lentil Lectin	200 µL 600 µL	29714917 29714918

PCC = periodic counter current chromatography

Hydrophobic interaction chromatography (HIC)

PreDictor™ RoboColumn® Capto™ Phenyl (high sub)	200 µL 600 µL	28986088 28986182
PreDictor™ RoboColumn® Capto™ Butyl	200 µL 600 µL	28986097 28986183
PreDictor™ RoboColumn® Capto™ Octyl	200 µL 600 µL	29275286 29275287
PreDictor™ RoboColumn® Capto™ Butyl ImpRes	200 µL 600 µL	29701637 17371941
PreDictor™ RoboColumn® Capto™ Phenyl ImpRes	200 µL 600 µL	29701638 17548441
PreDictor™ RoboColumn® Phenyl Sepharose™ 6 FF (high sub)	200 µL 600 µL	28986098 28986184
PreDictor™ RoboColumn® Phenyl Sepharose™ 6 FF (low sub)	200 µL 600 µL	28986099 28986188
PreDictor™ RoboColumn® Butyl Sepharose™ 4 FF	200 µL 600 µL	28986100 28986189
PreDictor™ RoboColumn® Octyl Sepharose™ 4 FF	200 µL 600 µL	29275284 29275285
PreDictor™ RoboColumn® Butyl-S Sepharose™ 6 FF	200 µL 600 µL	28986101 28986190
PreDictor™ RoboColumn® Octyl Sepharose™ 4 FF	200 µL 600 µL	28986102 28986191
PreDictor™ RoboColumn® Butyl Sepharose™ HP	200 µL 600 µL	28986173 28986195
PreDictor™ RoboColumn® Phenyl Sepharose™ HP	200 µL 600 µL	28986105 28986194

Accessories

	Quantity	
96-well array plate for PreDictor™ RoboColumn® units	1 plate	28986242
Microplate Foil, 96-well	100 × self-adhesive, transparent plastic foils	BR100578

Related Products

	Quantity	
HiScreen™ Capto™ S ImpAct	1 × 4.7 mL	17371747
HiScreen™ Capto™ Q	1 × 4.7 mL	28926978
HiScreen™ Capto™ S	1 × 4.7 mL	28926979
HiScreen™ Capto™ DEAE	1 × 4.7 mL	28926982
HiScreen™ Capto™ Q ImpRes	1 × 4.7 mL	17547015
HiScreen™ Capto™ SP ImpRes	1 × 4.7 mL	17546815
HiScreen™ Q HP	1 × 4.7 mL	28950511
HiScreen™ SP HP	1 × 4.7 mL	28950515
HiScreen™ Q FF	1 × 4.7 mL	28950510
HiScreen™ DEAE FF	1 × 4.7 mL	28978245
HiScreen™ SP FF	1 × 4.7 mL	28950513
HiScreen™ Capto™ MMC ImpRes	1 × 4.7 mL	17371620
HiScreen™ Capto™ adhere ImpRes	1 × 4.7 mL	17371520
HiScreen™ Capto™ MMC	1 × 4.7 mL	28926980
HiScreen™ Capto™ adhere	1 × 4.7 mL	28926981
HiScreen™ MabSelect PrismA™	1 × 4.7 mL	28926973
HiScreen™ MabSelect SuRe™ LX	1 × 4.7 mL	17549815
HiScreen™ Mabselect™ VL	1 × 4.7 mL	17542015
HiScreen™ MabSelect SuRe™	1 × 4.7 mL	28926977
HiScreen™ MabSelect Xtra™	1 × 4.7 mL	28926976
HiScreen™ MabSelect™	1 × 4.7 mL	17547415
HiScreen™ Capto™ L	1 × 4.7 mL	17547814
HiScreen™ Capto™ Phenyl (high sub)	1 × 4.7 mL	28992472
HiScreen™ Phenyl HP	1 × 4.7 mL	28950516
HiScreen™ Phenyl FF (high sub)	1 × 4.7 mL	28926988
HiScreen™ Phenyl FF (low sub)	1 × 4.7 mL	28926989
HiScreen™ Capto™ Butyl	1 × 4.7 mL	28992473
HiScreen™ Butyl HP	1 × 4.7 mL	28978242
HiScreen™ Butyl FF	1 × 4.7 mL	28926984
HiScreen™ Butyl-S FF	1 × 4.7 mL	28926985
HiScreen™ Octyl FF	1 × 4.7 mL	28926986

Related literature

Title	Product code
Instructions PreDictor™ RoboColumn®	28987015

Data files

Title	Product code
PreDictor™ 96-well filter plates and Assist software	CY13663
HiScreen™ prepacked columns	CY13473
Capto™ S ImpAct	CY11840
Capto™ S, Capto™ Q and Capto™ DEAE	CY13280
Capto™ SP ImpRes and Capto™ Q ImpRes	CY12674
Capto™ MMC ImpRes	CY13699
Capto™ MMC	CY13468
Capto™ adhere ImpRes	CY11775
Capto™ adhere	CY11848
MabSelect™ VL	CY26149
MabSelect PrismA™	CY11773
MabSelect SuRe™ LX	CY12583
MabSelect SuRe™	CY12754
Capto™ Phenyl (high sub), Capto™ Butyl, Capto™ Octyl, and Capto™ Butyl-S	CY13568

Handbook

Title	Product code
High-throughput process development with PreDictor™ plates	CY16051

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