

PreDictor™ RoboColumn™

PreDictor RoboColumn units (Fig 1) are miniaturized chromatographic columns prepacked with BioProcess™ chromatography media (resins) from GE Healthcare Life Sciences. 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 plates (Fig 2).

- Miniaturized column format: facilitates screening of a wide range of parameters with small sample consumption.
- Reduced experimental time: automation and parallel screening minimizes manual labor and saves time.
- Increased process understanding: high-throughput workflow allows investigation of enlarged experimental space for better process understanding.

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 media. 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 media, 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 (left). Once these have been identified, fine-tuning and verification are carried out on columns and ÄKTA systems (middle). Finally, scale-up is done under conditions in which a robust production scale process can be operated (right).



Table 1. PreDicator RoboColumn¹ 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 ²		
Avoid	Halogenated organic solvents, hexane		
Storage solution	PreDicator 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 PreDicator RoboColumn: 20% ethanol		
Recommended storage temperature	AIEX ³ , CIEEX ³ , HIC, and MM: 4°C to 30°C AC: 2°C to 8°C		
Working temperature	4°C to 30°C		
Maximum working pressure ⁴	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		

¹ PreDicator RoboColumn units are packed by Atoll GmbH and are identical to Atoll GmbH RoboColumn units.

² **Note:** The chemical stability of the packed chromatography media has also been taken into consideration. For more information, please refer to www.gelifesciences.com/bioprocess to find specifications for each chromatography medium.

³ AIEX = anion exchange, CIEX = cation exchange.

⁴ **Note:** Please refer to the pressure limit for each chromatography medium.

HTPD workflow

PreDicator 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

PreDicator 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) may 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 then be chosen for responses that require more advanced analytical methods.

Evaluate

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

Applications

Screening of chromatographic conditions

PreDicator RoboColumn units are miniaturized columns run in the same manner as conventional larger columns. They 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 medium is shown using two different column formats (prepacked PreDicator RoboColumn units and user-packed Tricorn™ column) and a prepacked 96-well plate format (PreDicator plate).

Figure 5 shows that PreDicator RoboColumn units give highly reproducible data, demonstrated in two different sets of DBC experiments.

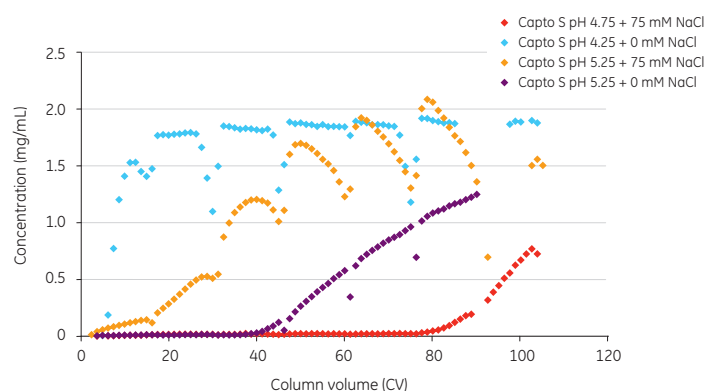


Fig 3. Breakthrough curves shown for conalbumin using PreDicator RoboColumn Capto S units, column volume 200 μ L, at different pH values and NaCl concentrations. Each data point represents a small fraction (droplet) from the column run.

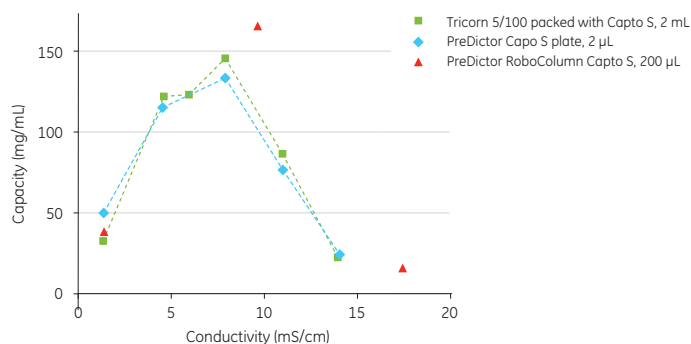


Fig 4. Binding capacity for conalbumin on Capto S medium at pH 4.75 shown for a 2 mL column (Tricorn 5/100), a 200 µL column (PreDicator RoboColumn), and 2 µL in batch mode (PreDicator plate). Capacities are shown as dynamic binding capacities (DBC) at 10% breakthrough for the two column formats and as static binding capacity (SBC) for the PreDicator Capto S, 2 µL plate. Fewer measurement points were measured for the PreDicator RoboColumn unit, however the observed trend is similar.

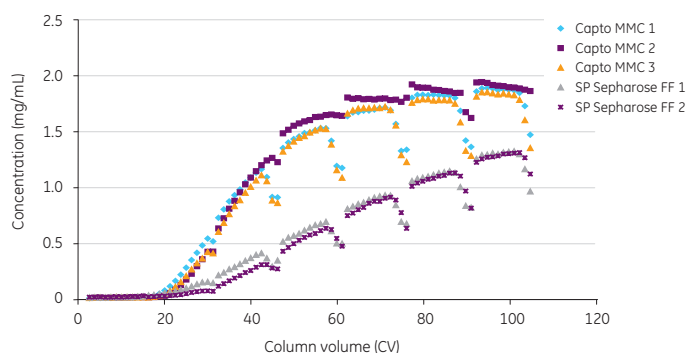


Fig 5. High reproducibility shown for breakthrough curves from two different experiments using PreDicator RoboColumn units. One set of experiments is conalbumin on three different PreDicator RoboColumn Capto MMC units at pH 5.25 with 150 mM NaCl. The second set of experiments is conalbumin on two PreDicator 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 PreDicator RoboColumn data (Fig 6A). The data using the miniaturized columns are similar to the results from the corresponding experiment using Tricorn 5/100 column (2 mL) shown in Figure 6B.

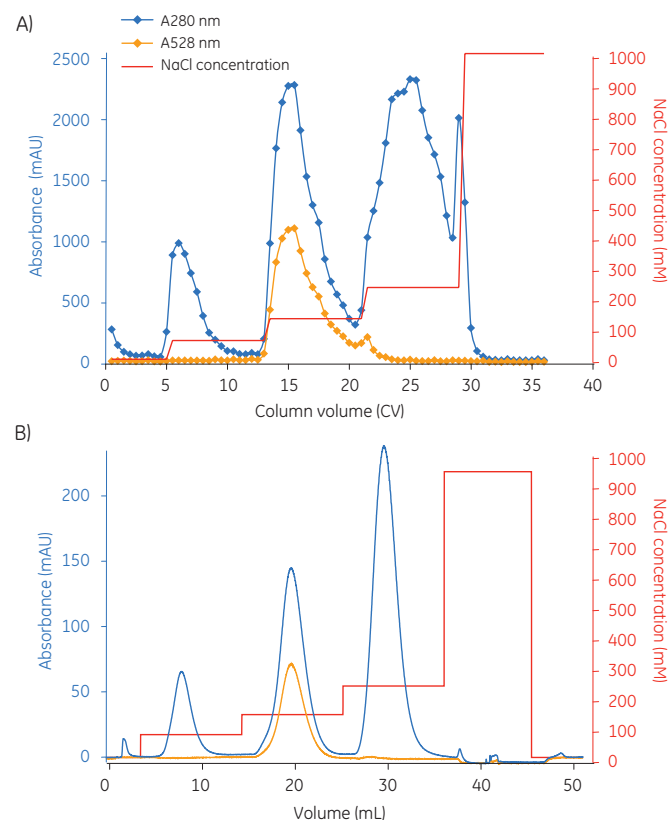


Fig 6. (A) Pseudochromatogram created by plotting absorbance and gradient versus column volume. Ribonuclease A, cytochrome c, and lysozyme were separated at pH 7.2 using PreDicator RoboColumn Capto S units, 200 µL. The elution of cytochrome c is easily detected at 528 nm as indicated by the orange curve. 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 medium. 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

Note: Pack size = one row of eight columns

Products	Code number
Ion exchange chromatography (IEX)	
PreDicator RoboColumn Capto S ImpAct, 200 µL	17-3717-71
PreDicator RoboColumn Capto S ImpAct, 600 µL	17-3717-72
PreDicator RoboColumn Capto Q, 200 µL	28-9860-72
PreDicator RoboColumn Capto Q, 600 µL	28-9861-75
PreDicator RoboColumn Capto S, 200 µL	28-9860-81
PreDicator RoboColumn Capto S, 600 µL	28-9861-76
PreDicator RoboColumn Capto DEAE, 200 µL	28-9860-82
PreDicator RoboColumn Capto DEAE, 600 µL	28-9861-77
PreDicator RoboColumn Q Sepharose HP, 200 µL	28-9861-03
PreDicator RoboColumn Q Sepharose HP, 600 µL	28-9861-92
PreDicator RoboColumn SP Sepharose HP, 200 µL	28-9861-04
PreDicator RoboColumn SP Sepharose HP, 600 µL	28-9861-93
PreDicator RoboColumn Q Sepharose FF, 200 µL	28-9860-86
PreDicator RoboColumn Q Sepharose FF, 600 µL	28-9861-80
PreDicator RoboColumn SP Sepharose FF, 200 µL	28-9860-87
PreDicator RoboColumn SP Sepharose FF, 600 µL	28-9861-81
PreDicator RoboColumn Capto Q ImpRes, 200 µL	28-9969-18
PreDicator RoboColumn Capto Q ImpRes, 600 µL	28-9973-91
PreDicator RoboColumn Capto SP ImpRes, 200 µL	28-9974-49
PreDicator RoboColumn Capto SP ImpRes, 600 µL	28-9974-50
Multimodal chromatography (MM)	
PreDicator RoboColumn Capto MMC ImpRes, 200 µL	17-3716-40
PreDicator RoboColumn Capto MMC ImpRes, 600 µL	17-3716-41
PreDicator RoboColumn Capto adhere ImpRes, 200 µL	17-3715-40
PreDicator RoboColumn Capto adhere ImpRes, 600 µL	17-3715-41
PreDicator RoboColumn Capto MMC, 200 µL	28-9860-84
PreDicator RoboColumn Capto MMC, 600 µL	28-9861-78
PreDicator RoboColumn Capto adhere, 200 µL	28-9860-85
PreDicator RoboColumn Capto adhere, 600 µL	28-9861-79
Affinity chromatography (AC)	
PreDicator RoboColumn MabSelect™, 50 µL	28-9862-02
PreDicator RoboColumn MabSelect, 200 µL	28-9861-06
PreDicator RoboColumn MabSelect SuRe™, 50 µL	28-9862-03
PreDicator RoboColumn MabSelect SuRe, 200 µL	28-9861-07
PreDicator RoboColumn MabSelect SuRe, 600 µL	29-0939-69
PreDicator RoboColumn MabSelect Xtra™, 50 µL	28-9862-04
PreDicator RoboColumn MabSelect Xtra, 200 µL	28-9861-08
PreDicator RoboColumn MabSelect SuRe LX, 200 µL	28-9974-40
PreDicator RoboColumn MabSelect SuRe LX, 600 µL	28-9974-51
PreDicator RoboColumn Capto L, 200 µL	29-0034-20
PreDicator RoboColumn Capto L, 600 µL	29-0034-21

Products	Code number
Hydrophobic interaction chromatography (HIC)	
PreDicator RoboColumn Capto Phenyl (high sub), 200 µL	28-9860-88
PreDicator RoboColumn Capto Phenyl (high sub), 600 µL	28-9861-82
PreDicator RoboColumn Capto Butyl, 200 µL	28-9860-97
PreDicator RoboColumn Capto Butyl, 600 µL	28-9861-83
PreDicator RoboColumn Phenyl Sepharose 6 FF (high sub), 200 µL	28-9860-98
PreDicator RoboColumn Phenyl Sepharose 6 FF (high sub), 600 µL	28-9861-84
PreDicator RoboColumn Phenyl Sepharose 6 FF (low sub), 200 µL	28-9860-99
PreDicator RoboColumn Phenyl Sepharose 6 FF (low sub), 600 µL	28-9861-88
PreDicator RoboColumn Butyl Sepharose 4 FF, 200 µL	28-9861-00
PreDicator RoboColumn Butyl Sepharose 4 FF, 600 µL	28-9861-89
PreDicator RoboColumn Butyl-S Sepharose 6 FF, 200 µL	28-9861-01
PreDicator RoboColumn Butyl-S Sepharose 6 FF, 600 µL	28-9861-90
PreDicator RoboColumn Octyl Sepharose 4 FF, 200 µL	28-9861-02
PreDicator RoboColumn Octyl Sepharose 4 FF, 600 µL	28-9861-91
PreDicator RoboColumn Butyl Sepharose HP, 200 µL	28-9861-73
PreDicator RoboColumn Butyl Sepharose HP, 600 µL	28-9861-95
PreDicator RoboColumn Phenyl Sepharose HP, 200 µL	28-9861-05
PreDicator RoboColumn Phenyl Sepharose HP, 600 µL	28-9861-94

Accessories	Quantity	Code number	Related literature	Code number
96-well array plate for PreDicator RoboColumn units	1 plate	28-9862-42	Instructions PreDicator RoboColumn	28-9870-15
Microplate Foil, 96-well	100 × self-adhesive, transparent plastic foils	BR-1005-78	Data files PreDicator 96-well filter plates and Assist software	28-9258-39
			HiScreen prepacked columns	28-9305-81
			Capto S ImpAct	29-0670-18
			Capto S, Capto Q and Capto DEAE	11-0025-76
			Capto SP ImpRes and Capto Q ImpRes	28-9837-63
			Capto MMC ImpRes	29-0356-74
			Capto MMC	11-0035-45
			Capto adhere ImpRes	29-0344-97
			Capto adhere	28-9078-88
			MabSelect	18-1149-94
			MabSelect SuRe	11-0011-65
			MabSelect Xtra	11-0011-57
			MabSelect SuRe LX	28-9870-62
			Capto L	29-0100-08
			Capto Butyl, Capto Phenyl (high sub)	28-9558-57
			Butyl Sepharose 4 FF	18-1020-70
			Phenyl Sepharose 6 FF (low sub) and Phenyl Sepharose 6 FF (high sub)	18-1020-53
			Sepharose Fast Flow IEX media and prepacked formats	18-1020-66
			Butyl-S Sepharose 6 FF	11-0026-34
			Butyl Sepharose HP and Phenyl Sepharose HP	18-1172-87
Related Products	Quantity	Code number		
HiScreen Capto S ImpAct	1 × 4.7 mL	17-3717-47		
HiScreen Capto Q	1 × 4.7 mL	28-9269-78		
HiScreen Capto S	1 × 4.7 mL	28-9269-79		
HiScreen Capto DEAE	1 × 4.7 mL	28-9269-82		
HiScreen Capto Q ImpRes	1 × 4.7 mL	17-5470-15		
HiScreen Capto SP ImpRes	1 × 4.7 mL	17-5468-15		
HiScreen Q HP	1 × 4.7 mL	28-9505-11		
HiScreen SP HP	1 × 4.7 mL	28-9505-15		
HiScreen Q FF	1 × 4.7 mL	28-9505-10		
HiScreen DEAE FF	1 × 4.7 mL	28-9782-45		
HiScreen SP FF	1 × 4.7 mL	28-9505-13		
HiScreen Capto MMC ImpRes	1 × 4.7 mL	17-3716-20		
HiScreen Capto adhere ImpRes	1 × 4.7 mL	17-3715-20		
HiScreen Capto MMC	1 × 4.7 mL	28-9269-80		
HiScreen Capto adhere	1 × 4.7 mL	28-9269-81		
HiScreen MabSelect	1 × 4.7 mL	28-9269-73		
HiScreen MabSelect SuRe	1 × 4.7 mL	28-9269-77		
HiScreen MabSelect Xtra	1 × 4.7 mL	28-9269-76		
HiScreen MabSelect SuRe LX	1 × 4.7 mL	17-5474-15		
HiScreen Capto L	1 × 4.7 mL	17-5478-14		
HiScreen Capto Phenyl (high sub)	1 × 4.7 mL	28-9924-72		
HiScreen Phenyl HP	1 × 4.7 mL	28-9505-16		
HiScreen Phenyl FF (high sub)	1 × 4.7 mL	28-9269-88		
HiScreen Phenyl FF (low sub)	1 × 4.7 mL	28-9269-89		
HiScreen Capto Butyl	1 × 4.7 mL	28-9924-73		
HiScreen Butyl HP	1 × 4.7 mL	28-9782-42		
HiScreen Butyl FF	1 × 4.7 mL	28-9269-84		
HiScreen Butyl-S FF	1 × 4.7 mL	28-9269-85		
HiScreen Octyl FF	1 × 4.7 mL	28-9269-86		

For local office contact information, visit
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www.gelifesciences.com/predictor

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