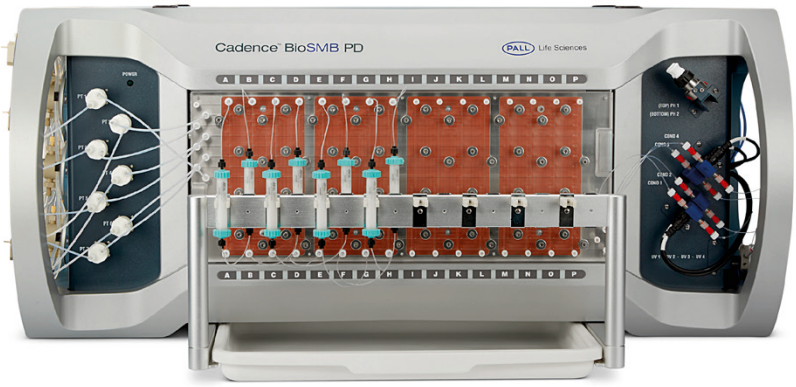
SARTORIUS

Product Datasheet

BioSMB PD System

Continuous Single-Use, Multicolumn Chromatography



Benefits

- Inherent unit operation efficiency of the BioSMB PD system reduces the cost of chromatographic media by up to 80% without changing either the resin or buffer used in the chromatographic process.
- Entire chromatographic process can be conducted in a smaller system containing a fraction of the media and buffer that would be required in a standard batch process to produce the same amount of material.
- Ability to use up to 16 columns increases specific productivity and application flexibility. Position of the buffer selection valve eliminates composition gradients and wash steps.

Product Information

The BioSMB platform is the first disposable flow path, continuous multicolumn chromatography solution that is fully scalable from the Process Development (PD) laboratory to GMP manufacturing. The BioSMB system is specifically designed to allow users to convert an existing batch process into a continuous chromatography step without changing the chromatographic resin, buffer system or product quality assays. BioSMB technology provides process consistency across all scales – development, clinical and full production – and is also practical to implement in flexible, multi-product facilities.

Applications

BioSMB PD technology is the ideal solution for biopharmaceutical production applications ranging from early stage process development through clinical manufacture and beyond. This integrated single-use device contains all the valves necessary to fully automate a wide variety of chromatographic processes, including bind | elute chromatography (Protein A affinity, ion exchange, mixed mode, hydrophobic interaction) and flow-through such as size exclusion or ion exchange polishing. It provides an open platform for downstream processing that enables the use of any separation technology, including packed bed chromatography, membrane chromatography, monoliths and expanded bed adsorption (EBA) chromatography.

Benefits

Batch chromatographic processing typically utilizes only 50% to 70% of the chromatographic column's total binding capacity. The BioSMB PD system, on the other hand, uses a series of substantially smaller, interconnected columns. The first column in the load zone is allowed to reach breakthrough and the product breakthrough is captured on a second column. The binding capacity of the first column can thus be exploited well beyond its batch dynamic binding capacity. In many cases, such processes can be operated close to the equilibrium or static binding capacity of the chromatographic media, thus leading to a significant reduction in chromatographic media use.

The BioSMB PD system use of continuous counter current loading means that the load zone must accommodate only the mass transfer zone, which generally represents a small percentage of a batch column. This allows the entire process to be conducted in a much smaller system carrying only a fraction of the chromatography media used in a standard batch process. When used in larger scale applications, BioSMB technology can eliminate the need for packing skids, large stainless steel columns, and other support infrastructure. This results in a smaller overall footprint and a more scalable configuration. While competitive systems use a complex set of valves, the BioSMB technology uses an integrated valve cassette specially designed and patented as a single-use component. The new valve system eliminates the need for a difficult cleaning validation process.

The ability to use up to 16 columns with the BioSMB PD system means that it supports the broader application base of capture and polishing steps such as in hydrophobic interaction chromatography (HIC), size exclusion chromatography (SEC), mixed mode chromatography, as well as combinations of these technologies. The availability of a greater number of columns provides a particular benefit to applications with feeds that have been concentrated and those with production titers greater than 5 g/L.

Compared with competing systems, the BioSMB system is designed to offer far greater capabilities than those that can be provided by simple chromatographic media utilization optimization. As an example, the position of the buffer selection valves in the BioSMB PD system is very different from other systems and contributes directly to process optimization in multiple ways. Because each column used with the BioSMB PD system is assigned a series of valves arranged in a single-use array, the result is that every pump is delivering one buffer throughout the entire process and will never undergo composition gradients and | or wash steps. In addition, the system volume that actually is subject to composition changes in the BioSMB PD system is minimized well beyond that of other system designs. This eliminates many of the uncertainties associated with scale-up | scale-down, validation and process control.

Technical Data

General Specifications

Width | Depth | Height	120 | 73 | 58 cm (47.2 | 28.7 | 22.8 in.)
Weight	170 kg (375 lbs)
Electrical Requirements	115 V or 230 V
Required Air Supply	At least 1 barg (14.5 psig) above process pressure

System and Valve Cassette Specifications

Flow Rate Range	1 mm cassette: Up to 50 mL/min 3 mm cassette: Up to 100 mL/min
Inlets	Maximum 8 (including loopback)
Outlets	Maximum 6 (including loopback)
Columns	Up to 16
Maximum Operating Pressure	10 barg (145 psig)

Sensor Specifications

Pressure	Linear up to 13.8 barg (200 psig)
Ultraviolet-Visible (UV-VIS)	Four UV-VIS sensors each with wavelengths in 210 – 850 nm range
pH	Range of 0 – 14, accuracy of 0.1 pH unit (from 2 to 12)
Conductivity	Range: 1 µS/cm – 200 mS/cm Accuracy: 0.25 mS/cm (range 10 – 200 mS/cm) 3.0 µS/cm (range 0 – 100 µS/cm)

Pump Specifications

Maximum of 7 pumps

Stepper motor belt drive dual piston pumps, PEEK fluid path, automated piston seal wash, double capsule check valve with additional anti-siphoning valve

Accuracy	0.5 – 50 mL/min ± 5% (with 1 mm cassette) 0.5 – 100 mL/min ± 5% (with 3 mm cassette)

Ordering Information

Part Number	Description
BIOSMB-PD-LD100	BioSMB PD 1 mm process development system
BIOSMB-VC-1	BioSMB PD 1 mm process development valve cassette only
BIOSMB-VC-3	BioSMB PD 3 mm process development valve cassette only
BIOSMB-TK-1A	1 mm tubing kit - LD100 pumps only with 1 mm cassette
BIOSMB-TK-3A	3 mm tubing kit - LD100 pumps only with 3 mm cassette
BIOSMB-PH	BioSMB pH probe for both sizes of housing
BIOSMB-PH-1	BioSMB pH housing for 1 mm setup
BIOSMB-PT-1	BioSMB pressure transducer
BIOSMB-COND	BioSMB conductivity sensor
BIOSMB-UV-1S	BioSMB UV flow cell, 2.5 mm optical path
BIOSMB-UV-1L	BioSMB UV flow cell, 10 mm optical path
BIOSMB-PD-CH	Pack of column holders

Sales and Service Contacts

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DIR: 2578756-000-00
Status: 04 | 2020