

BioSMB™ System

Continuous Disposable Multi-Column Chromatography

BioSMB™: An Overview

Tarpon Biosystems has developed BioSMB™, the first Simulated Moving Bed (SMB) chromatographic systems designed to bring the proven manufacturing efficiencies and economic benefits of SMB to bioprocess. BioSMB™ is enabled through the use of proprietary disposable product contact elements, including a specially designed valve array, which uniquely ensure the sanitary operation necessary in biopharmaceutical manufacturing. BioSMB™ can replace most batch chromatographic steps while maintaining current separation chemistries and buffer systems. Improvements in productivity, flexibility in manufacturing configurations, decrease in manufacturing facility footprint and buffer tank requirements, as well as overall cost savings, are some of the reasons continuous approaches are used.

Designed for Disposability and Scalability

To meet the demands of multi-product operation and ever increasing titers, BioSMB™ technology overcomes the hurdles of system complexity, validation, and cleanability through a novel modular, disposable format. This modular design offers full flexibility to configure the system to the process requirements from process development to processing the output of a 20,000L bioreactor. The disposable, integrated valve array can service up to 16 columns or devices and does so without adding significant complexity to the system.



Fig. 2 Integrated 16 column position BioSMB™ valve cassette



Fig. 1 BioSMB™ System

An Open Platform for Downstream Processing

BioSMB™ provides an open platform for fully disposable continuous countercurrent purification. The BioSMB™ platform enables a fully disposable fluid path by using a bank of much smaller, multiple separations devices to achieve the same or better separation as a large batch process. The BioSMB™ may be run with BioFlash DFC™ (disposable-format chromatography) columns, which are available pre-packed with virtually any commercially available bioprocess media. The BioSMB™ also enables the use of functionalized membrane adsorbers and monoliths in capture mode using this multi-device format. The option to pack your own columns or run any manufacturer's separations products complete the open platform approach.

Continuous Purity™

Disposable Protein A?

Many process engineers ask, “Can BioSMB™ be used in the capture step of a Monoclonal Antibody process and if so, how is it economically feasible to dispose of Protein A media?” The answer lies in the understanding of how the process is developed and run in BioSMB™ mode. When running in a countercurrent multi-column format, each small column sees the same exact process steps that a batch column would go through multiple times. In BioSMB™ it’s possible to size the system such that the Protein A columns are each cycled to their useful life and are therefore disposable. The installed media volume is significantly decreased in this multi-column approach. For example, 100 cycles may be reached on each small column, providing substantial savings and enabling disposability.

Benefits of BioSMB™

Tarpon Biosystems BioSMB™ continuous downstream processing systems, regardless of scale, share common elements:

- Multi-column approach enables economic, fully disposable process including the capture step
- Significant savings in buffer consumption and chromatographic media
- Fully disposable downstream allows dedicated flow paths for multi-product facilities
- High titer processes fit into existing facilities
- Sizing is volume driven; higher titers can be accommodated by adding disposable columns
- Lower fixed cost and faster start up
- No storage or under utilization of chromatographic media (especially Protein A in clinical settings)
- Suitable for CGMP manufacturing

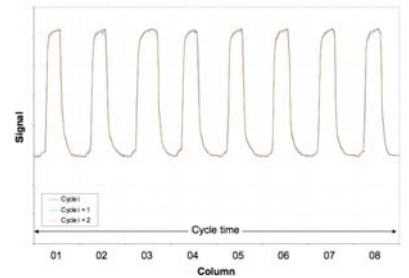


Fig. 3 BioSMB™ Data Trace

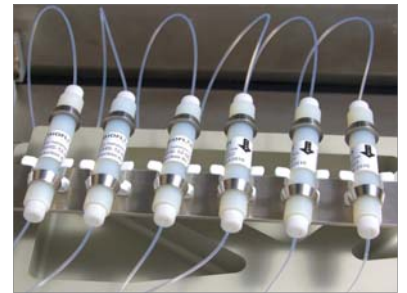


Fig. 4 BioFlash DFC™ 12 Columns

BioSMB™ Specifications

General Specifications

Width / Depth / Height	47.2 / 29.5 / 47.2 in 120 / 75 / 120 cm
Weight	756.8 lbs / 344 kg
Electrical Requirements	2 power 115 VAC or 230 VAC
Air Supply	At least 1 bar above process pressure

Valve Cassette Specifications (1 & 3 mm cassette)

Capacity	Up to 50mL/min (1 mm) Up to 500mL/min (3 mm)
Inlets	Max 8
Outlets	Max 6
Columns	Max 16
Max operating pressure	145 psi / 10 bar

Sensor Specifications

Pressure	Linear up to 72.5 psi / 5 bar
UV-VIS	Four UV-VIS sensors each with wavelengths in 200-850 nm range
pH	Range of 0-14; accuracy of 0.1 pH unit (from 2-12); 88 µL cell volume
Conductivity	Range: 1µS/cm - 200mS/cm Accuracy: 0.25mS/cm (range 10-200mS/cm) 3.0µS/cm (range 0-100µS/cm)
Pumps	Maximum of 7; cover a range of 0.5-500 mL/min; variety of pump heads can be installed depending on the application

info@tarponbiosystems.com
www.tarponbiosystems.com