



QUANTASEP® Trusty Elite 15000

Chromatography System Plus Inline Buffer Blending

Overview

Sepragen QuantaSep chromatography Trusty Elite systems are designed to automate the purification of biopharmaceuticals in a GMP environment, all the way from inline buffer Blending (IBB) to chromatography. The QuantaSep Trusty Elite 15000 System enables the performance of both flexible chromatographic functions as well as independent precision buffer dilution functions in a single system. Thus, for instance, chromatographic columns can be run at up to 15 LPM by using 2X – 10X concentrated buffers.

Chromatography

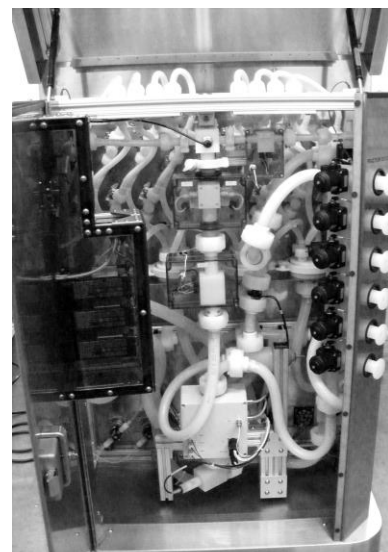
The QuantaSep® Trusty Elite 15000 is the Trusty 15000 plus IBB System in an integrated compact process chromatography system platform capable of providing an operating flow range of 150ml – 15000ml/min. It is of sanitary design and has capabilities of all standard chromatography functions like manual or automatic buffer switching, gradient formation, air ejection, conductivity and pH sensing (pre- and post-column), UV sensing, forward and reverse column flow and fraction switching, based on process parameters. The system provides alarms in the event of overpressure, air or leaks. The system automatically generates reports of batch history, sensor data and all alarms and events for GMP reporting.

Buffer Blending

In addition, it has the powerful capability of enabling inline dilution and auto pH adjustment of concentrated buffers. The QuantaSep Trusty Elite 15000 can enable you to make buffers at point of use starting with buffer concentrates. One can scale up in-house buffer making capacity easily by working with buffer concentrates and diluting on line or outsource concentrated buffer making and then leverage making larger volumes through in-house dilutions. This saves on space and labor and avoids unnecessary stoppages in production.

System Design

The QuantaSep® 15000 plus IBB is a fluid handling and control device, composed of two modules, the fluid module and the electronic module, integrated into a single unit, approximately 36" wide by 34" deep by 56" tall. . The PC/PLC based controller operates on a MS Windows 10 Professional environment (operating system software specifications are likely to change in line with current standards) using a SCADA software with SQL database. The software allows the control and monitoring of the QuantaSep® system, acquisition and storage of data and data processing and export capabilities. The computer on which the control software resides is separate from the system to provide the option of remote control, up to 25 feet away.



- Flow Rate range of 0 – 15 LPM
- Complement of 4 Positive Displacement Pumps for pumping sample, WFI, buffers, acid and base
- 4 Inlet, 4 Outlet; column up flow/ down flow diaphragm valves
- Precision flow meters, static in-line mixers and sanitary tubing and connectors
- 3 Conductivity Sensors monitor conductivity of concentrated and diluted buffers as well as post column operation
- Additional Pressure, Air, Leak and UV detectors
- 3 pH monitors help regulate pH of buffers pre- and post-dilution as well as monitor post column elution
- Manual and Automated runs with easy to use 21CFR pt. 11 compliant software
- Buffer and fraction changes based on time, volume and sensor based parameters.
- Dilute buffers 2X – 10X
- Generate Automated cGMP Reports.
- Full Validation Package, FAT/SAT & IQQ. Onsite Commissioning and Service

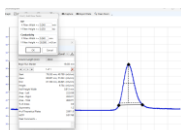
QuantaSep® Trusty Elite 15000 Operation

The PC-controlled chromatography system is 21CFR Part11 compliant and includes:

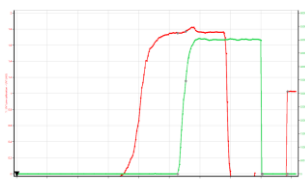
- An interactive P&ID screen for manual operation
- Automated screen for sequenced buffer dilutions based on time, volume or other parameters
- Multiple cycling capability for multi-batch runs or large buffer preps
- A trend display that shows currently running sensor data along with an historical overlay
- Alarm and Event summaries

Chromatography

Multiple standard Purification protocols can be stored and run including data analysis, such as Asymmetry and HETP calculations.

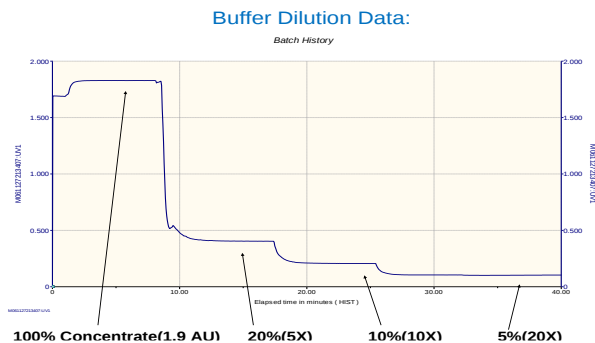


See below an Antibody capture from cell culture.



Buffer

Buffer Blending is possible from 300 ml/min - 15 LPM with a better than 3% accuracy. Buffer blending can be provided by setting the relative pumping speeds of Pump A and Pump B to the desired dilution or blend level. The WFI/Sample and concentrate pumps have a flow rate range of 150 ml/minute to 15 LPM and the acid and base pumps have flow rates of 0 - 100 ml/minute. See below up to a 20X dilution.



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Chromatography Plus Buffer Blending System Specs

- Dilution Range 2X – 10X
- Pump A 4 user selectable Valves for samples/WFI
- Pump B 150 ml/min – 15 LPM
- 4 user selectable buffer concentrates
- 1 Acid Pump 0 – 100 ml/min
- 1 Base Pump 0 – 100 ml/min
- 2 Flow Meters 0 – 20 LPM (Optional)
- 6 User Selectable Outlets
- 2 In-line Mixers
- Column Manifold Forward Flow, Reverse Flow, Bypass
- Sanitary and Cleanable Flow Path

Sensor Specification

- Conductivity 1 Range 0-200 ms; $\pm 5\%$ F.S.
- Conductivity 2 Range 0-20 ms; $\pm 5\%$ F.S.
- 3 pH Sensors Range 1-14; ± 0.2
- Pressure Sensor Range 0-100 psi; ± 1 psi
- UV Post Column 254 & 280 nm; Range 0 – 2 Au

Wetted Materials of Construction

- Braided, silicon tubing
- Polyethylene, polypropylene valves
- PTFE diaphragms; glass/quartz/316L stainless steel sensor components
- Compatible with 1N NaOH

General

- Small Footprint 36" x 34" x 56"
- Pressure Rating 50 psi
- Pneumatic Air 90 psi
- Power 20 Amps/115 VAC or 10 Amps/230 VAC
- Software PC/PLC Based SCADA
21 CFR Pt 11 Compliant
- Panel NEMA 4X Enclosure
- Connections 1" Tri-clover
- Casters (4) Plastic Swivel & Locking

Warranty, Installation & Support

All QuantaSep Systems are backed by Sepragen's one year limited warranty. Installation and training, along with IQ/OQ are performed by Sepragen Service Group. Preventive Maintenance service is available. Validation support packages are also available.

To learn more call:

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