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Product Datasheet

AliquoT[®] Fill Drain System for Pallet

Automated Filling and Draining of Large Volume Bulk Drug Substance

Product Information

AliquoT[®] Fill Drain System for Pallet is an advanced, automated system designed to accurately fill and drain bulk drug substance (BDS) to and from palletized Celsius[®] FFT containers. The system can accommodate a broad volume range of Celsius[®] FFT containers, making it an easy and scalable solution for filling and draining volumes up to 300 L per pallet, and batch size of up to several thousands of liters. AliquoT[®] uses Biobrain[®] as the automation platform that provides an intuitive interface with recipe driven processing for easy operation, with the option for integration to DCS/MES. AliquoT[®] Fill Drain System for Pallet ensures consistent and repeatable filling and draining while maximizing product recovery from the entire fluid path. Qualified single-use assemblies featuring configurable connections, disconnection, pre-filters, filters, and sampling capabilities make the system suitable for diverse process needs.



Features and Benefits

- Scalable volumes (Celsius® FFT 6 L, 12 L, and 75 L on a Celsius® FFT Pallet)
- Single-use, predefined, and configurable AliquoT^{*} transfer sets
- Accurate filling (± 100 g)
- High product recovery (99.98% for a 1,200 L batch)
- Multi-pallet sequential filling or draining allowing > 2,000 L batch processing
- Automated tilting of containers to maximize product recovery while draining Celsius® FFT containers
- Streamlined cGMP compliance with Biobrain[®]-enabled automation

Applications

AliquoT° Fill Drain System for Pallet is designed to streamline the dispensing process of BDS into palletized single-use Celsius° FFT containers. The Celsius° FFT Pallet can accommodate Celsius° containers in a scalable range of volumes: 6 L, 12 L, or 75 L. AliquoT° Fill Drain System for Pallet can handle batch volumes above 2,000 L with high accuracy and consistent filling, ensuring that your cold chain management steps always remain within validated tolerances.

With automatic draining capabilities enhanced by tilting of Celsius[®] FFT containers, AliquoT[®] Fill Drain System for Pallet simplifies the transfer of drug substances into the formulation vessel at drug product location.

AliquoT[®] Pallet is part of the Celsius[®] FFT Platform that includes single-use containers and equipment for freezing, thawing, mixing, and draining, creating a fully integrated solution for large-volume commercial manufacturing.

Accurate and Consistent Filling

AliquoT[®] Fill Drain System for Pallet is designed to achieve consistent filling of Celsius[®] FFT containers, with an accuracy of ± 100 g. This standardized solution can be expanded to multiple sites, maximizing consistency and quality across all production sites.

Quick and Easy Installation

Celsius® FFT and AliquoT® transfer sets are purposefully designed to ensure a secure fit onto the equipment while reducing the number of connections and manual interventions required. Moreover, AliquoT® transfer set packaging has been optimized to simplify installation, and our equipment has been engineered to meet ergonomic requirements for ease and safety during installation. To further enhance ease of use, our color-coded visual indicator system supports an intuitive, fast, and error free set-up prior to filling, ensuring a streamlined process from start to finish. Installation of the pumping, distribution, and container transfer sets and interaction with HMI prior to filling should take no longer than 30 minutes with a single operator. Once installed, filling four palletized Celsius® FFT 75 L containers with 300 L of BDS can be completed in just one hour.

Ready-To-Use Configurable Single-Use Transfer Set

AliquoT[®] transfer sets are predefined to fit perfectly to AliquoT[®] Fill Drain System. They are configurable to adapt to process requirements for connection | disconnection, filters, and sampling. There are three different transfer sets:

- 1. The pumping transfer set is installed onto the control tower and will remain in place during the complete batch filling. It connects to the supply (filling) or receiving (draining) vessel on one end and to the distribution Transfer Set on the other end. Filtration cartridges can be included in the pumping transfer set (one pre-filter and/or one filter or no filter) as well as the sampling capabilities. Sampling of product being transferred can be taken in different ways:
 - Using sampling bags already pre-connected to the Transfer Set
 - By aseptically biowelding sampling bags
 - By connecting a sampling bag to an aseptic connector on the Transfer Set
 - Sampling via clave (non-sterile sample)

Figure 1: Pumping Transfer Set With Filter (Example With One 20" Filter, 10 Sampling Bags, and 1 Clave)



2. The distribution transfer set is installed onto the weighing module and is connected to the pumping TS on one side and Container TS on the other side. It allows the connection of multiple container transfer sets thanks to multiple connections, supporting the sequential filling of multiple Celsius® FFT Pallets.

Figure 2: Distribution Transfer Set (Example With 8 Aseptic Connectors Supporting the Filling of 32 Celsius® FFT 75 L Containers or 40 Celsius® FFT 12 L or Celsius® FFT 6 L Containers)



3. The container transfer set is installed onto the valve tower and is connected between the distribution TS and the FFT container filling or draining tubes. Once a pallet is filled or drained, the transfer set is disconnected and replaced by a new one in cases where multiple pallets are filled or drained sequentially.

Figure 3: Container Transfer Set (Example With 4 Aseptic Connectors to Connect to 4 Celsius® FFT Containers)



High Product Recovery

Air purging is employed to recover as much product as possible from the entire fluid path to reduce product loss and enable significant cost savings. Instead of using traditional recovery bags, the product is transferred into the Celsius[®] FFT containers on the pallet (weight of the recovered product into the containers is accounted for automatically). As a result, for a batch of 1,200 L, up to 99.98% of the product is automatically recovered, ensuring maximum yield.

Ready for cGMP

Biobrain[®]-powered products provide a rich functional scope satisfying all requirements to be implemented in regulated cGMP environments. Development and testing of the software modules are performed according to the GAMP life-cycle approach, enabling the system to apply to GAMP 5 Category 4 requirements for configurable standard software (DIN ISO-9000 quality management). A 21 CFR Part 11 assessment report is provided along with the documentation package.

Among the functionalities tailored for the deployment of Biobrain[®]-powered products in regulated environments are advanced access control, audit trail, alarms & event management, and batch management.

Seamless Integration

Biobrain[®]-powered process units can be deployed and operated in diverse IT infrastructures. The systems do not only provide interfaces to file servers, NTP servers for time and date synchronization, or domain servers for authentication, but also provide a powerful OPC UA interface. The latter enables connection to DCS, SCADA, Historian, or MES solutions from various providers, such as Sartorius or Siemens.

To learn more about the variety of integration opportunities, please refer to our separate application note covering all possible integration scenarios.

Unit Recipe Control

To further automate bioprocesses and reduce operator errors, recipes can be created and run to schedule the execution of equipment phases. Unit recipes are tailored to execute the process of a single process unit and are created using BioPAT[®] MFCS as a standalone tool, available for installation on any office PC.

BioPAT® MFCS recipe editor for Biobrain® allows users to create comprehensive unit recipes using sequential and/or parallel branches, as well as jumps. User guidance steps and decision phases can be included to reduce operator failures. Recipes can be transferred to the Biobrain®-powered instrument for local execution or remotely from BioPAT® MFCS.

Figure 4: Installation of Palletized Celsius® 75 L Containers Onto Aliquot® Fill Drain Using Celsius® FFT Lift



Technical Specifications

AliquoT[®] | Control Tower

Weight	225 kg 496 lbs
Dimensions [L×W×H]	820×770×1,800 mm 32.2×30.3×70.8 in
Mobility	Configurable: 4 casters with breaks or 4 NGI seismic feet
Operator Interface	17" touchscreen. Display resolution 1920 × 1080 px
Different User Level Login	Four levels: Operator - Supervisor - Service - Administrator
Auxiliary Power Outputs	4×24 VDC, 10 A
Mounting Configurations	4×DIN rails for mounting accessories in multiple configurations
Peristaltic Pump	Watson-Marlow 620-Series
Valves	Two pneumatic Acro pinch valves
Barcode Scanner	Included
Label printer	Included
Provision for Filter(s) and Filter(s) Flushing	Included (up-to 20" pre-filter and filter cartridges)
Provision for Multiple Sampling	3 types of aseptic sampling possible: Biowelding or aseptic connection or 2 to 12 bags of volumes 30 or 100 mL
Visual & Audio Indicators	Stack light: 4×light colors (white, green, blue, and red), with horn
Enclosure	IP54 and NEMA3R rated
Main Material	304 L Stainless Steel, Number 4 finish
PLC Туре	Siemens SIMATIC S7-1500
Power, Main Disconnect	12.5 Amp Main Disconnect, with protective interlock
Cleanroom Compatibility	ISO 7 I Grade C
Compliance	UL, (CE in progress)

Facility and Utility Requirements

Power Supply	
Power I Frequency I Consumption	100 - 240 VAC single phase 50 or 60 Hz max 0.5 kW
Gas Supply	
Instrument Air	Min. 7 bar I 100 PSI
Process Air	Min. 2 bar I 30 PSI
Environmental Operating Requirement	
Ambient Temperature	20 °C ±2 °C
Relative Humidity Range	40-60%

AliquoT[®] | Pallet (Weighing Station)

Weight	360 kg 793.7 lbs
Dimensions (L×W×H)	2,050 × 1,010 × 1,660 mm 80,7 × 39,8 × 65,4 in
Material	Stainless steel
Tilting	For draining containers weighing platform can tilt 15° leftward, rightward or forward
Pallet for Containers	Euro pallet 1,200×800 mm I 47.2×31.5 in
Valves	Twelve pneumatic Acro pinch valves
Floor Mounting	Weighing Station can be bolted to floor— feet can be adjusted for non-level floor and weighing platform can be leveled with height adjusters on the four corners
Safety	 2 × Safety Laser Scanners for 360-degree protection around weighing Station, used during tilting 2 emergency stop buttons (one on each valve tower)
Possible Container Loads	 Palletized Celsius[®] FFT 75 L – Up to 4 container (300 L) max. per pallet Palletized Celsius[®] FFT 6 or 12 L – Up to 10 containers (60 L or 120 L) max. per pallet Several pallet can be filled drained (up to 8 with standard tranfer sets) in a row to adapt to batch size
Enclosures	IP54
Cleanroom Compatibility	ISO7 / Grade C
Compliance	UL, (CE in progress)

Process Control (Sensor and Measurement)

Pressure Sensor, Single-Use		
Туре	BioPAT [®] pressure sensor	
Measurement range	0-4 bar (g)	
Fluid Sensor Switch		
on/off	8 units	
Scale		
Туре	4×Minebea 250 kg Novego-series load cells	
Measurement Range	Max. load capacity 450 kg	
Recalibration Function	Scale must be recalibrated once every 12 months	
Filling Accuracy	±100 g	

Communication I Control Tower Interface

Remote Interface	OPC UA
Ethernet Ports	1 PLC, 1 HMI, 1 Valve Tower, Printer, 1 spare
Analog IN	 2 pressure transmitters
	 2 tilt angle sensor
	 1 instrument air pressure
	 1 process air pressure
	 2 spares
USB	Barcode scanner, 1 spare

Dimensions

Control Tower





Weighing Station



Operational Dimensions

AliquoT[®] for Pallet Space Requirements



Peripherals and Accessories

Celsius® FFT Platform Equipment

Celsius® FFT 75 L container, pallet and accessories are designed to be used with the following Sartorius equipment for cold chain management of BDS in large volume.





Celsius® FFT Lift

Containers



Handle | move palletized Celsius® FFT containers and load | unload Celsius® FFT Platform equipment and AliquoT[®] Pallet



4 × Celsius® FFT 75 L Containers on Celsius® FFT 75 L | Pallet Base

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USA

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