SciLog® SciPure FD System

- bulk filtration & dispense
- fully automated processing
- fully enclosed sterile flow path

The SciLog® SciPure FD System is an automated single-use system for the bulk filtration and dispense of biopharmaceutical products into either bags or bottles.

Both the hardware and the consumables have been designed in tandem to minimize product losses and maximize yield.

As the flow path is completely enclosed, the two operations of filtration and dispensing can be performed in areas of lower classification, thereby eliminating the need for vertical laminar flow cabinets.

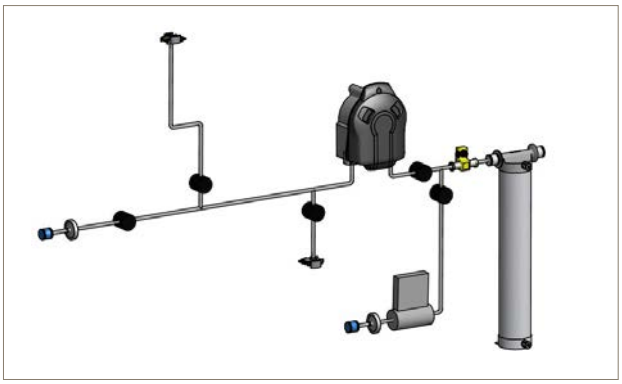
The SciLog® SciPure FD System is designed and built to ensure containment, protecting the both the operators and the product.

Note: SciLog®, SciPure® and SciPres® are registered trademarks of Parker Hannifin Corporation.

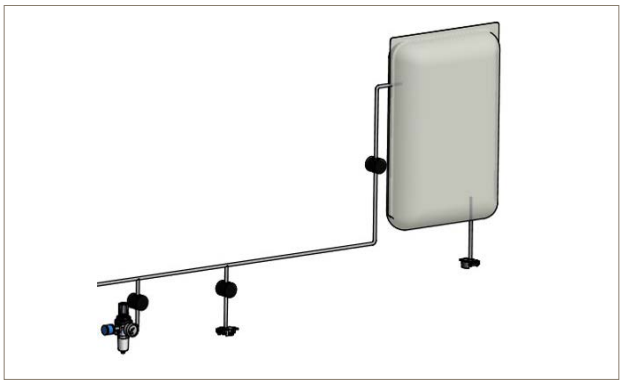
Features and Benefits

- Automated system for filtration and dispense of bulk active pharmaceutical ingredients.
- Up to 9999 receiving containers per batch
- Standard sterile flow paths
- Option to specify ten samples during the dispense process
- In line pre and post use integrity testing
- Fully enclosed processing
- Barcode reader for manifold tracking (optional)
- Automated filter flushing and conditioning
- Load cells located under receiving containers ensuring direct measurement for high dispense accuracy
- Calibrated SciPres® Pressure Monitors ensure validated pressure limits are not exceeded
- Recipe driven process with industrial standard HMI and PLC
- Fully programmable alarms and interlocks to protect the product and the process
- Four standard dispense modes
- Integrated label printer with labels suited to cryogenic storage
- Reverse flow and purge options to maximize product recovery
- Configurable dual dispense rates minimize dispense time while maximizing accuracy

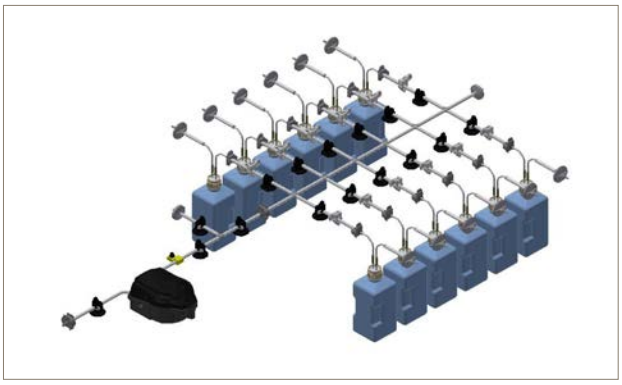
Standard Assemblies



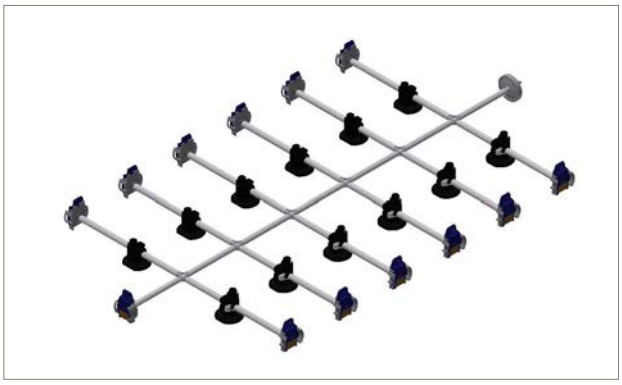
Filtration Manifold
- Vendor neutral filters
- In-situ flushing conditioning and integrity testing



Header Bag
- Ensures efficient filling process
- Optional (system can be fed directly from off skid bag or tank



Dispensing Manifold
- Bags or bottles
- Minimal connections



Open Manifold
- Allows any configuration
- Different volumes

Validated Shipping Solution

While the SciLog® SciPure FD System can be used with either bottles or bags in a wide variety of sizes to meet individual process requirements, Parker have designed and fully validated a shipping solution to compliment and extend the system's capabilities.

Drawing on extensive material science knowledge within Parker, the unique bottle design offers manufacturers confidence that their bulk drug product will arrive at its final destination without contamination. Based on customer feedback, Parker also developed an anti-foaming device that both eliminates foam and allows for a higher filling speed.

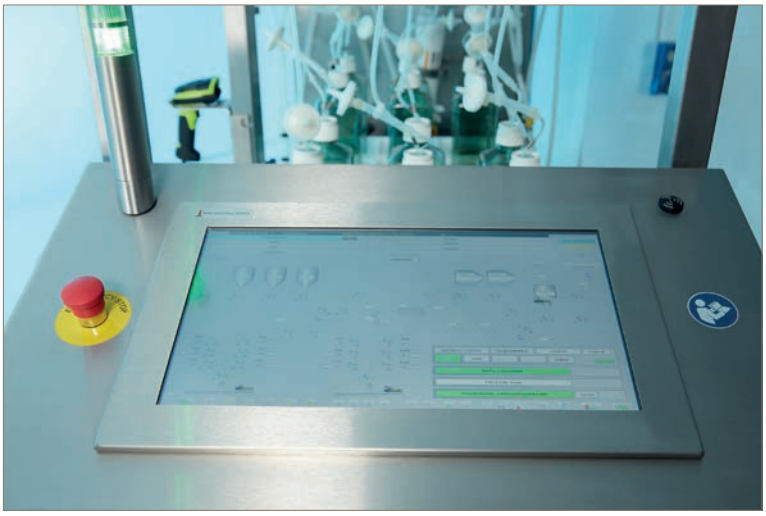
- Material selection based on FMEA study
- Patent pending sealing technology
- Integrity validated down to -89°C
- Wide range of connections available
- Silicone or TPE tubing

- Foaming minimized
- Filling time optimized

- Validated shipping
- Crimped tubing protected during shipping via transport cap

Software

- Recipe driven processing
- Four user access levels:
  - Allows any configuration
  - Different volumes
- Three dispense modes:
  - Manual
  - Semi-automatic
  - Automatic
- Batch records creation and storage
- Audit trail
- User configurable alarms
- Diagnostic monitoring of critical components
- Meets requirements for 21 CFR part 11 and EudraLex Vol 4, Annex 11 compliance
- Tracking of filters and manifolds



Services and Support

FAT
- Included

IQ/OQ
- Standard documentation available
- Execution support available

Training
- Standard user training included
- Custom packages available

SAT
- Standard documentation available
- Execution support available

Maintenance and support
- Standard package available depending on use
- Custom service and support packages available

Specifications

System Detail	
Approx. Footprint	0.9 m (W) x 2.5 m (L) x 2.2 m (H) / 35¨ (W) x 98¨ (L) x 87" (H)
Label Printer	Cryogenic compatible labels
IP Rating	IP 54
Integration	OPC driven communication with third party systems
Material of construction	316L stainless steel (frame and cabinet)
HMI / PLC	19" touch screen
Load cells (Receiving)	2 (0 - 120 kg range)
Load cell (Intermediate Bag)	2 (0 -100 kg combined)
Pump	2 peristaltic (transfer and dispense)
Filling Range (Volume)	50 ml to 20 L
Receiving Containers	Bottles or bags
Filling Points	Maximum of 12 per cycle (batch limit 9999)
Pressure Rating Assemblies	1.2 barg (3.4 barg reinforced section for integrity testing)
Max / Min Flow Rate	0.04 L / min and 12.0 L / min (design flow rate 19 L / min)
Product Recovery	Pump and / or air blow down
Dispense Accuracy	50 g to 100 g (±10%) 101 g to 250 g (±2%) 251 g to 1000 g (±1%) 1001 g to 16000 g (±0.5%) (Accuracy dependent on dispense rates)

Compliance	
21 CFR Part 11	Software enables compliance
EudraLex Vol 4, Annex 11	Software enables compliance
GAMP	Meets the requirements of GAMP 5
CE Mark	Yes
2006/42/EC	Machinery Directive
2014/68/EU	Pressure Equipment Directive
2014/30/EU	Electromagnetic Compatibility Directive
ATEX	No
Recipe Creation	Follows S88 protocol
Validated bottle shipping	ASTM D4169 - Cycle 13 level 11
Sterile Assemblies	Current ISO 11137

Utilities	
Power Requirements V / Hz / Ph	230 / 50-60 / 1
Compressed Air Quality	Minimum ISO 8573-1:2010 [-:4:-]
Air Supply Pressure / Volume	5.5 - 8 barg / <0.2 m^2/hr
Operating Environment Temperature	5 - 30°C
Noise Level	<80 dB (A) at 1 m
Approx System Weight	700 kg

Ordering Information

SciLog® SciPure FD System:

386-FD-440PS-02

Please contact your local Parker representative to discuss your application in detail.

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