Celeros Separations, LLC

APD125 PRODUCT SPECIFICATION

Celeros Separtions designs, manufactures, sells, and services the APD high-speed flow through centrifuges. The Model APD125 is a unique centrifuge that employs automated piston discharge technology. The flexible design of the APD ensures superior separation performance over a range of biological products and this versatility results in efficient separation, high purity, and exceptional yield.

This product specification of the APD Model APD125 includes standard and optional configurations to achieve varying levels of automatic product separation, recovery, cleaning, and sterilization (CIP/SIP) processes along with other customized design options. Please contact APD Holdings at +1-617-512-4547 or email bcarr@celerosseparationsllc.com for more detailed information.

1. General Characteristics of the Model APD125 Separation System

#	Item	Description
1.1	Bowl type	Narrow tubular design.
1.2	Feed	Continuous upstream flow, multiple batch/cycle control.
1.3	Separation	High centrifugal force to separate masses with different densities.
1.4	Clarified liquid output	Low shear near-gravity drain from top of bowl.
1.5	Solids discharge	Automatic piston discharge (APD) method with low shear and full recovery.
1.6	Solids receiver	Integrated receiver or customer-preferred methods such as bags.
1.7	Scalability	From lab, prototype, pilot, to small/medium/large production volumes.
1.8	Cleaning & Sterility	Semi-automatic CIP (Clean-in-Place) and SIP (Steam-in-Place) capable. (SIP option)
1.9	Controls/Software	Local access or remote central command.
1.10	Utility integration	Directly connected with facility or through local supporting modules.
1.11	Quality	Compliance to FDA/cGMP, BPE-ASME

2. Key Performance Parameters

#	Item	Unit	Description	Min	Normal	Max	Comment
2.1	Rotational speed	RPM	+/- 50 RPM accuracy	0		16,900	
2.2	Centrifugal force wall	G's	Specific gravity at bowl wall			20,000	
2.3	Hydraulic capacity	LPM	Using water	0.5		7	Product dependent
2.4	Material Bulk density	g/ml				1.4	Concentrated cells, cell debris, paste, etc.
2.5	Bowl volume	L	Solids holding volume=0.8 x BV			5	
2.6	Separation operating temperature	°C		-4		+40	
2.7	Product temperature change through centrifuge	°C				0	With cooling Product temp & feed rate dependent.
2.8	Internal bowl case pressure rating	Barg (psig)	At 134°C			2 (30)	
2.9	Noise level	dBA	Measured at 1meter distance from machine at full speed			85	Weighted mean average
2.10	Drain of centrate liquid		Zero back pressure	Gravity drain			
2.11	Speed acceleration	Min		1.0 min	2 min		
2.12	Speed deceleration	Min		1.0 min	2 min		
2.13	Discharge time	Min	Discharge full volume	1.0 min	2 min		
2.14	CIP cycle time	Min	Per solution with single sequence including multiple steps (≤80°C)		40		
2.15	SIP: temperature ramp	Min	From room temperature		30		
2.16	SIP: dwell time	Min	At ≥ 121°C		30		
2.17	SIP: cool down time	Min	Cool down to 60°C		60		

3. Utility Requirements for Facility

#	Item	Unit	Description	Min	Normal	Max	Comment
3.1	Bowl case cooling water: flow rate	LPM (gph)		0.6 (10)		3.8 (60)	Process dependent
3.2	Bowl case cooling water: temperature	°C		4		10	
3.3	Bowl case cooling water: pressure	Barg (psig)				10 (150)	
3.4	CIP solutions: flow rate	LPM	Requires Intermittent supply	30		40	
3.5	CIP solutions: pressure	Barg (psig)	Requires Intermittent supply			4 (60)	
3.6	CIP solutions: temperature	°C	Measured by feed inlet RTD			80	
3.7	SIP steam: pressure	Barg	To achieve ≥ 121°C inside of centrifuge		2		
3.8	SIP steam: flow rate	Lb/hr	At 1.7barg (25 psig)	100			
3.9	Air		Instrument-quality, non-lubricated, supplied at 6 – 8 barg (90 to 120 ± 5 psig) Recommended setting at filter-regulator is 6 barg (90 ± 5 psig) Continuous flow: 1.70 Nm3/Hr (<1.0 SCFM) Maximum flow: 10.2 Nm3/Hr (6 SCFM) Air Blow: 15.3 Nm3/Hr (9 SCFM)				
3.10	Power for centrifuge		230 VAC, 3 phase,50- 60 Hz Total system amperage: 30A at 230VAC Requires Category II dedicated supply				

#	Item	Unit	Description	Min	Normal	Max	Comment
			circuit with a remote means of power interruption that is lockable in the OFF position.				

4. Process Connections (The following are sanitary clamp fittings unless otherwise noted)

#	Items	Size (inch)	Comment
4.1	Seal / Case cooling inlet	½	
4.2	Seal / Case cooling outlet	½	
4.3	Centrate outlet	½	
4.4	Centrate tank drain/sample (manual valve)	½	
4.5	CIP Cap outlet	1 ½	
4.6	CIP Cap CIP inlets	½	
4.7	Condensate drain outlet	1 ½	
4.8	Feed inlet	½	
4.9	Manifold drain outlet	1 ½	
4.10	Residual liquid outlet	½	
4.11	SIP manifold inlet	1	
4.12	Solids tank outlet	1 ½	
4.13	Case vent	½	

5. Automation and Safety Interlocks

5.1 Programmable Logic Controller (PLC)
- 5.1.1 Siemens PLC
- 5.1.2 HMI, Operator Interface: Color Touch Screen

5.2 Safety interlock Based on field inputs from:

Bearing temperature	Bearing coolant temperature	Case pressure	Bearing coolant flow
Coolant temperature	Solids Valve position	Air seal pressure	Air seal flow
Drive faults	System air pressure	Emergency stop button	Valve actuator pressure switches
Piston position	Vibration	RPM signal	Coolant water Reservoir level

6. Materials

6.1 Process contact
- 6.1.1 Metal: 316L/317L, 17-4 PH stainless steel, hard chrome AMS-QQC-320, Ti-6AL-4V titanium (with 3.1 certificate)
- 6.1.2 Surface finish: Interior: Ra 0.4 μm or better, electro-polished / Exterior: Ra 0.8 μm or better
- 6.1.3 Elastomers: EPDM, PTFE & Silicon
- 6.1.4 Other PEEK & Glass

6.2 Non-process contact
- 6.2.1 Metal: 303/304 or better
- 6.2.2 Surface finish: Ra 3.2 μm or better

7. Physical Weight and Dimensions

7.1 Example working area for standard machine configuration (actual area requirements dependent on final machine configuration)
- 7.1.1 Dimensions *: 3,050 mm height x 2,625 mm width x 1,550 mm depth (assuming 900mm wide working space from machine)

7.2 Centrifuge with frame & optional, solids receiver
- 7.2.1 Total Weight 1125 Kg approximate + 150 Kg empty solids receiver

7.2.2 Dimensions 2,150 mm height x 1,725 mm width x 650 mm depth

7.3 Maintenance lift cart (option)

7.3.1 Total Weight 180 Kg (397 lb)

7.3.2 Dimensions 1,600 mm height x 838 mm width x 850 mm depth

*dimensions and weights can vary depending on actual limit of supply

8. Model APD125 Machine Configuration Matrix

8.1 The Model APD centrifuge can be configured for specific applications and installations.

#	Module	Component	Standard	Option	Comment
8.1	Centrifuge	APD125	X		5 liter bowl
8.2.1	Cleaning and Sterilization	CIP multi-inlet manifold	X		
8.2.2		SIP manifold and sub-frame		X	
8.2.3		CIP/SIP cap (in lieu of solids receiver)		X	Stainless steel; 18kg or 39.5 lbs
8.3.1	Solids receiving	Solids receiver (20L)		X	20 Liter working volume
8.3.2		Solids receiver (40L)		X	40 Liter working volume
8.3.4		Mixer		X	Process dependent
8.3.5		Single-use Bag		X	
8.4.1	Automation	High Voltage Panel Rated NEMA 4X with 230 VAC, 3 Phase,50- 60 Frequency supply requirement	X		Direct connection with facility or through local supporting element
8.4.2		Siemens: PLC S7-1500	X		
8.4.3		Siemens: Comfort Panel TP1500	X		HMI: color touch screen, all information displayed in English
8.4.4		Communication for remote access	X		
8.4.5		Data collection of Operation parameters		X	
8.4.6		Process control valves and actuators	X		Feed back through pressure switch and mechanical witness indicator on GEMU actuator valves
8.5.1	Flow Systems	Feed Control	X		Feed pump, Qattro type with flow meter
8.5.2		Centrate Pump	X		Qattro type

#	Module	Component	Standard	Option	Comment
8.5.3		Residual Pump	X		Qattro type
8.6	Centrate & Residual Tanks	5 liter, with sight glass, CIP spray ring, Level sensor	X		
8.8.1	Analytic tools	Mass flow meter	X		
8.8.2		Conductivity meter		X	
8.8.3		Turbidity switch	X		
8.9.1	Location and Start-up	Maintenance lift cart		X	
8.9.2		Tool kit		X	
8.9.3		Start-up Elastomers Kit		X	
8.10.1	Documentation	cGMP packages		X	
8.10.2		System documents (P&ID, GA)	X		Need to confirm custom-design level.
8.10.3		Electrical schematics	X		
8.10.4		FAT protocols	X		
8.10.5		Operator's manual (English)	X		Optional Translation services
8.11.1	Maintenance	Contract		X	
8.11.2		Spare Parts/Critical Stocking Parts		X	
8.12.1	Regulatory and standards compliance	FDA 21 CFR Part 11		X	
8.12.2		ASME/BPE 2012	X		
8.12.3		SI Units (International Standards)	X		
8.12.4		ISA – Symbols	X		

9. Notes

1: More detailed system component description is available in response to a user requirement specification (URS).

2: Product specification and description are subject to change without notice.