



Allegro™ 200 L Single-Use Mixer



Robust, easy-to-use, single-use mixers provide scalable performance to 'stir your imagination'

Mixing is a critical operation within biopharmaceutical processes for many applications ranging from buffer and media preparation to final formulation. The Allegro single-use mixer is part of Pall's expanding range of Allegro products and services providing integrated process solutions throughout the drug production process. The Allegro mixer combines critical requirements for single-use technologies, such as extreme ease-of-use, with established criteria for robust engineering principles for mixer design to deliver the ultimate in mixing performance.

The mixer bag film is the same as standard Allegro 2D and 3D biocontainer products – Pall provides consistent materials of construction for systems used anywhere from small scale pre-clinical to full scale production batches, reducing the burden of validation and requalification.

When you need repeatable high performance mixing, with the flexibility to deal with a wide range of applications and solutions, in a system which is extremely easy-to-use, then look no further than the Pall Allegro mixer.

Applications

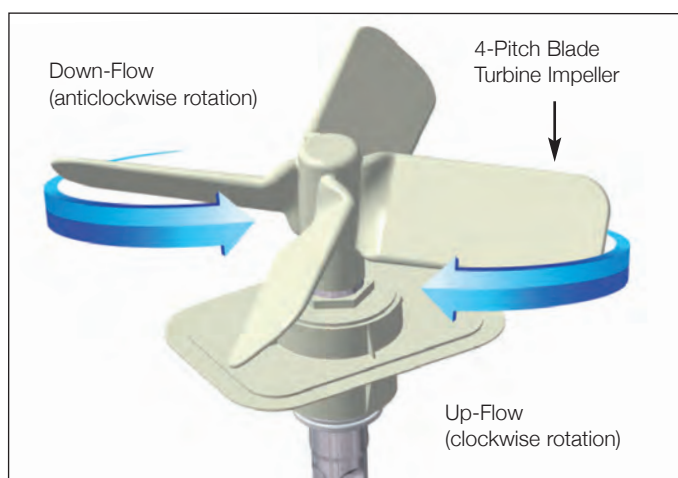
The Allegro 200 L mixer is designed to provide exceptional mixing performance for a wide range of applications from upstream through the downstream process to formulation and filling. Potential applications include:

- ▶ Upstream media preparation
- ▶ Downstream buffer preparation
- ▶ Downstream product formulation mixing
- ▶ Drug formulation mixing

In addition to the mixer, Pall also offers a wide range of complimentary technologies within the Allegro single-use platform (such as filters incorporating state-of-the-art membranes and sterile connection and disconnection devices) providing fully validated, integrated processing solutions from upstream to final formulation and filling. The high performance mixer lends itself especially well to difficult mixing applications (mixing dense powders or high viscosities), applications requiring repeatable, fast mixing performance, or where biologicals sensitive to shear are being mixed.

Product Features and Benefits

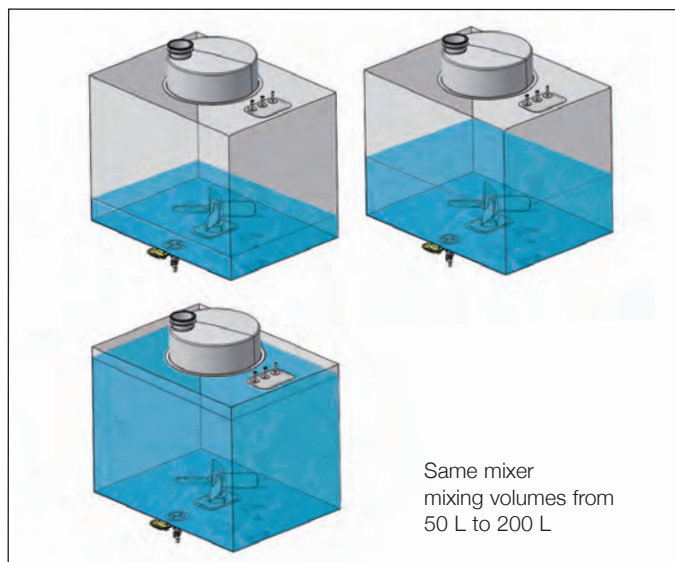
Feature	Benefit
4 pitch blade impeller	Efficient, low shear general purpose mixing over a wide range of applications and shear sensitive solutions
Impeller rotation in clockwise or counter-clockwise direction	Flexibility to perform both up-flow and down-flow for floating (low density) and settling (high density) fluid or solids



Feature	Benefit
Design principles based on existing Allegro 3D tote format for ease-of-use	Very easy and quick to install and remove the single-use systems pre- and post-use



Feature	Benefit
Inflation of the mixer bag	Provides mixing envelope for consistent performance from 50 – 200 L and the ability to have a gas blanket in operation and mix a range of volumes

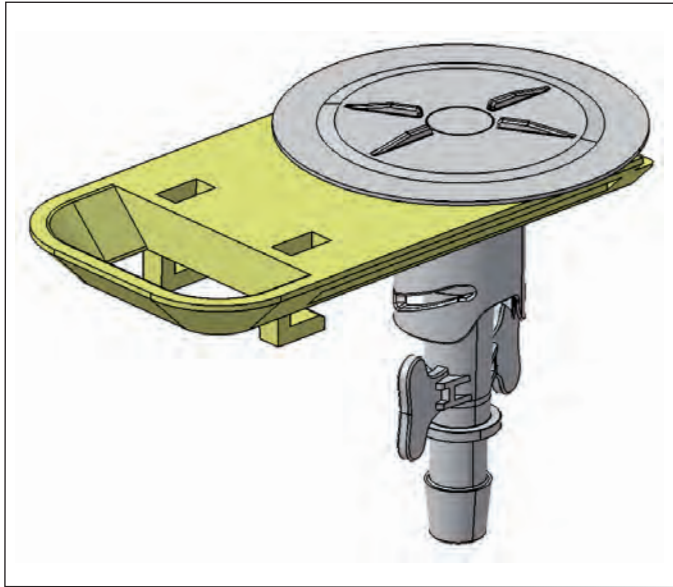


Feature

Flush drain valve

Benefit

Prevents entrapment of high density/ settling solids into a dead leg which will not be mixed in operation

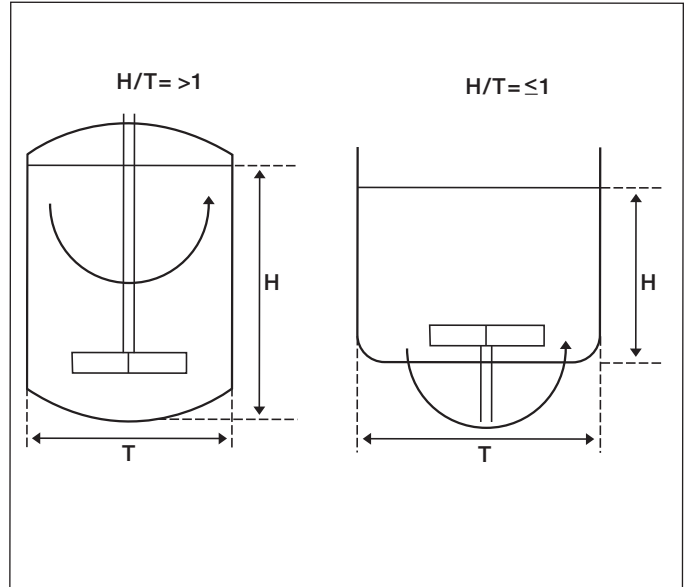


Feature

Design based on proven Good Engineering Practice (GEP) for mixing technology

Benefit

Sound basis for performance and scale-up to stirred tank devices



Feature

Uses existing Allegro film

Benefit

Material/validation consistency across all Allegro biocontainer based systems



Feature

Optional baffles available

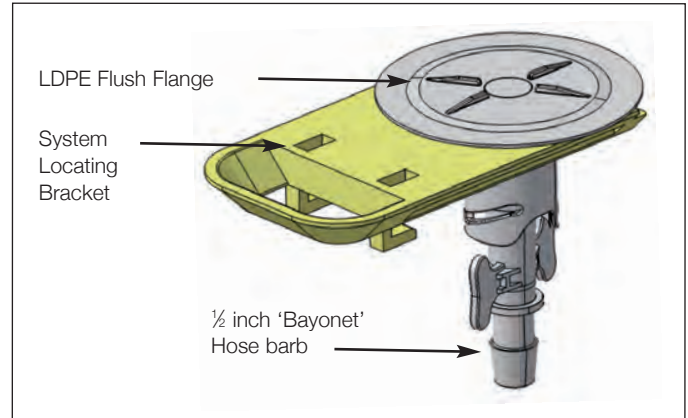
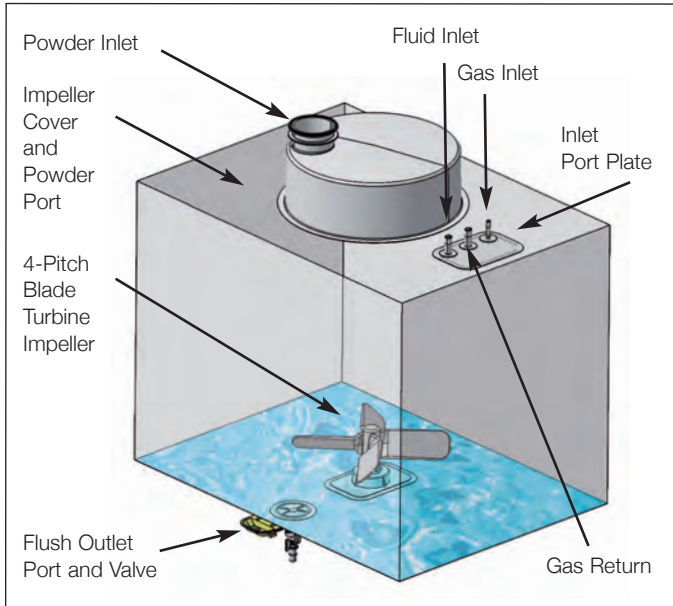
Benefit

To assist in reducing air entrapment at high rotation speed for sensitive molecules



Single-Use Mixer Design

The Allegro single-use mixer is designed on proven engineering principles used to develop efficient and appropriate mixing in a wide range of biopharmaceutical applications. Aspects of power input, impeller geometry and position, flow characteristics, flow pattern, pumping and shear were all considered as part of the design process.



High Performance Mixing

The Allegro mixer has been tested on a wide range of applications representing a broad range of biopharmaceutical operations where mixing is required. Table 1 below summarizes the applications tested and the mixing performance achieved.

Performance Testing Summary

The Allegro 200L single-use mixer demonstrates capability to mix a wide variety of liquid-liquid, solid-liquid, and high viscosity solutions. For further details on mixing performance, please refer to the Application note, document reference: USD2744.

Quality Standards and Validation

The Allegro single-use mixer biocontainers are 100% leak tested at manufacture.

All Allegro biocontainers, including the mixer, are manufactured in a controlled environment (Class 10,000) certified to ISO 13485 and ISO9001.

The materials of construction of the Allegro mixer biocontainer meet:

- ▶ USP<88> Biological reactivity test *In Vivo* for Class VI - 50 °C Plastics
- ▶ USP<87> Biological Reactivity Tests *In Vitro*, Cytotoxicity
- ▶ ISO 10993 Biological Evaluation of Medical Devices
- ▶ USP<661> Physico-chemical testing for plastics
- ▶ European Pharmacopeia (section 3.1.5)
- ▶ Japanese Pharmacopeia (section 61 Part 1)
- ▶ USP<85> LAL Endotoxin
- ▶ USP<788> Particulates

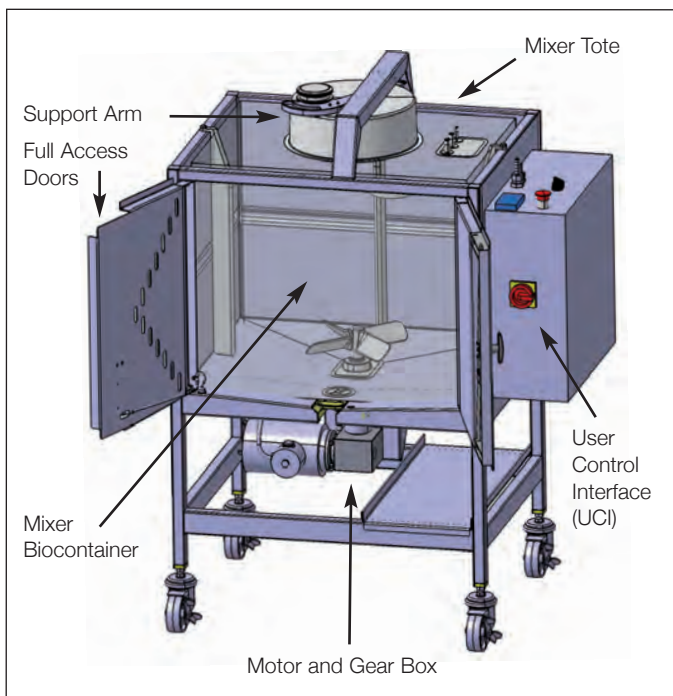


Table 1

Summary of mixing trials

	Solute	Mixing Application	Mixing Time (min)	
Liquid-Liquid Mixing	1% (v/v) acetone	Final Formulation	<1	
	NaCl (final 3 g/L)	Conductivity Adjustment	<1	
	NaCl (initial 200 g/L; final 10 g/L)	Conductivity Adjustment	<1	
	200 mL of dye into 250 cP corn syrup	Final Formulation	<1	
	1.25% (v/v) Polysorbate 80	Final Formulation	10	
Solid-Liquid Mixing	0.17 M NaCl (10 g/L)	Conductivity adjustment	<1	
	1 M NaCl (58.44 g/L)	Conductivity adjustment	<1	
	Dulbecco's Phosphate Buffered Saline (9.6 g/L)	Buffer Preparation	<5	
	21 g/L Citrate Buffer	Buffer Preparation	6	
	1 M Ammonium Sulfate (132.14g/L)	Buffer Preparation	15*	
	5.36 g/L Dulbecco's Modified Eagle's Medium (DMEM)			5
				14
				4
	5 g/L Terrific Broth (high density pellet form)		Media Preparation	6
				10
	47.6 g/L Terrific Broth (low density powder form)	Media Preparation	18	
	30 g/L Tryptic Soy Broth	Media Preparation	4	
1.4 g/L Aluminum Hydroxide (powder)-	Vaccine Formulation	8		

* In the ammonium sulfate experiment, the mixing time incorporates the powder addition time, which required about 7 minutes to put 26.5 kg of solid into the biocontainer.

Product Validation

As part of our rigorous approach to product validation, Pall has conducted a wide range of tests in addition to the general performance tests to prove the robustness of the Allegro mixer. A summary of key validation tests are summarized below:

- ▶ Biological safety (USP<87> and <88>)
- ▶ Physico-chemical tests (USP<661> and USP<788>)
- ▶ Extractables testing (Water and ethanol)
- ▶ Gamma resistance (Maximum 50 kGy)
- ▶ Leak tests
- ▶ Drainage/product recovery
- ▶ Tubing connection robustness

The mixer totes are manufactured under a Quality Management System Certified to ISO 9001 and ISO 14001 and is in conformity with the requirements of the European Directive 2004/108/EC (Electromagnetic Compatibility) and European Directive 2006/95/EC (Low Voltage Safety).

Technical Specifications

Mixer Tote Part Number	LGRMXTTE200L230	LGRMXTTE200L120
Voltage	230 Vac	120 Vac
Current	5.1 A	9.2 A
Frequency	50 Hz	60 Hz
UCI details	LGRMXUCI200L230	LGRMXUCI200L120
Volume	50 – 200 L	50 – 200 L
Gas Supply	4 – 6 barg	4 – 6 barg
Operating Temperature	4 – 40 °C	4 – 40 °C
Gas Connection	10 mm Pneumatic tubing outside diameter	10 mm Pneumatic tubing outside diameter
Weight	120 kg (without fluid in system)	120 kg (without fluid in system)
Footprint	1054 mm (W) x 748 mm (D)	1054 mm (W) x 748 mm (D)
Height	1378 mm	1378 mm

Materials of Construction

Mixer Tote Part Number	LGRMXTTE200L230	LGRMXTTE200L120
Mixer Tote	304 SS	304 SS
Mixer Biocontainer	Biocontainer film, outlet flange, inlet manifold and top hat: Low Density Polyethylene (LDPE)	Biocontainer film, outlet flange, inlet manifold and top hat: Low Density Polyethylene (LDPE)
	Impeller: Polysulfone (PS)	Impeller: Polysulfone (PS)
	Outlet port: Polysulfone (PS)	Outlet port: Polysulfone (PS)
	Shaft: Stainless Steel (SS)	Shaft: Stainless Steel (SS)
	Outlet O-rings: Silicone	Outlet O-rings: Silicone
Motor	0.37 kW	0.37 kW
RPM	50 - 200	50 - 200

Ordering Information

Mixer Tote Part Number	LGRMXTTE200L230	LGRMXTTE200L120
Voltage	230 Vac	120 Vac
Current	5.1 A	9.2 A
Frequency	50 Hz	60 Hz
Baffle Kit	LGRMXBK200L	LGRMXBK200L
Powder Bag Support Frame (to support powder bags up to 25 kg in weight)	LGRMPBS200L	LGRMPBS200L

Single-Use Mixer Systems

Single-use mixer systems are designed according to specific application requirements. For a customized design, please contact your Pall representative with your specific application details.

The following irradiated system exists as a basic system for mixing applications:

Basic Allegro Single-Use System Part Number

609-40C

Details

Gamma irradiated

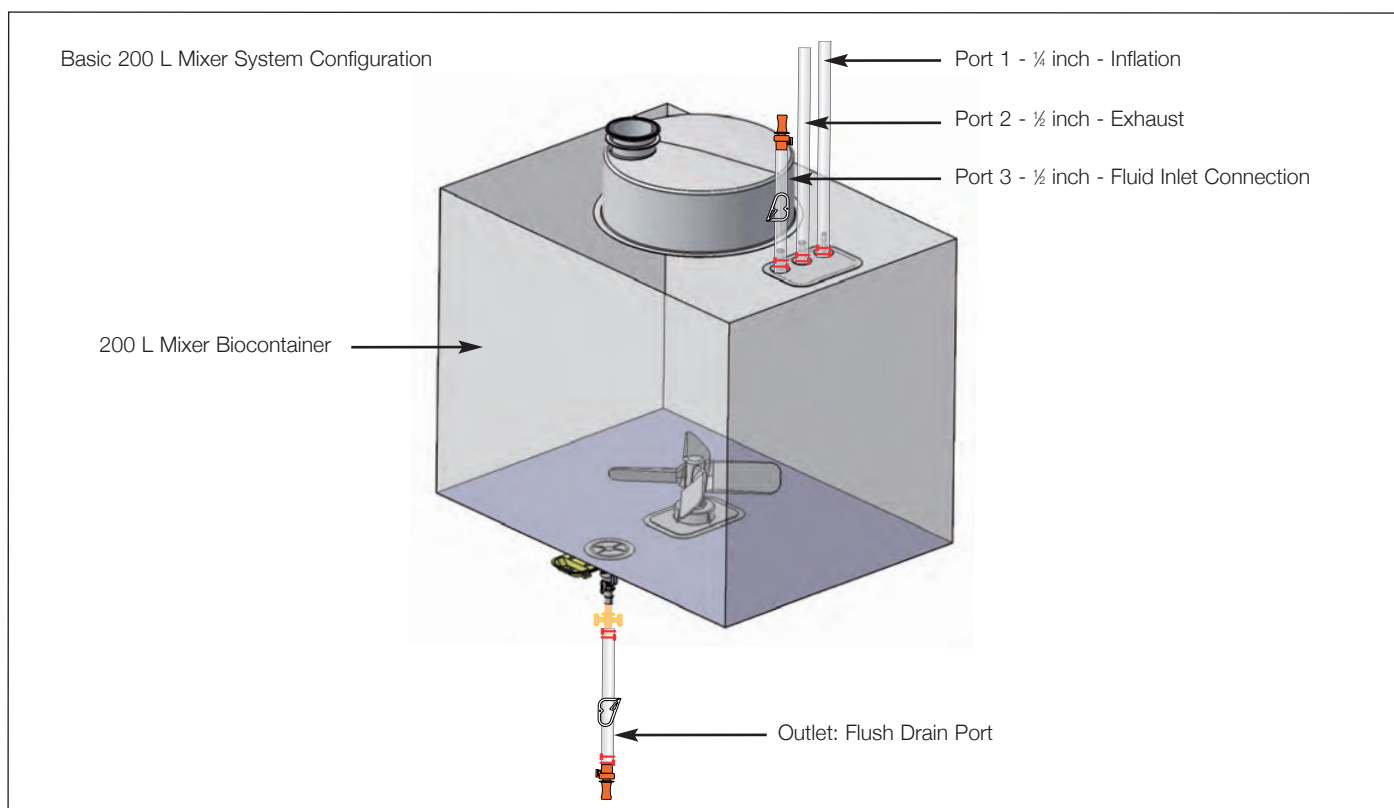
C-Flex Inflation and exhaust tubing (welded shut)

Quick connect inlet line with 1/2 inch ID platinum cured silicone tubing

Flush port outlet with 1/2 inch ID platinum cured silicone tubing and quick connect

3 inch sanitary powder addition port (blanked)

Powder addition bags of different capacities (up to 25 kg) are available to connect to the Allegro mixer. Please contact Pall for further details.





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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

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