Allegro™

2D BIOCONTAINER WITH POWDER PORT

Integrated into Allegro™ 2D single-use systems for mixing applications

Single-use systems have been widely implemented throughout biopharmaceutical processes in many fluid management applications. The main drivers for this are to improve operational flexibility, eliminate cleaning and cleaning validation, improve safety, and ultimately reduce costs by removing non-value-added steps from the process and shortening drug development time. Single-use technologies and systems are now available for more advanced applications, such as tangential flow filtration for concentration and diafiltration and in-process mixing.

Mixing is an essential operation for any biopharmaceutical process, such as mAbs, therapeutic proteins or vaccines. Mixing is applied at multiple stages and for many applications within a process.

Typical applications include preparation of buffer and media solutions, control of important fluid parameters such as pH and conductivity around chromatography operations, and final formulation prior to filling.

Fig 1. Allegro 2D biocontainer with powder port.

Features and benefits

Features	Benefits
Biocontainer uses the standard Allegro 2D and 3D biocontainer film	Consistent materials across full range of Allegro biocontainers
Powder addition port included on biocontainer	Allows for powder to be added into the biocontainer for recirculation mixing
Inert low-density polyethylene (LDPE) fluid contact layer	High clarity and flexibility
Compatible with a wide range of chemicals	Very low level of extractables and leachables
No animal-derived ingredients	Appropriate materials for biopharmaceutical applications
Excellent gas-barrier properties	Stability of product during storage

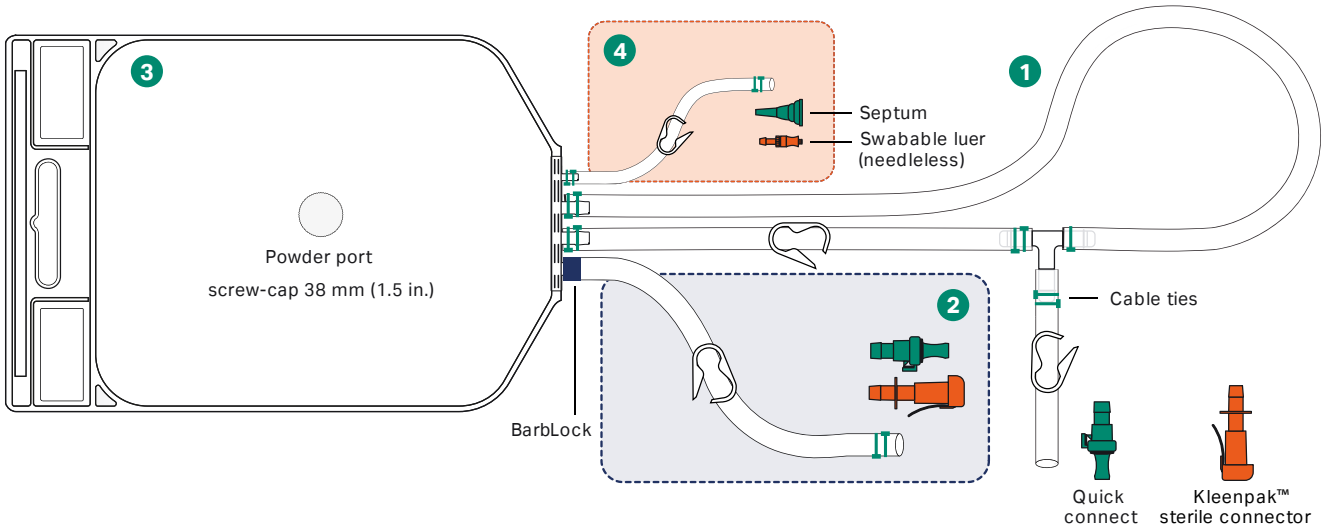

Fig 2. Typical system (with options for connections) for a recirculation set-up.

Item	Description	Notes
1	Recirculation loop (with fluid inlet line)	Lengths (and connections) defined by application
2	Outlet	Showing typical connectors used
		Kleenpak sterile connector
		Quick connect
		Showing options for tubing/hose barb connection
		Cable ties
		BarbLock
3	Allegro biocontainer (with powder port)	Available in 20 or 50 L
4	Optional sampling line	Showing options for sampling
		Swabable luer (needleless)
		Septum

Mixing systems can vary for a wide range of applications and volume sizes. Cytiva provides a two dimensional (2D) pillow-type Allegro biocontainer equipped with a screw cap powder port for single-use mixing system for small volume batches (10 to 50 L). The Allegro 2D biocontainer with powder port can be integrated into Allegro single-use systems to provide mixing using a recirculation method, or for use on an appropriate rocking mechanism. A typical system configuration for recirculation mixing, showing various options for connections, is shown in Figure 2.

This typical set-up can be adapted as required to provide a customized solution, depending on the specific mixing application requirements.

Cytiva provides additional hardware in the form of trolleys and trays to support and protect the Allegro systems during operation. Examples of these are shown in Figure 3 opposite and can be ordered through your sales representative.

Fig 3. Allegro 2D system supporting hardware.

Typical mixing applications (via recirculation approach):

- Media preparation
- Buffer preparation
- Homogeneity during hold steps

A number of performance tests have been carried out for mixing using the Allegro 2D powder port biocontainer configured for recirculation. The full details of the application work can be found in the application note: Allegro 2D powder port biocontainer – recirculation mixing. A summary of mixing performance is shown in Table 1.

Table 1. Mixing performance

Solution	Mixing achieved in 1 hour	
	20 L	**50 L**
1 M NaCl	Yes	Yes
0.75 mM NaOH	Yes	Yes
Phosphate buffered saline (Dulbecco's formulation)	Yes	Yes
Tris buffer	Yes	Yes
Sodium citrate buffer	Yes	No
1 M Ammonium sulfate	No	No
13.4 g/L DMEM (Dulbecco's modified eagle's medium)	Yes	Yes
47.6 g/L terrific broth	Yes	Yes
30 g/L tryptic soy broth	Yes	No

Quality standards

- The Allegro trolleys, trays and biocontainers are manufactured under a quality management system certified to ISO 9001 and are suitable for use according to GMP
- The Allegro biocontainers are leak tested
- Allegro biocontainers are manufactured in a controlled environment (class 10,000, grade C)
- The materials of construction of the Allegro biocontainers meet:
  - USP 88 biological reactivity *in vivo* for class VI plastics -50°C
  - USP 87 (cytotoxicity)
  - ISO 10993 (biological compatibility)
  - USP 661 physicochemical tests for plastics
  - European Pharmacopoeia (Section 3.1.5)
  - Japanese Pharmacopoeia (Section 61 Part 1)
  - European directive 85/572/EEC for food contact plastic materials

An extensive validation program has been conducted to include testing for:

- Oxygen permeability
- Carbon dioxide permeability
- Water vapor transmission rate
- Gamma stability and shelf life
- Sterilization according to AAMI/ANSI/ISO 1137
- Endotoxin and particulate testing
- Extractables

Technical specifications

Materials of construction

Inner layer	LDPE
Oxygen barrier layer	EVOH (ethylene-vinyl alcohol copolymer)
Outer layer	LDPE
Fluid inlet / outlet / sample ports	Polyethylene
Powder port	Polyethylene (LDPE)

Operating parameters

Temperature	4°C to 60°C

Sterilization method

Gamma irradiation maximum dose	50 KGy

Film typical data

Thickness		0.325 mm
Haze		5%
Water vapor transmission rate	ASTM F-1249	0.32 g / (m^2/ day) at 23°C
Oxygen transmission rate	ASTM D-3985	<0.05 cm^3 / (m^2/day/bar) at 23°C, 0% RH
Carbon dioxide transmission rate	Mocon Permatran C-IV	<0.2 cm^3 / (m^2/day/bar) at 23°C, 0% RH

Hardware specifications

Component	Length	Width	Height	Weight
Trolley base section	1092 mm (43.0 in.)	821 mm (32.3 in.)	628 mm (214.7 in.)	30 Kg
Trolley stacking section	1092 mm (43.0 in.)	821 mm (32.3 in.)	550 mm (21.6 in.)	13 Kg
10 and 20 L tray	800 mm (31.5 in.)	530 mm (20.1 in.)	110 mm (4.3 in.)	5.7 Kg
50 L tray	1052 mm (41.4 in.)	812 mm (31.2 in.)	110 mm (4.3 in.)	10.4 Kg
Adapter for 200 and 500 L totes	826 mm (32.5 in.)	541 mm (21.3 in.)	183 mm (7.2 in.)	3.6 Kg

Pump flow rate

Typical pump flow rate during recirculation mixing	13 L/min

Note: Cytiva can provide specifications of specific pumps to meet the above flow requirement

Allegro biocontainer nominal dimensions

Biocontainer volume	Max width	Max length (without ports)	Inlet/ outlet ports	Sampling port	Powder addition port
20 L	485 mm (19.5 in.)	738 mm (29.7 in.)	12.7 mm (0.5 in.)	6.3 mm (0.25 in.)	38 mm (1.5 in.)
50 L	678 mm (27.2 in.)	909 mm (36.5 in.)	12.7 mm (0.5 in.)	6.3 mm (0.25 in.)	38 mm (1.5 in.)

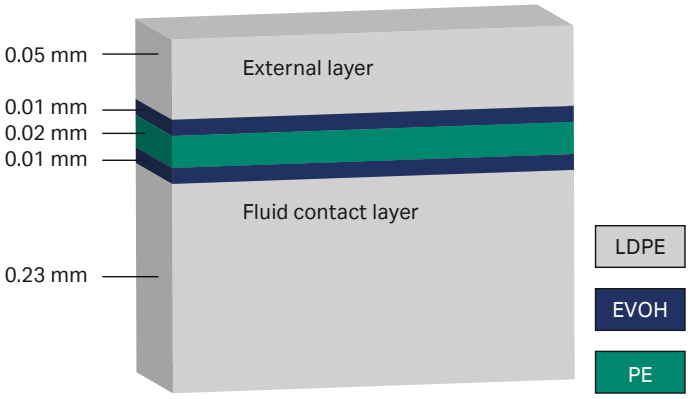

Fig 4. Schematic structure of Allegro films.

The powder port biocontainer has the same innovative low extractable/high transparency film structure as the standard Allegro biocontainers. The only additional material compared to the standard biocontainer range is the powder port (LDPE) to allow the addition of powders or fluids or access for sensors during operations.

Ordering information

The Allegro 2D biocontainers with powder port are supplied as part of an integrated Allegro single-use system. These systems include the powder port biocontainer integrated with other components (e.g. tubing, fittings, standard biocontainers, Kleenpak sterile connectors and disconnectors and filters) to comprise a fully operational system.

Please talk to us regarding your requirements so we can provide a suitable system design for your application.

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For local office contact information, visit cytiva.com/contact

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