

## Flexboy® Mixing System by Recirculation

Mixing is required for many stages within a biopharmaceutical process. Being able to mix in pre-assembled, pre-sterilized single-use bags considerably enhances process flexibility. Single-use technology for mixing offers the following benefits :

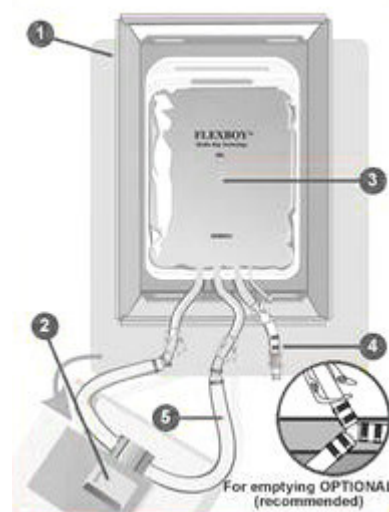
- No Cross-Contamination
- No CIP/SIP procedure using chemicals, clean steam and water
- No maintenance as no equipment required
- Reduces the amount of time associated with writing User requirement specifications and validation plans as well as minimizing the time for on site validation after delivery of the assembled mixing system

### Applications:

#### 1. Flexboy® Aseptic Mixing System

The method of mixing that Sartorius Stedim Biotech recommends for biopharmaceutical processing is aseptic mixing by recirculation using a peristaltic pump. This technique offers added convenience for 20L & 50L closed bag mixing applications, including:

- In-process intermediate blending and homogenisation
- In-process pooling
- Product homogenisation prior to filling



#### Simple design for best performance!

As a company, Sartorius Stedim Biotech is constantly striving to extend the benefits of single-use, disposable technology to each step of the customers process. At the same time, solutions must be simple and easy to implement. With this in mind, Sartorius Stedim Biotech recommends the method of mixing by recirculation: A trouble-free very efficient design utilizing your existing Sartorius Stedim Biotech system requiring no additional maintenance or investment.

**1 The Flexboy® bag tray** accommodates the Flexboy® bag with recirculation loops, facilitating handling during mixing

**2 One type of peristaltic pump can be used for several bag volumes.** Sartorius Stedim Biotech recommends use of Watson Marlow-Model 704U/R peristaltic pump, performance at 100% flow rate = 780L/hour

**3 The Flexboy® bag system.** Very simple set-up whilst working with your existing system.

**4 Latex-free septum on male cap.** This feature allows sampling or compounds addition using a needle syringe.

**Female luer lock connection.** By unscrewing the male cap, the female luer lock connection allows:

- Sampling or compound addition using a needle-less male luer lock syringe.
- Satellite bag connection e.g. small Flexboy® sample bag

**5 The recirculation loop is already pre-assembled, ready for process use** - This feature reduces the number of connections and associated contamination risks.

Results of tests carried out by Sartorius Stedim Biotech on the basis of several scenarios show that mixing by recirculation is effective in Flexboy® Bags 20L & 50L **in less than 5 minutes**.

Mixing Times		
Flexboy® bag	2M NaOH diluted in water	2M HCL diluted in water
20L	3 min.	2 min.
50L	3 min.	4 min.

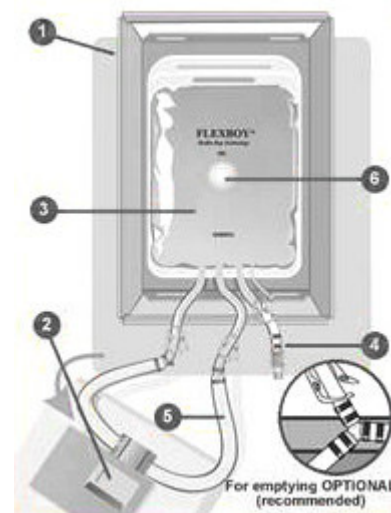
The above test results were obtained with 12,7mm (1/2") tubing. Sartorius Stedim Biotech recommends the peristaltic pump Watson Marlow-Model 704U/R, performance at 100% flow rate = 780L/h.

## 2. Flexboy® Mixing System by Recirculation for Clean, Non-sterile Applications

Dissolution of powder is required in a variety of applications in the biopharmaceutical industry. Powders are reconstituted to make either buffer or media, which are used throughout cell culture, chromatography, ultra/diafiltration etc. Buffer and media do not require sterility in a first step and can be sterile filtered after formulation. Small volumes (20&50L) are well adapted for concentrated solutions.

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The method of mixing that Sartorius Stedim Biotech recommends in this case is mixing by recirculation in Flexboy using a peristaltic pump and a screw cap (bung) for the introduction of powders.

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- Satellite bag connection e.g. small Flexboy® sample bag

**5 The recirculation loop is already pre-assembled**, ready for process use - This feature reduces the number of connections and associated contamination risks.

**6 The 1,49" (38mm) screw-cap / bung** for easy powder introduction.

Results of tests carried out by Sartorius Stedim Biotech on the basis of several scenarios show that mixing by recirculation is effective in Flexboy® 20L and 50L in **less than 10 minutes**.

Mixing Times		
Flexboy® bag	0.1M NaCL dissolved in water	NaCO <sub>3</sub> dissolved in water
20L	3 min.	3 min.
50L	7 min.	8 min.

The above test results were obtained with 12,7mm (1/2") tubing. Sartorius Stedim Biotech recommends the peristaltic pump Watson Marlow-Model 704U/R, performance at 100% flow rate = 780L/h.

### 3. Worst-case scenario: Maintaining a highly viscous product in a homogeneous aseptic suspension

Sartorius Stedim Biotech has tested the ability to aseptically mix a highly viscous and sticky product by recirculation. The chosen compound is a common vaccine adjuvant: aluminium hydroxide gels.

Results of tests carried out by Sartorius Stedim Biotech on the basis of this scenario show that mixing by recirculation is effective in Flexboy® Bags 20L & 50L in **15 minutes**.

Mixing Time	
Flexboy® bag	AlO <sub>3</sub> Gel of viscosity 1 mPaS (10 cp) re-homogenisation in water
20L	15 min.
50L	15 min.

The above test results were obtained with 12,7mm (1/2") tubing. Sartorius Stedim Biotech recommends the peristaltic pump Watson Marlow-Model 704U/R, performance at 100% flow rate = 780L/h.

Sediment re-homogenisation is studied on a case-by-case basis, as gel parameters are specific: dosage, quality or viscosity, decantation etc. Please consult Sartorius Stedim Biotech for a personalized study based on required performance.