

Mitigate Your Risk!



Store your drug substance in PharmaTainer™ Bottles.

What's wrong with alternatives?

Bags pose a high risk of failure; especially for freezing and transport applications; unacceptable for high value drug substance.

Re-usable containers pose a risk of carry-over in addition to cleaning, sterilization and related validation costs.

Stainless steel and polypropylene containers lack clarity for visual inspection.

Legacy sterile plastic bottles were designed for general laboratory use and media storage; a quality standard lower than today's pharma manufacturing requirements. In general, legacy bottles are made in older facilities using older equipment and processes that do not support the quality levels you require.

Common problems in legacy bottles:

- Failure to seal
- Packaging failure
- Black specks

PharmaTainer Highlights

Designed to meet current industry standards

Molded in Class 100 environment

Leading edge molding technology

Sizes: 125mL to 20 liters

Materials: polycarbonate or PET (copolyester)

Validation information: leachables, biocompatibility, resin identity, -80 °C testing and more available free of charge

Lot Certified:

- Sterile (gamma irradiated)
- No animal derived materials
- All components pass UPS VI testing
- Endotoxin: none detected
- USP 788/787 low particulate

What makes PharmaTainer™ products so good?



We have years of experience providing container to the biopharmaceutical industry. We know the capabilities and limitations of various manufacturing processes and common customer concerns.

PharmaTainer bottles are physically better:

PharmaTainer products are made with state of the art HEPA-filtered injection stretch blow molding machines that provide cleanliness and the best control of the container molding process.

Clean molding in ISO class 5 means no post-molding cleaning process is necessary, eliminating a variable.

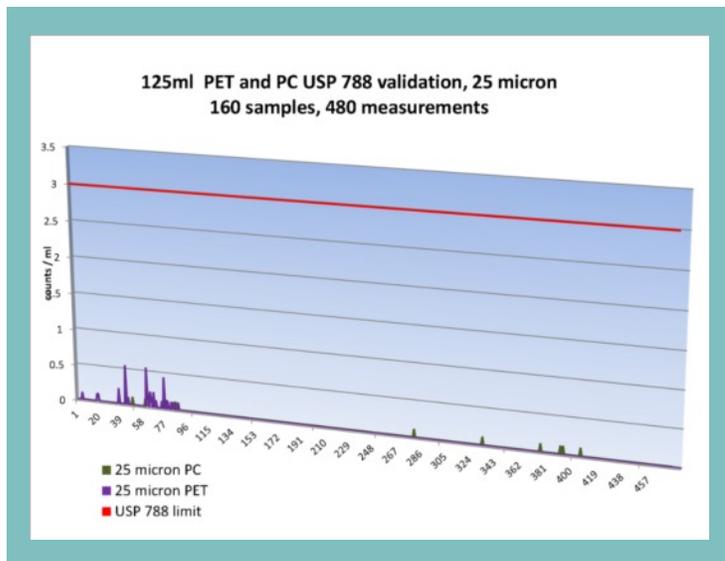
Precision molding dramatically reduces variability in critical neck dimensions, part weight and generally increases reproducibility.

The PharmaTainer bottle with its double-seal closure system has been demonstrated to hold seal from ambient to -80° C and back to ambient.

Regrind is a common cause of black specks in molded containers; Regrind is never used in PharmaTainer products.

Why we audit better.

1. Cellon built the PharmaTainer molding facility in 2011; designed specifically to meet pharmaceutical industry standards.
2. Cellon uses permanent well-trained employees; no temp workers.
3. Cellon has only one quality standard (pharmaceutical). There is no confusion for employees trying to remember which of several quality levels are applicable.
4. Product traceability is top-notch. Containers carry expiration date, lot number, serial number and a 2-D optical code for easy inventory management.
5. PharmaTainer packaging is designed to pass through 3 levels of cleanliness. The innermost pack is vacuum sealed; an indicator of



USP 788/787 Compliant

The graph depicts results from particulate counting of 160 bottles. Three samples were tested from each container and averaged. Measurements made using APSS 2000 Liquid Particle Counter. Note that all readings were well below the USP 788 standard (red line). The 125mL bottle has the highest surface area to volume ratio and should therefore have the highest concentration of particulate.

All containers are routinely tested at 10, 25 and 50 microns.

When particulate levels are low, it is not surprising that bioburdens are also low, and this has proven to be the case.

For more information on particulate in sterile bottles, see *Are Bioprocess Containers a Source of Particulate Contamination*

Octopus Tubing Assemblies

Tubing assemblies for aseptic transfer are custom made to your specifications. We will supply single-use assemblies to bioreactors and other systems as well as for PharmaTainer products. You specify:

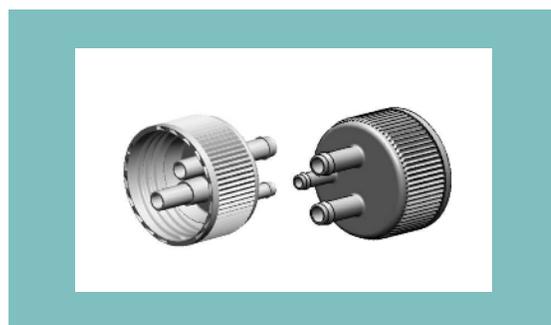
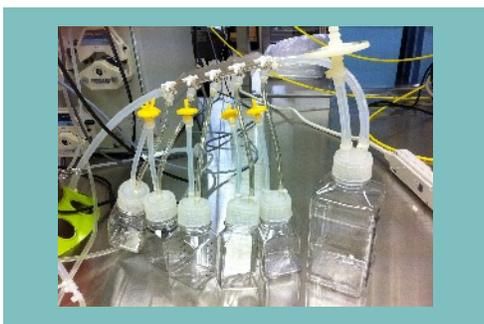
- Tubing type and length
- Terminal connectors
- Filters
- Containers (optional)

Assemblies for PharmaTainer products may be obtained already mounted on containers or packaged separately.

Cellon will supply any brands you specify or offer a suggestion if you do not specify a brand. Cellon has pre-selected common items such as T-connectors and tubing clamps.

Octopus assemblies are managed under ISO 9001 - 2008 quality system. After your input, the assembly is designed with selection of materials, specification of testing requirements and post-assembly processing. A drawing of the assembly with a parts list is created and submitted for your review/approval. Prototypes can be supplied for testing.

The entire design process is carefully documented.



Ported Closures

You can make your own tubing assemblies for PharmaTainer bottles and carboys. Ported closures are molded in polypropylene and are autoclavable. Liquid ports have tubulations inside and out. Air vent ports (3-port style) are slightly smaller diameter and have only an external tabulation.

Ported Closures			
	Cat. No.	Ports	Size
48 mm for bottles			
	4048CP2	2	8.3mm OD
	4048CP3	2	8.3mm OD
		1	5.3mm OD
70 mm for carboys			
	4070CP2	2	8.3mm OD
	4048CP3	2	8.3mm OD
		1	5.3mm OD
	4070CP4	4	10.6mm OD



Torque Fittings

In order to be sure of a good cap seal, closures should be applied with a specific amount of force. We provide excellent tools for this purpose. These fittings are designed for use with ¼ inch drive torque wrenches. The standard style also has a built-in 'T' bar and is useful to assist in removing closures as well as applying torque to them. Get one free with your first PharmaTainer order. Molded in polycarbonate with a metal inset.

Special open-top torque fittings are available for use with ported closures. Aluminum.

Recommended Torque			
In-lbf (Nm)			
Non-freezing applications			
Minimum	Nominal	Maximum	
35 (4)	44 (5)	88 (10)	
Freezing applications			
62 (7)	71 (8)	88 (10)	

60 mL Stability Tubes

Stability tubes are actually what is known in the molding industry as preforms. This is the injection molded tube from which a bottle may be blown in the final step of the ISBM molding process. So, the stability tube is molded on the same equipment and in the same environment as Pharma-Tainer bottles. The tubes use the standard PharmaTainer 48mm double-seal closures.

The stability tube rack is a convenient way to handle the tubes since they are not self-standing. The rack is of durable polyethylene foam construction. Tubes have a snug, friction-fit in the rack. Useful at temperatures down to -80°C.



Graduations	± 2%
Cap sizes (nominal)	
Bottles (≤ 2 L)	48 mm
Carboys (≥ 5 L)	70 mm
Neck I.D. (Nominal)	
Bottles (≤ 2 L)	35 mm
Carboys (≥ 5 L)	52-54 mm

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