

# PharmaTainer™

The Best Home a Drug Can Get™



 **SANISURE**<sup>®</sup>  
Solution Based Innovation

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Know more about PharmaTainer™

## Outstandingly clean and strong bottles

**PharmaTainers™ from SaniSure® are very clean and strong bottles for single use applications.**

Our rigid containers are produced with ADCF virgin medical-grade resins in an ISO 5-classified environment. PharmaTainer™ bottles are certified sterile SAL 10<sup>-6</sup> and conform to USP788 and USP85. They are delivered in triple-bag packaging with a vacuum-sealed innermost packing layer.



### Cleanliness

**Less particles, more safety in the process!**

<1,7% of the USP788 limits\*

\* USP788/787 testing results are only applicable to final drug product in its final packaging format. 787/787 testing of PharmaTainer™ bottles is performed to demonstrate that use of PharmaTainer™ bottles at any stage in the production process of a drug product will not contribute any significant level of particulate to the total particle load of the final drug product



### Toughness and integrity

**Withstands heat and cold in all your process steps.**

- Withstands the 110cm drop test at -80 °C with PC bottle
- The temperature use range for PharmaTainer™ bottles is from 135 °C to -135 °C for PC and from 60 °C to -40 °C for PET



### Traceability

**Full tracking along the process**

- Serial and lot numbers (printed via inkjet) provide 100% traceability to each PharmaTainer™
- Traceability level to the resin lot and machine operating settings



### Regulatory compliance

**Meets all current standards and compliances – state of the art!**

- Regulatory compliance with E&L and Biocompatibility studies
- Full validation guide available

Available materials

## Offered in PET and PC

The PharmaTainer™ products by SaniSure® are manufactured from 100% virgin ADCF resins approved by our suppliers for medical applications and selected by SaniSure® for their performance, clarity, and biocompatibility. Bottles and Carboys are manufactured from polyethylene terephthalate (PET) and polycarbonate (PC).

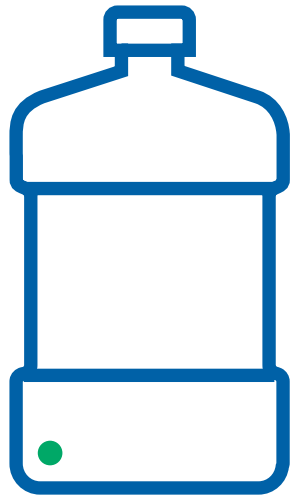
Our closures are manufactured from natural (non-colored) high-density polyethylene (HDPE). All raw materials are supported by drug master files held by the FDA. Our PET PharmaTainers™ have excellent gas barrier properties, while our PC PharmaTainers™ are ideal for freezing applications.



For more details, visit  
[sanisure.com/products/bottle-solutions/](https://sanisure.com/products/bottle-solutions/)  
or [linkedin/sanisure.com](https://linkedin.com/company/sanisure)

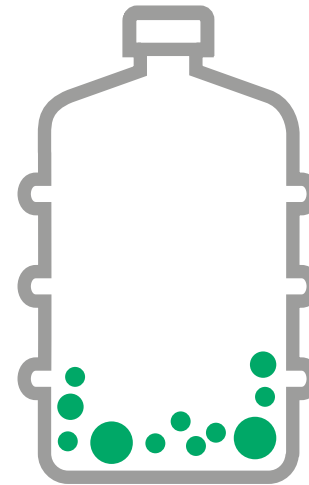
Bottle Particle Level Comparison

## Outstandingly clean



**PharmaTainer™**  
**<1.7% of the USP788 limits**  
Injection stretch blow molding.

**VS.**



**Next-Best Competitor**  
**20x more particles than PharmaTainer™**  
Extrusion blow molding.

SaniSure's injection-stretch-blow molding technology has many valuable quality benefits, including dramatically lower particle counts, when compared to traditional extrusion blow molding.

The six key facts about PharmaTainer™ cleanliness

## Setting the standards for cleanliness

### Extractables



We have partnered with a leading bio-processing institute and several fully-accredited, third-party laboratories to provide one of the most extensive extractables packages in the industry today following the new USP and BPOG drafts.

### No Detectable Endotoxins



All PharmaTainer batches are endotoxin tested. Endotoxin testing for our bottles is based on a validated assay method using a 5% rinse volume and detection limit of 0.001 EU/ml. The method complies with current USP <85> and EP Bacterial Endotoxin Testing (BET) methodologies.

### Control Over Product Contact Material



All PharmaTainer™ bottles are manufactured in a facility dedicated to the production of sterile single-use containers. PharmaTainer™ bottles are made of 100% virgin ADCF approved medical grade resins with existing DMF files. This provides lot-to-lot consistency and enhanced change control for product contact material. SaniSure® holds safety stocks of resin and finished products.

### 3 Layers of Poly Packaging



Bottles are packaged in an ISO Class 7 clean room for transfers. The innermost layer is vacuum-sealed to provide assurance of sterility. The second bag is heat-sealed and the third poly layer is taped closed.

### Extremely Low Particle Level



Every batch of PharmaTainer™ is tested to meet USP 788. Our PharmaTainer™ bottles are 20x cleaner than the Next-Best Competitor.

### Quality Assured



- Bottle Molding/Capping in ISO Class 5
- ISO 9001 2015 certified
- Each bottle is printed with lot, serial number and expiration date
- USP 787, ISO 10993 06, 10, 11
- FDA CFR 21 compliant
- Animal-Derived-Component-Free (ADCF) components

Toughness and integrity

# Outstandingly Strong



## The Drop Test

Gamma irradiated 10L PharmaTainer™ bottles were filled to nominal volume and frozen to -80°C for 2 days. The bottles were then dropped two times in a row onto a flat concrete surface from a height of 110cm. After the contents thawed, leak tests were performed on the sides, base and closure. All bottles passed the drop test with only minor scratches.



## One-Piece Molded Cap Design | Cap2V8®

Reduces contamination and product loss while maintaining a closed system for your process. Our Cap2V8® PharmaTainer™ Assemblies are available in different configurations. Standard 125ml to 2L bottles use the SaniSure® 48 Cellgyn® or C-Flex® Cap2V8® with an 18-inch feed line with pinch clamp, dip tube, and 4-inch vent line with hydrophobic vent filter. Standard 5L to 20L bottles use our 70 Cellgyn® or C-Flex® Cap2V8® with a 24-inch feed line and the same possible additions. SaniSure® also offers barbed caps.



## No Seal Leakage

We have generated an outstanding container-cap combination to provide the best container closure integrity in the market. PharmaTainer™ bottles are made with a precision, flash and burr free neck, eliminating the primary cause of seal failure. Our bottles passed a positive pressure test with freeze & thaw cycles from ambient to -80 °C.

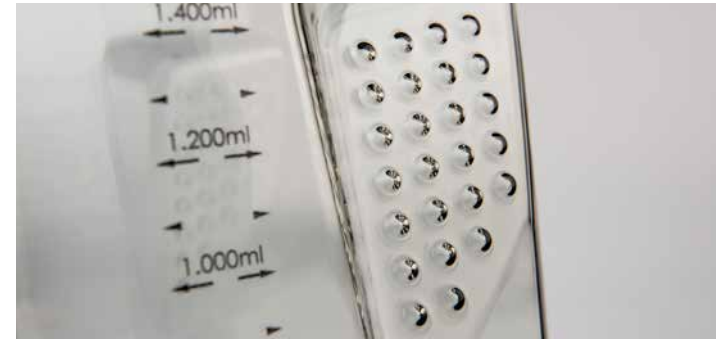
More key facts about PharmaTainer™

## Top quality bottles for outstanding performance



### Traceable

Serial number to allow the bottle to be traced in each step of the process



### Easy to manipulate

The PharmaTainer™ design includes a grip ensuring you can manipulate the bottle without difficulty.



### Compliant

Our manufacturing process is ISO 9001-2015 certified, and our cleanrooms are ISO 14644 Class 7 compliant.



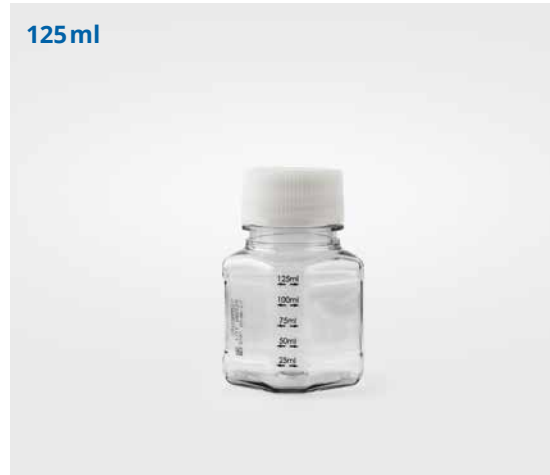
### No Leakage

Our PharmaTainer™ caps are manufactured with a double seal to provide a fail-safe closure. No gasket is required and no overwinding is possible.

SaniSure® PharmaTainer™

Available PharmaTainer™ sizes

# Outstanding bottles for bioprocessing





2L



5L



10L



20L



# Order information

Catalog Number	Nominal Volume	Material	Closure Type	Vacuum Pack	Units/Carton	
<b>100S10-49</b>	10ml	PET	28mm HDPE	49 bottles	245 (5 X 49)	
<b>200S10-49</b>		PC				
<b>100125-05</b>	125ml	PET	49mm HDPE	5 bottles	100 (20 X 5)	
<b>100125-01</b>				1 bottle	48 (48 X 1)	
<b>200125-05</b>		PC		5 bottles	100 (20 X 5)	
<b>200125-01</b>				1 bottle	48 (48 X 1)	
<b>100250-05</b>	250ml	PET		5 bottles	60 (12 X 5)	
<b>200250-05</b>		PC				
<b>100500-05</b>	500ml	PET		49mm HDPE	5 bottles	60 (12 X 5)
<b>100500-01</b>					1 bottle	36 (36 X 1)
<b>200500-05</b>		PC	5 bottles		60 (12 X 5)	
<b>200500-01</b>			1 bottle		36 (36 X 1)	
<b>101000-05</b>	1L	PET	49mm HDPE		5 bottles	30 (6 X 5)
<b>101000-01</b>					1 bottle	24 (24 X 1)
<b>201000-05</b>		PC			5 bottles	30 (6 X 5)
<b>201000-01</b>					1 bottle	24 (24 X 1)
<b>102000-05</b>	2L	PET		49mm HDPE	5 bottles	20 (4 X 5)
<b>102000-01</b>					1 bottle	14 (14 X 1)
<b>202000-05</b>		PC			5 bottles	20 (4 X 5)
<b>202000-01</b>					1 bottle	14 (14 X 1)

Catalog Number	Nominal Volume	Material	Closure Type	Vacuum Pack	Units/Carton
105000-01	5L	PET	70mm HDPE	1 bottle	6 (6 X 1)
205000-01		PC			
110000-01	10L	PET			2 (2 X 1)
210000-01		PC			
120000-01	20L	PET			
220000-01		PC			

## SaniSure® Certifications

If SaniSure containers and mixers are the heart of your biological process, then the tubing are the arteries! Neither functions properly without the good health of the other.

It is for this reason that we identified the need to create a common, global-quality platform which brings our complete portfolio of products to a single standard.

We asked the internationally recognized Bio Process Institute to develop a “Best in Class” quality strategy that takes into account the current regulatory landscape, such as BPOG and USP 665, but which also goes beyond to address future trends.

As a result of the collaboration, we have one of the most comprehensive taxological and chemistry profiles available.



## Contact

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Please visit our website  
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**SaniSure.com**