

Container Overview Table

Container Information

| | Sizes | Molding | Environment | Closure | Decoration | Sterility | Biocompatibility | | |
|---------------------------------|--------------|---------|---------------|----------------------------------|---|-------------------------------|--|----------------------|--|
| | | | | | | | Reports | Lot Testing | Traceability |
| PharmaTainer™ PC Containers | 125 mL - 20L | ISBM | Class 100 | HDPE 2L: 49mm 5L: 70mm | graduations lot number serial no. exp. date QR code | SAL 10 ⁻⁶ gamma | USP VI <i>in vitro</i> cytotoxicity hemolysis sterility validation leachables -80 C seal Integrity | Endotoxin USP 788 | On all levels of packaging and on container. |
| PharmaTainer™ PET Containers | 125 mL - 20L | ISBM | Class 100 | HDPE 2L: 49mm 5L: 70mm | graduations lot number serial no. exp. date QR code | SAL 10 ⁻⁶ gamma | USP VI <i>in vitro</i> cytotoxicity hemolysis sterility validation leachables | Endotoxin USP 788 | On all levels of packaging and on container. |
| Purillex™ FEP Bottles | 50mL - 2L | ISBM | HEPA filtered | FEP 50mL: 33mm 100mL: GL45 | NA | Autoclave | USP VI | | Labeled on inner-most poly bag |
| Purillex™ PFA Bottles | 50mL - 2L | ISBM | HEPA filtered | PFA 50mL: 33mm 100mL: GL45 | NA | Autoclave | USP VI | | Labeled on inner-most poly bag |

Notes:

ISBM, injection stretch blow molding, is significant because bottle necks are injection molded. This produces greater precision, repeatability and seal integrity. The process produces enhanced clarity with clear plastics as compared to extrusion blow molding.

Closures are molded using unscrewing molds to obtain deep threads for better engagement with the container.

FEP and PFA bottles have closures of same material, i.e. FEP closure for FEP bottle.

PharmaTainer™ closures are a double seal design, sealing at the container rim and on the inside of the neck.

Resin Information on page 2

Container Overview Table

Resin Information

| Resin | Suitability | Strength | Gas Permeability | Brittleness | Max. Use | Glass Transition | Class | Resin Grade |
|---------------|------------------------------|-----------|---|-------------|----------|------------------|------------------|-------------|
| Polycarbonate | Aqueous solutions | Excellent | N ₂ 19.4 O ₂ 116.6 CO ₂ 417.7 H ₂ O 115 | -135°C | 135°C | 154°C | amorphous | medical |
| PET copolymer | Aqueous solutions | Very good | N ₂ 3.9 O ₂ 9.7 CO ₂ 48.6 H ₂ O 18.1 | -40°C | 70°C | 70°C | semi-amorphous | medical |
| HDPE | NA | Very good | NA | -100 | 70°C | -25°C | semi-crystalline | medical |
| FEP | Acids, bases, solvents, etc. | Excellent | N ₂ 124.4 O ₂ 291.4 CO ₂ 857.8 H ₂ O 6.2 | -270°C | 205°C | NA | semi-crystalline | USP VI* |
| PFA | Acids, bases, solvents, etc. | Excellent | N ₂ 118.1 O ₂ 342.3 CO ₂ 873.1 H ₂ O 2.0 | -270°C | -270°C | -80°C 90°C | semi-crystalline | USP VI* |

Permeability: N₂, O₂, CO₂ reported as cc-mm/M²-24 hr-100 KPa
H₂O (vapor) reported as g-mm/M²-24 hr-100 KPa at 37°C, 90% relative humidity*

* See ["DuPont POLICY Regarding Medical Applications of DuPont Materials"](#)



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