



Purillex® Fluoropolymer Bottles Designed For Life Sciences

Savillex's Purillex® range of fluoropolymer bottles are the cleanest, safest, and highest performing fluoropolymer bottles ever produced. Available in PFA, FEP, and ETFE, Purillex bottles are manufactured by a stretch blow molding process, adapted for fluoropolymer use by Savillex. This process provides several key benefits, including cleaner, smoother fluid contact surfaces, easier pouring, and superior seal integrity.

Purillex bottles are used in a variety of critical applications, from storing FDA-approved biologics and vaccines to shipping licensed cell therapies. What is also unique about the Purillex range is that all bottles are also available ready-to-use (RTU), clean and pre-sterilized.

Design Features

Compared with the traditional extrusion blow molding process used to manufacture all other fluoropolymer bottles, stretch blow molding produces a better seal, even at extremely low temperatures, and allows the bottles to be produced using clean methods inside a Class 7 cleanroom.

A full 2.5 thread turns provides Purillex bottles greater thread engagement than any other fluoropolymer bottle and allows the large GL45 closure to be tightened more securely, eliminating the need for a cap liner and ensuring long-term seal integrity. The smooth, injection-molded inner neck shape and the absence of burrs, flash, or other molding imperfections on the lip of the bottle allow controllable, drip-free pouring and complete removal of contents. Purillex bottles have even been validated as a container closure system using Container Closure Integrity Testing (CCIT) methods.

Size Availability

Purillex bottles are available in sizes ranging from 50 mL – 2000 mL.

| Bottle Size | PFA | FEP | ETFE |
|-------------|-----|-----|------|
| 50 mL | ✓ | ✓ | |
| 100 mL | ✓ | ✓ | ✓ |
| 250 mL | ✓ | ✓ | ✓ |
| 500 mL | ✓ | ✓ | ✓ |
| 1000 mL | ✓ | ✓ | ✓ |
| 2000 mL | ✓ | ✓ | |

The wide mouthed 45 mm diameter neck accepts a GL45 threaded closure (33 mm diameter neck and closure on 50 mL bottle). A closure is included with each bottle.

Material Working Temperature Range

PFA Bottles: -328°F to 500°F (-200°C to 260°C)

FEP Bottles: -328°F to 392°F (-200°C to 200°C)

ETFE Bottles: -328°F to 122°F (-200°C to 50°C)

Available Pre-Sterilized

All Savillex Purillex bottles are available pre-sterilized, RTU, with up to a 5-year shelf life. Bottles are double-bagged and available with tamper-evident closure seals to ensure sterility is maintained prior to use. All sterilization processes are validated to ensure a SAL (sterility assurance level) of 10⁻⁶ which is the industry standard for use in aseptic applications. PFA bottles have also been tested to ensure compatibility with dry heat sterilization processes to 250°C for up to a two-hour exposure time.

Sterilization Process for RTU Products

| Material | Sterilization Process |
|----------|-----------------------|
| PFA | Autoclave |
| FEP | Autoclave |
| ETFE | Gamma |

Benefits of Gamma Stability

Purillex ETFE bottles are gamma stable, providing compatibility to your process. Additional benefits include:

- Excellent assurance of product sterility and batch consistency
- Long product shelf life
- Compatible with wider variety of industry standard accessories
- No residual moisture in the container or packaging

Testing

Savillex has performed comprehensive internal testing on all Purillex bottles, including drop test, leakproof test, vacuum resistance and pressure burst test. Test data is available on request.

In addition, the 170 series Purillex bottles are Class IV and have undergone full USP extractable and biocompatibility testing and come with manufacturing lot certification and full support for bioprocess applications. Please contact us for pricing and to request the validation binder, available under NDA.

Bottle Ordering Information

| Bottle Size | Closure | PFA Part # (non-sterilized) | PFA RTU Part # | FEP Part # (non-sterilized) | FEP RTU Part # | ETFE RTU Part # |
|-------------|---------|--------------------------------|----------------|--------------------------------|----------------|-----------------|
| 50 mL | 33 mm | 170-01-0050 | 170-01-0050-A | 170-02-0050 | 170-02-0050-A | |
| 100 mL | GL45 | 170-01-0100 | 170-01-0100-A | 170-02-0100 | 170-02-0100-A | 170-03-0100-G |
| 250 mL | GL45 | 170-01-0250 | 170-01-0250-A | 170-02-0250 | 170-02-0250-A | 170-03-0250-G |
| 500 mL | GL45 | 170-01-0500 | 170-01-0500-A | 170-02-0500 | 170-02-0500-A | 170-03-0500-G |
| 1000 mL | GL45 | 170-01-1000 | 170-01-1000-A | 170-02-1000 | 170-02-1000-A | 170-03-1000-G |
| 2000 mL | GL45 | 170-01-2000 | 170-01-2000-A | 170-02-2000 | 170-02-2000-A | |

- All Purillex bottles include a closure
- Pre-sterilized FEP bottles are available upon request

Purillex bottles are a registered trademark of Savillex, LLC.



Savillex

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