



Purillex® PFA, FEP and ETFE Bottles For Bioprocessing



Savillex's Purillex® range of fluoropolymer bottles is the cleanest, safest and highest performing fluoropolymer bottles ever produced. Available in PFA, FEP, and new to the market gamma sterilized ETFE, Purillex bottles are manufactured by a stretch blow molding process, adapted for fluoropolymer use by Savillex. This provides several key benefits, including lower particles, smoother surface finish, easier pouring and superior sealing. Purillex bottles are used in the biopharmaceutical and vaccine industry for storing and shipping bulk drug substance (BDS). What is also unique about the Purillex range is that all bottles are available ready-to-use (RTU).

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 extreme low temperatures and allows the bottles to be produced inside a Class 7 cleanroom.

A full 2.5 thread turns gives 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.

Size Availability

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

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

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 the 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 bottles are available pre-sterilized, RTU. 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 bioprocess applications.

PFA bottles have also been tested to ensure compatibility with dry heat sterilization processes to 250°C for up to two-hour exposure times.

Sterilization Process for RTU Products

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

Benefits of Gamma Stability

The new ETFE bottles are gamma stable, providing less risk to your process and lowering your chance of product loss. Additional benefits include:

- Better assurance of product sterility than other sterilization methods
- Longer product shelf life
- Compatible with wider variety of industry standard accessories
- No residual moisture in the container or packaging
- No absorption and outgassing of sterilant



Purillex® Bottles and Stability Vials

Testing

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

In addition, the 170 series Purillex bottles have undergone full USP 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) | ETFE RTU Part # |
|-------------|---------|--------------------------------|----------------|--------------------------------|-----------------|
| 50 mL | 33 mm | 170-01-0050 | 170-01-0050-A | 170-02-0050 | Coming Soon |
| 100 mL | GL45 | 170-01-0100 | 170-01-0100-A | 170-02-0100 | 170-03-0100-G |
| 250 mL | GL45 | 170-01-0250 | 170-01-0250-A | 170-02-0250 | 170-03-0250-G |
| 500 mL | GL45 | 170-01-0500 | 170-01-0500-A | 170-02-0500 | 170-03-0500-G |
| 1000 mL | GL45 | 170-01-1000 | 170-01-1000-A | 170-02-1000 | 170-03-1000-G |
| 2000 mL | GL45 | 170-01-2000 | 170-01-2000-A | 170-02-2000 | Coming Soon |

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