

Purillex® Fluoropolymer Bottles

Savillex Data Sheet

The Savillex Purillex® range of fluoropolymer bottles are the cleanest, safest, and highest performing fluoropolymer bottles ever produced. Available in PFA, FEP, and ETFE resins, Purillex bottles are manufactured by a stretch blow molding process, adapted for fluoropolymer use by Savillex.

Design Features

This proprietary process provides several key benefits, including cleaner and smoother fluid contact surfaces, easier pouring, superior seal integrity, and more.

PFA/FEP/ETFE Resin Attributes:
Wide temperature range
Low leachable and extractable profile
Extreme chemical resistance
Smooth interior surface
Autoclavable (PFA/FEP) or gamma irradiated (ETFE)

Available sterilized or non-sterilized, Purillex bottles are used in a variety of critical applications.

Life Sciences Applications:
Autologous Cell Therapy
Bulk Drug Storage and Transport
Formulation Stability Testing and Storage

Available Sizes

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.

Available Sterilized

All Savillex Purillex bottles are available sterilized. Bottles are individually double-bagged to ensure sterility is maintained prior to use. All sterilization processes are validated to ensure an SAL



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(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 Method and Working Temperature Range

Material	Sterilization Method	Temperature Range
PFA	Autoclave	-328°F to 500°F (-200°C to 260°C)
FEP	Autoclave	-328°F to 392°F (-200°C to 200°C)
EFTE	Gamma	-328°F to 122°F (-200°C to 50°C)

Testing

Comprehensive internal testing has been performed on all Purillex bottles, including drop, leakproof, vacuum resistance, and pressure burst. Test data is available on request. Furthermore, Purillex bottles are Class VI compliant and have undergone full USP extractable and biocompatibility testing. Sterilized bottles also come with manufacturing lot certification. See the table below for certification differences between sterile and non-sterile bottles.

Test	Non-Sterilized	Sterilized
USP Class VI	✓	✓
USP <87> Cytotoxicity	✓	✓
USP <661.2>	✓	✓
BSE/TSE Free	✓	✓
Savillex Internal Leakproof Test	✓	✓
Bioburden	-	✓
USP <788> Particle	-	✓
USP <85> Endotoxin	-	✓

[Click here to learn more about Purillex Fluoropolymer Bottles and shop online.](#)

Bottle Ordering Information

Bottle Size	Closure	PFA Part # (non-sterilized)	PFA Part # (sterilized)	FEP Part # (non-sterilized)	FEP Part # (sterilized)	EFTE Part # (sterilized)
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

Purillex® bottles are a registered trademark of Savillex, LLC.



Savillex

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