

# Stability Vials for Bioprocessing

Savillex offers a range of stability vials in support of biopharmaceutical process validation through stability testing programs. These stability vials are produced using the exact same resin manufacturer and resin grade as our Purillex® bioprocessing bottles to support regulatory filing. Savillex stability vials also come with full manufacturing lot certification.

## Design Features

Savillex stability vials and closures are injection molded from virgin resin, using the same resin grade as the Purillex bottles used for storage and transport of API and intermediates. Stability vials are also perfect for lot retention.

Available in 3 mL, 7 mL and 15 mL sizes, these vials are suitable for a wide range of stability test protocols, and minimize the usage of valuable bulk drug substance for testing and validation.

The injection molding process produces excellent thread quality and avoids the need for secondary machining of the vial lip, greatly reducing the risk of particulate contamination. A high integrity seal is ensured, without the need for secondary seals or inserts. All vials are round bottomed for ease of extracting contents.

Savillex stability vials can easily withstand temperatures down to blast freeze conditions (-70°C), while maintaining seal integrity.

## Material Working Temperature Range

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

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

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



Stability Vials



PFA 3 mL Stability Vial



FEP 7 mL Stability Vial



ETFE 15 mL Stability



## Available Pre-Sterilized

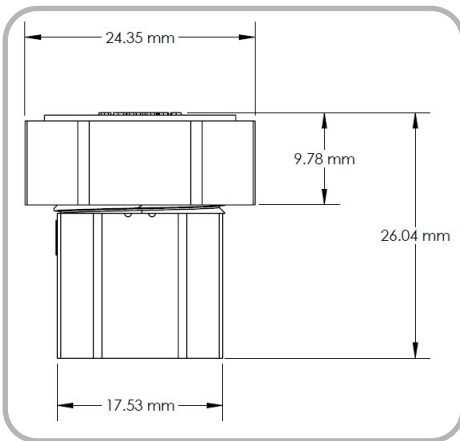
All Savillex stability vials are available pre-sterilized, ready-to-use (RTU) and double-bagged in pack quantity. All sterilization processes are validated to ensure a SAL (sterility assurance level) of  $10^{-6}$  which is the industry standard for use in bioprocess applications.

## Sterilization Process for RTU Products

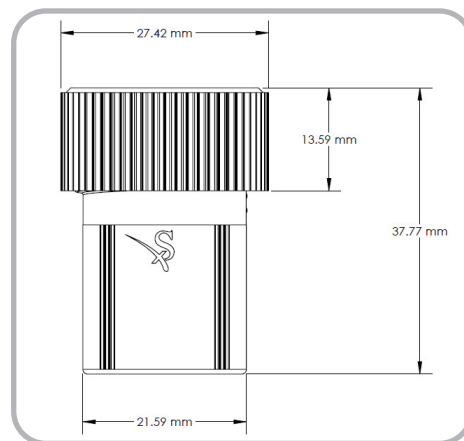
Material	Sterilization Process
PFA	Autoclave
FEP	Autoclave
ETFE	Gamma



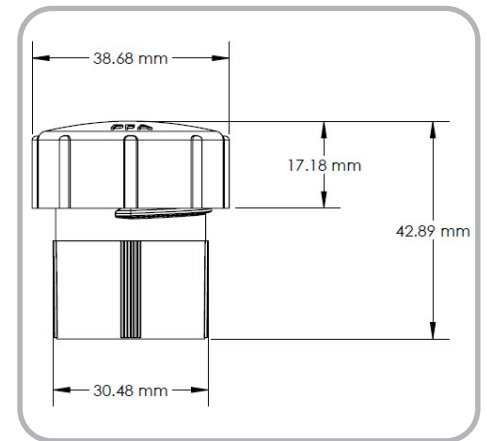
Purillex® Bottles and Stability Vials



3 mL Stability Vial  
23 mm Closure



7 mL Stability Vial  
24 mm Closure



15 mL Stability Vial  
33 mm Closure with Lugs

## Ordering Information

Vial Size	Closure Size	PFA Part # (non-sterilized)	PFA RTU Part #	ETFE RTU Part #	Minimum Order Qty
3 mL	23 mm	271-01-003-20	271-01-003-20-A		300
7 mL	24 mm	271-01-007-20	271-01-007-20-A	271-03-007-20-G	300
15 mL	33 mm	271-01-015-20	271-01-015-20-A	271-03-015-20-G	300

- Also available in FEP by special order
- All vials include closure