

Vented Bottle Assemblies (PETG Bottle)

mdi gamma sterilized Vented Bottle Assemblies are suitable for safe transfer, sampling, and storage of biopharmaceutical products and reagents.

These assemblies are fitted with a self supporting light weight, sterilizing grade 0.2µm PVDF vent filter to prevent ingress of microorganisms during filling and removal of high value products. The unique bottle cap design allows easy opening without rotating the tubing and vent connections.

Applications

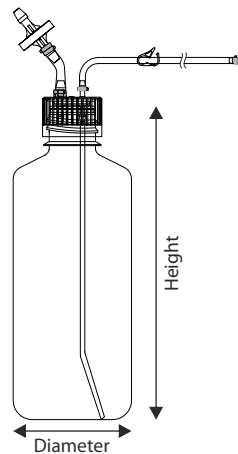
- Storage and transfer of Cell culture media
- Aseptic sampling
- Sterile filling and transfer

Dimensions

Bottle

Capacity	Diameter	Height*
50 mL	40 mm	80 mm
60 mL	40 mm	80 mm
125 mL	53 mm	104 mm
250 mL	59 mm	142 mm
500 mL	73 mm	174 mm
1000 mL	92 mm	213 mm
2000 mL	116 mm	266 mm

*without cap



Hydrophobic PVDF Vent Filter

Capacity	Filter Size
upto 1000 mL	25 mm
2000 mL	50 mm

Inlet Tube

18 inch with press in plug

Specifications

Materials of Construction

- Bottle** : Polyethylene Terephthalate Glycol (PETG)
Cap : High-density polyethylene (HDPE)
Inlet Tube : Thermoplastic Elastomer (TPE)
Dip Tube : Platinum Cured Silicone (PCS)



Toxicity

Passes Bioreactivity test, *In Vivo*, as per USP <88> for Class VI plastics

Endotoxin Testing

Aqueous extracts exhibit <0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Extractables

Passes NVR test as per USP <661>

Fiber Release

Passes test as per USP and comply with USFDA Title 21 CFR Part 210.3(b)(6) for fiber release

Particle Release

Complies with USP <788> test for particulate matter in injections

Sterility Assurance

mdi LDPE vented bottle assemblies are sterilized by gamma irradiation to provide a sterility assurance level of 10^{-6} . The sterilization process has been validated as per ISO 11137-2 which includes dose verification, dose mapping and quarterly dose audits.

The sterilization dose of 25 kGy has been substantiated through careful definition of the test samples, bio-burden testing of multiple lots of the selected test samples, calculation of verification dose and sterility testing.

Quality Management System

mdi PETG vented bottle assemblies are well designed products with in-built quality assurance. ISO-9001:2018 Certified Quality Management System, careful selection of raw materials, validated production processes and testing procedures based on international standards and guidelines such as CFR, PDA, and ASTM, ensures manufacture of consistently high quality assemblies.

Manufacturing Facilities

These are manufactured in clean rooms certified by external agencies and monitored in-house for viable and non viable particles. Employee hygiene, change rooms, gowning and de-gowning procedures and continuous monitoring of the areas is an essential part of these facilities. These facilities have been designed for unidirectional work flow with appropriate change rooms for personnel and pass boxes for material movement.

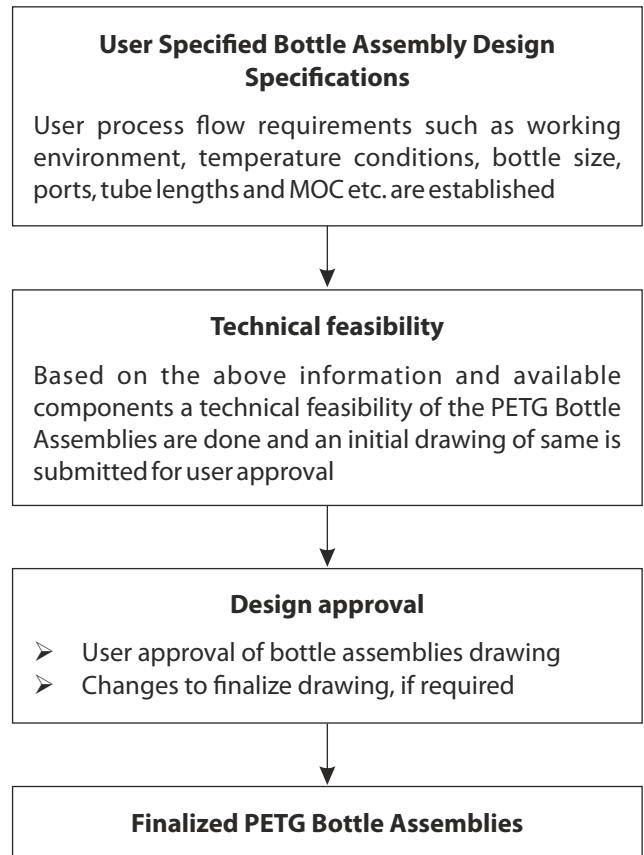
Ordering Information for Standard PETG Bottle Assemblies

for 50 mL Bottle Assembly	: VBAPS38TXXX301
for 60 mL Bottle Assembly	: VBAPR38TXXX301
for 125 mL Bottle Assembly	: VBAPP38TXXX301
for 250 mL Bottle Assembly	: VBAPB38TXXX301
for 500 mL Bottle Assembly	: VBAPV38TXXX301
for 1000 mL Bottle Assembly	: VBAPC38TXXX301
for 2000 mL Bottle Assembly	: VBAPD53TXXX301

Customization

mdi PETG vented bottle assemblies can be customized to suit user requirements in terms of tubing, fittings, end connections, bottle sizes and connectors.

Product Realization Flow Chart



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