Membrane Technologies

AseptiMix VC
Vented Mixer Assemblies

DATASHEET

mdi *AseptiMix VC* are gamma sterilized vented mixer assemblies, suitable for mixing, safe transfer and storage of biopharmaceutical products and reagents. The assembly does not require any additional hardware and can directly be placed on a magnetic mixer for mixing with a stir bar placed inside.

The PVDF stir bar inside the mixer assembly has wide chemical compatibility and it ensures the proper mixing of solution without any particle shedding.

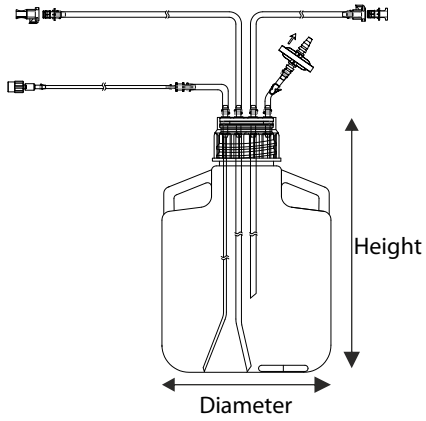
These assemblies are fitted with a self supporting light weight, sterilizing grade 0.2µm PVDF vent filter to prevent ingress of microorganisms during filling and removal of high value products.

Applications

- Mixing, storage and transfer of cell culture media and buffers

Dimensions

Capacity	Diameter	Height
10 L	249 mm	390 mm
20 L	285 mm	535 mm



Specifications

Materials of Construction

Carboy : Low density polyethylene
Cap : High density polyethylene
Inlet Tube : Platinum cured silicone
Dip Tube : Platinum cured silicone
Vent Filter
- Membrane : 0.2µm hydrophobic PVDF
- Body : Polypropylene

Stir Bar : PVDF

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 *AseptiMix VC* vented mixer 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 *AseptiMix VC* vented mixer 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

Ordering Information for Standard Mixer Carboy Assemblies

for 10 L Bottle Assembly: VCALF83XXXXX301
for 20 L Bottle Assembly: VCALG83XXXXX301

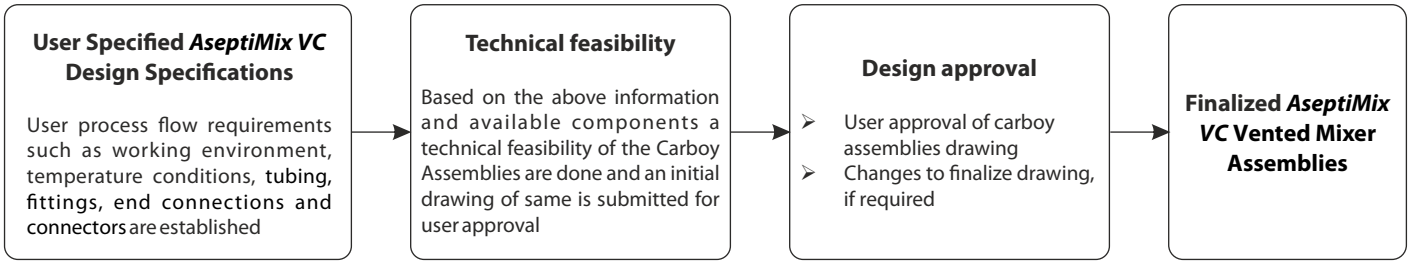
Customization

mdi *AseptiMix VC* vented mixer assemblies can be customized to suit user requirements in terms of tubing, fittings, end connections and connectors.

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.

Product Realization Flow Chart



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