AseptiMix™

Mixer Bottle and Carboy Assemblies

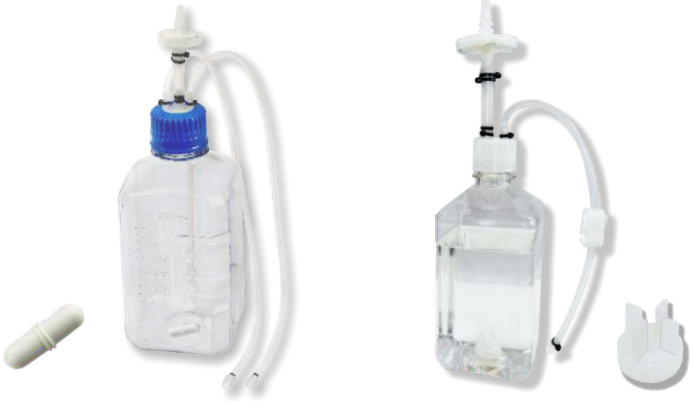
DATASHEET

Product Description

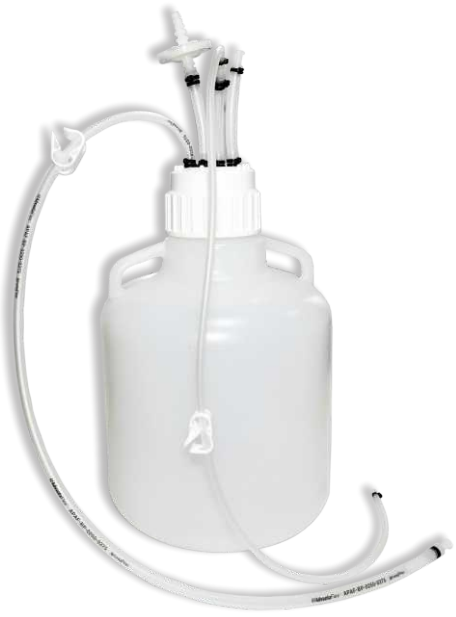
mdi *AseptiMix*™ are gamma sterilized vented bottle and carboy mixer assemblies, suitable for mixing, safe transfer and storage of biopharmaceutical products and reagents. The assembly does not require any additional hardware and can directly be placed on a magnetic mixer for mixing with a stir bar or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

The stir bar/impeller 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.



AseptiMix™ VB vented bottle mixer assemblies



AseptiMix™ VC vented carboy mixer assemblies

DST AMVBVCX2404D

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Applications

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

Specifications: Material of Construction

AseptiMix™ VB Mixer Bottle Assemblies

Bottle	LDPE
	PETG
Cap	Polypropylene
Inlet Tube	Platinum Cured Silicone
Dip Tube	Platinum Cured Silicone
Vent Filter Membrane	0.2 µm Hydrophobic PVDF
Vent Filter Body	Polypropylene
Impeller	Polypropylene
Stir Bar	PVDF

AseptiMix™ VC Mixer Carboy Assemblies

Carboy	LDPE
	Polypropylene
	HDPE (white color)
	HDPE (amber color)
Cap	Polypropylene
Inlet Tube	Platinum Cured Silicone
Dip Tube	Platinum Cured Silicone
Vent Filter Membrane	0.2 µm Hydrophobic PVDF
Vent Filter Body	Polypropylene
Impeller	Polypropylene
Stir Bar	PVDF

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Specifications

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* ™ vented mixer bottle and carboy 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.

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Quality Management Systems

mdi *AseptiMix*™ vented mixer assemblies are well designed products with in-built quality assurance. ISO-9001:2015 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 Systems

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.

Customization

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

Product Realization Flow Chart

User Specified *AseptiMix*™ Design Specifications
User process flow requirements such as working environment, temperature conditions, tubing, fittings, end connections and connectors are established

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Technical Feasibility
Based on the above information and available components a technical feasibility of the Mixer Assemblies are done and an initial drawing of same is submitted for user approval

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Design approval
- User approval of mixer assemblies drawing
- Changes to finalize drawing, if required

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Finalized *AseptiMix*™ Vented Mixer Assemblies

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