SterilGuard® Asepto

Ready-to-Use Single-Use Sterility Test Canister

A practical single-use solution engineered to simplify pharmaceutical sterility-testing workflows while maintaining controlled filtration, product

SterilGuard® Asepto provides a practical filtration platform for sterility testing where the test sample is passed through a membrane capable of retaining microorganisms.

Following filtration, appropriate rinsing and culture-media introduction procedures can be performed according to the applicable sterility-test method and laboratory procedure.

The single-use construction supports efficient laboratory workflow while helping maintain separation between individual test operations.

VANGUARD

SterilGuard® Asepto

Ready-to-Use Sterility Test Canister
Simplifying Sterility Testing. Protecting Every Step.

SterilGuard® Asepto is a sterile, ready-to-use single-use canister designed for membrane-filtration sterility testing of pharmaceutical products in accordance with USP <71>.

Designed to minimize preparation and handling before testing, SterilGuard® Asepto provides an integrated filtration solution for routine sterility testing applications. Each canister is supplied sterile and individually packaged, allowing operators to establish a controlled filtration pathway with reduced assembly requirements.

The system incorporates a 47 mm, 0.2/0.45 µm MCE/PVDF membrane and is manufactured from carefully selected polymeric materials suitable for pharmaceutical laboratory use.

Ready When You Are

SterilGuard® Asepto is supplied as a pre-assembled, EO-sterilized single-use system, eliminating the cleaning, assembly and sterilization steps associated with reusable filtration assemblies.

Its disposable configuration helps simplify workflow while reducing the risk of contamination associated with repeated handling and reprocessing.

Key Benefits

Ready-to-use sterile configuration
Single-use design
Reduces preparation and assembly steps
Minimizes handling before sterility testing
Integrated 47 mm membrane filtration area
0.45 µm MCE membrane
Individually packaged for controlled use
EO sterilized using an ISO 11135 validated process
Sterility Assurance Level (SAL) of 10^{6}
Designed for membrane-filtration sterility testing according to USP <71>
Eliminates cleaning and reprocessing of reusable canisters
Lot-controlled manufacturing and quality verification.

Typical Applications

SterilGuard® Asepto is intended for membrane-filtration sterility testing of pharmaceutical products where a ready-to-use disposable filtration system can improve operational efficiency.

- Sterility testing of pharmaceutical products
- Injectable product testing
- Sterile solution testing
- Antibiotic and antimicrobial product testing*
- Ophthalmic preparation testing
- Water-based pharmaceutical preparation testing
- Quality-control microbiology laboratories
- Pharmaceutical manufacturing sterility laboratories

*Appropriate rinsing and neutralization procedures should be selected according to the characteristics of the test product and applicable validated method.

MCE Membrane

At the heart of SterilGuard® Asepto is a 47 mm diameter, 0.45 µm Mixed Cellulose Ester (MCE) membrane.

MCE membrane is widely suited to microbiological membrane-filtration applications and provides the microbial retention characteristics required for sterility-testing workflows.

PVDF Membrane

At the heart of SterilGuard® Asepto is a 47 mm diameter, 0.45 µm PVDF membrane.

PVDF membrane is widely suited to microbiological membrane-filtration applications and provides the microbial retention characteristics required for sterility-testing workflows.

Product Specifications

Quality by Design

SterilGuard® Asepto is manufactured and assembled under controlled production conditions.

Critical product characteristics are monitored through defined inspection and quality-control procedures to ensure consistent performance from lot to lot.

Quality controls include verification of applicable characteristics such as:

Product assembly
Membrane installation
Component integrity
Dimensional conformity
Packaging integrity
Sterilization status
Lot identification and traceability

Representative samples from each production lot are subjected to defined quality-control testing according to approved procedures.

Materials of Construction

Product Family:	SterilGuard®
Product:	SterilGuard® Asepto
Description:	Ready-to-Use Single-Use Sterility Test Canister
Test Principle:	Membrane Filtration
Membrane Material:	MCE/PVDF
Membrane Pore Size:	0.2 µm / 0.45 µm
Membrane Diameter:	47 mm
Canister Material:	PMMA
Lid Material:	PMMA
Tubing Material:	PVC
Sterilization Method:	Ethylene Oxide (EO)
Sterilization Validation:	ISO 11135
Sterility Assurance Level:	SAL 10^6
Primary Packaging:	Tyvek® + PE
Validated Shelf Life:	1 Year
Configuration:	Single Use
Intended Application:	Membrane-filtration sterility testing according to USP <71>

Validated EO Sterilization

Every SterilGuard® Asepto canister is supplied sterile following Ethylene Oxide (EO) sterilization.
The sterilization process is validated in accordance with: ISO 11135 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process.
The validated sterilization process is designed to achieve:
Sterility Assurance Level (SAL) 10^6
Sterilization status and applicable manufacturing records are maintained under controlled quality procedures.

Individual Sterile Packaging

Each SterilGuard® Asepto assembly is individually packed using Tyvek® and polyethylene sterile barrier system.

The packaging is designed to maintain product integrity and ste throughout the validated shelf-life period when transported and stored under the specified conditions.

Subject to specified storage conditions and package integrity.

Tyvek pouch

Single-Use Construction

SterilGuard® Asepto is designed as an integrated disposable assembly to reduce the number of components that need to be prepared by the operator.

Main Construction Materials

Canister Body: PMMA
Canister Lid: PMMA
Tubing: PVC
Primary Sterile Packaging: Tyvek® + PE

The transparent canister construction allows visual observation of the filtration process and liquid condition during operation.

bottom Lock

Venting Needle

Single-Press Secure Clamp

Ordering Information

Filter Media		Rating (µm)		Sterile
VGC-D120	-	0.2	-	S
D = MCE		0.20		S = Sterile
P = PVDF		0.45		N = non-sterile

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