ТЕСТЕР СТЕРИЛЬНОСТИ STERITEST NEO

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Steritest™ NEO
Sterility Testing Devices

Convenience, Reliability and Safety

Sterility testing is one of the most crucial steps in pharmaceutical product release.

Our Steritest™ NEO devices simplify every aspect of testing, from handling to traceability, all within a closed concept system. The ease and convenience of this closed assembly enables you to increase productivity while maintaining the highest levels of quality and reliability. When used with the Steritest™ Symbio pump, the Steritest™ sterility test system delivers unmatched sterility testing consistency.

Since 1974, we are the market leader in sterility testing. The Steritest™ NEO devices, set a new standard for excellence, while maintaining all the advantageous membrane-base sealing technique.

Benefits

- Thermo-sealed filtration membranes onto the base in all Steritest™ NEO units, ensure full integrity of the device, efficient membrane rinsing and eliminate the risk of by-pass
- Ergonomically designed needles fit the majority of test containers while maintaining a closed concept system
- Pre-installed colored clamps prevent any media filling errors and improve your workflow
- Canister design reduces foaming, enabling faster filtration
- Engraved information on each canister and peel-and-stick box label optimize traceability
- Volume graduation on the canisters improve your workflow accuracy (addition of a 25 mL graduation)
- Pre-cut line on accessories bag to ease the opening
- Placement mark on tubing to ease the placement in the pump head*

* coming soon

For Antibiotics and Products With Antimicrobial Agents

Ideally suited for antibiotic sample testing, the "Red Base" Steritest™ NEO devices incorporate our Durapore® (PVDF) membrane, offering broad chemical compatibility and low binding properties. The chemical composition of the extremely thin 0.45 µm Durapore® membrane provides low antibiotic binding, which improves rinsing efficiency and reduces the risk of false negatives. The canister design ensures efficient rinsing of residual antimicrobial agents and the needle and connections minimize the risk of antibiotic residuals.

For Products Without Antimicrobial Agents

The "Blue Base" Steritest™ NEO devices offer the ultimate in flexibility. Perfect for use with the majority of pharmaceutical drugs that do not have antimicrobial activity, our mixed esters of cellulose HA membrane allows fast flow rates for optimum throughput performance, and reduced testing time. A range of ergonomic needles is available to meet specific drug packaging requirements as well as simplify handling by gloved operators.

For Products requiring increased Chemical Compatiblity

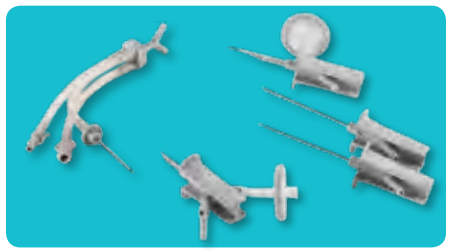
The "Green Base" Steritest™ NEO devices are suited for viscous products, such as creams and ointments, which are normally diluted in a sterile solvent, such as isopropyl myristate (IPM) to improve filterability. The solvent-resistant nylon canister and the Durapore® (PVDF) membrane ensure a perfect chemical compatibility with IPM and other solvents. The reinforced base structure and canister connection guarantee an unmatched resistance of the testing device during the whole filtration process.
The "Green Base" Steritest™ NEO devices are the perfect choice for testing solvents, creams, ointments and veterinary injectables.

Pre-installed Colored Clamps and Secure Tubing Length for Easy Handling

Steritest™ NEO canister tubing includes pre-installed colored clamps, eliminating the risk of error during media filling. Closing and re-opening the clamps during testing is as simple as pressing down or releasing as necessary. The 850 mm tubing length and the placement mark offer easier set-up with ample room and precision to perform the manipulations involved in sterility testing.

Canister Inlet Reduces Foaming and Speeds Filtration

In the past, analysts needed to reduce pump speed in order to minimize foaming when filtering protein solutions or adding media. The Steritest™ NEO canister inlet design reduces foaming, enabling faster filtration. This feature, coupled with our high-flow mixed esters of cellulose membrane, improves reliability while allowing you to maintain high pump speeds and reduce testing time.



Needle Increase Efficiency and Security

Multiple needles adapters enable fast and easy manipulation of liquid drugs.

- Fits the majority of drug containers; reducing the risk of blockage when testing drugs in vials with thick septa
- Ergonomic, non-skid design provides a firm grip for gloved operations, especially in isolators

Closed Environment for Complete Testing Confidence

Using Steritest™ NEO devices ensures that pharmaceutical products are never exposed to the environment during the testing process. Sampling, filtering, rinsing, media transfer and incubating are all conducted within the Steritest™ NEO closed system. There is no need to open the containers or manipulate the membrane at any time-greatly reducing the risk of adventitious contamination.

Documented Qualification

We have compiled comprehensive Steritest Qualification Reports (available upon request) that confirms Steritest™ NEO device performance.

Consistent Performance

From the people who know sterility testing, we still take nothing for granted. We rigorously test each device during and after manufacturing.

- 100% integrity testing on every canister
- Strict physical and microbiological tests at every step of the assembly of the Steritest™ NEO device prior to release from manufacturing
- Certificate of quality provided with each system for your batch records
- Easy traceability with catalogue number, lot number, serial number and expiration date engraved on each canister

Specifications

Steritest™ NEO "Red Base" devices

For Antibiotics and Products Containing Antimicrobial Agents

Canister Base Color	Red
Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Materials of Construction *Filtration Chamber (Canister):* *Double Lumen Tubing:* *Needle:*	 Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation

Steritest™ NEO "Blue Base" devices

For Products without Antimicrobial Agents

Canister Base Color	Blue
Canister Base Membrane	Mixed Esters of Cellulose membrane, 0.45 µm
Materials of Construction *Filtration Chamber (Canister):* *Double Lumen Tubing:* *Needle:*	 Styrene acrylonitrile PVC, 850 mm length Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation

Steritest™ NEO "Green Base" devices

For Products requiring increased chemical compatibility

Canister Base Color	Green
Canister Base Membrane	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Materials of Construction *Filtration Chamber (Canister):* *Double Lumen Tubing:* *Needle:*	 polyamide 6-6 (nylon) PVC, 850 mm length Stainless steel and polyamide 6-6
Sample Container Capacity	120 mL (graduation marks at 25, 50, 75 and 100 mL)
Minimum Flow Rate (for water)	300 mL/min at 690 mbar (10 psi)
Maximum Temperature	45 °C
Maximum Operating Pressure	3.15 bars at 25 °C (45 psi at 77 °F)
Sterilization	Gamma irradiation

Ordering Information

Steritest™ NEO devices for products without antimicrobial agents

Description	Pack size	Catalog number
Liquids in ampoules and collapsible bags		
Steritest™ NEO device	10	TZHALA210
Steritest™ NEO device double packed	10	TZHALA205
Liquids in large vials		
Steritest™ NEO device	10	TZHALV210
Steritest™ NEO device double packed	10	TZHALV205
Liquids in small vials		
Steritest™ NEO device	10	TZHASV210
Steritest™ NEO device double packed	10	TZHASV205
Medical devices and collapsible bags		
Steritest™ NEO device	10	TZHAMD210
Liquids in syringes		
Steritest™ NEO device	10	TZHASY210
Liquids in plastic containers		
Steritest™ NEO device	10	TZHAPC210
Soluble powders in ampoules		
Steritest™ NEO device	10	TZHADA210
Soluble powders in vials		
Steritest™ NEO device	10	TZHADV210

Steridilutor® NEO devices and accessories

Description	Pack size	Catalog number
Steridilutor® NEO device for vials		
Steridilutor® NEO device without expansion chamber	10	TZV000010
Steridilutor® NEO device with expansion chamber	10	TZVC00010
Steridilutor® NEO device for liquid transfer		
Steridilutor® NEO device for liquid transfer	10	TZA000010
Sterile vent needles		
Sterile vent needles	25	TEFG02525

Steritest™ NEO devices for antibiotics and products with antimicrobial agents

Description	Pack size	Catalog number
Antibiotics		
Steritest™ NEO device	10	TZHVAB210
Steritest™ NEO device double packed	10	TZHVAB205
Powders and superpotent antibiotics		
Steridilutor® NEO device with expension chamber	10	TZVC00010
Steritest™ NEO device	10	TZHVAB210
Recommended accessories		
Holder for Steridilutor® NEO vent chamber	1	SYMBSVB01
Sterile vent needles	25	TEFG02525
Liquids in large vial		
Steritest™ NEO device	10	TZHVLV210
Steritest™ NEO device double packed	10	TZHVLV205
Liquids in small vial		
Steritest™ NEO device	10	TZHVSV210
Steritest™ NEO device double packed	10	TZHVSV205
Soluble powders in vials		
Steritest™ NEO device	10	TZHVDV210
Steritest™ NEO device double packed	10	TZHVDV205
Medical devices and collapsible bags		
Steritest™ NEO device	10	TZHVMD210

Note: For antibiotics or strong inhibitory products, the use of the TZHVAB210 filtration devices is highly recommended. Prior to the filtration step, it is recommended to dissolve and/or pool samples with the Steridilutor® NEO device.

Steritest™ NEO devices for increased chemical compatibility

Description	Pack size	Catalog number
Solvents, creams, ointments, and veterinary injectables		
Steritest™ NEO device	10	TZHVSL210

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