

# 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 enable you to increase productivity while maintaining the highest levels of quality and reliability. When used with the Steritest™ Symbio pump and Steritest™ culture media and fluids, the Steritest™ system delivers unmatched sterility testing consistency.

Since 1974, we have been the market leader in sterility testing. Our Steritest™ NEO devices set a new standard for excellence while maintaining all the advantages of membrane-base sealing technique.



#### Closed device for complete testing confidence

Using Steritest<sup>TM</sup> NEO devices ensures that pharmaceutical products are never exposed to the environment during the testing process. Filtering, rinsing, media transfering and incubating are all conducted within the Steritest<sup>TM</sup> 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 resulting in false positive results.

#### **Consistent performance**

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



#### **Benefits**

- Thermo-sealing of filtration membranes in all Steritest™ NEO units ensures full device integrity, efficient membrane rinsing and elimination of by-pass and false negative results
- New needle design fits the majority of test containers while maintaining a closed concept system
- Pre-installed colored clamps prevent any media filling errors and improve your workflow
- 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 optimize the placement in the pump head
- Engraved information on each canister and peel-and-stick box label improve traceability



#### Latest innovations



New needle designs for increased safety and flexibility

New needle guard and needle protector designs increase confidence in manipulating the needle.

The protective cap comes in two options, either a short (35 mm) or a long (60 mm) needle best fitting your sample packaging configuration.

In addition to the multiple needle configurations, a new short (20 mm) needle is now dedicated to cartridges and small soft plastic containers. Learn more with our video on SigmaAldrich.com/video-steritestneo-ca



Pre-installed colored clamps and tube marking for testing method reliability

Steritest™ NEO canister tubing includes pre-installed colored clamps, eliminating the risk of error during media filling. Closing and reopening 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.



Simplified product identification and traceability

Clear packaging identification is offered with the canister base color codes and units drawing printed on the box label.

1D bar code is also available and can be sticked into your lab book thanks to the peel-and-stick bottom part of the label

### 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 for gloved operators.

### For antibiotics and products with antimicrobial agents

The "Red Base" Steritest™ NEO devices, ideally suited for antibiotic sample testing, incorporate our Durapore® (PVDF) HV 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 negative results. The canister design ensures efficient rinsing of residual antimicrobial agents and the needle and connections minimize the risk of antibiotic residuals.

### 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) HV membrane ensure a perfect chemical compatibility with IPM and other solvents. The reinforced base structure and canister connection quarantee an unmatched pressure 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.







#### **Specifications**

Blue	Red	Green
Mixed Esters of Cellulose membrane, 0.45 μm	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF	Low adsorption Durapore® membrane, 0.45 µm hydrophilic PVDF
Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6	Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6	Polyamide 6-6 (nylon) PVC, 850 mm length Stainless steel and polyamide 6-6
120 mL (graduation marks at 25, 50, 75 and 100 mL)	120 mL (graduation marks at 25, 50, 75 and 100 mL)	120 mL (graduation marks at 25, 50, 75 and 100 mL)
300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)	300 mL/min at 690 mbar (10 psi)
45 °C	45 °C	45 °C
3.15 bars at 25 °C (45 psi at 77 °F)	3.15 bars at 25 °C (45 psi at 77 °F)	3.15 bars at 25 °C (45 psi at 77 °F)
Gamma irradiation	Gamma irradiation	Gamma irradiation
	Mixed Esters of Cellulose membrane, 0.45 µm  Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6  120 mL (graduation marks at 25, 50, 75 and 100 mL)  300 mL/min at 690 mbar (10 psi)  45 °C  3.15 bars at 25 °C (45 psi at 77 °F)	Mixed Esters of Cellulose membrane, 0.45 μm hydrophilic PVDF  Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6  120 mL (graduation marks at 25, 50, 75 and 100 mL)  300 mL/min at 690 mbar (10 psi)  45 °C  3.15 bars at 25 °C (45 psi at 77 °F)  Low adsorption Durapore® membrane, 0.45 μm hydrophilic PVDF  Styrene acrylonitrile (SAN) PVC, 850 mm length Stainless steel and polyamide 6-6  120 mL (graduation marks at 25, 50, 75 and 100 mL)  300 mL/min at 690 mbar (10 psi)  45 °C  3.15 bars at 25 °C (45 psi at 77 °F)

#### **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 <sup>™</sup> NEO device double packed	10	TZHASV205
Medical devices and collapsible bags		
Steritest™ NEO device	10	TZHAMD210
Liquids in syringes		
Steritest <sup>™</sup> 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
NEW Liquids in cartridges and small soft plastic containers		
Steritest™ NEO device	10	TZHACA210

#### 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		
Steritest™ 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
Steritest™ vent needles	25	TEFG02525
Liquids in large vial		
Steritest™ NEO device	10	TZHVLV210
Steritest <sup>™</sup> 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
NEW Liquids in cartridges and small soft	plastic	containers
Steritest™ NEO device	10	TZHVCA210

**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		Catalog number		
Solvents, creams, ointments, and veterinary injectables				
Steritest™ NEO device	10	TZHVSL210		

#### Learn more at SigmaAldrich.com/steritestneo

# To place an order or receive technical assistance

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