

thermo scientific

Nalgene low and ultralow particulate containers

Protecting your
products, processes,
and quality.



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Multi-tier portfolio to suit your application needs

When working in a critical environment such as a clean room or when producing critical bioproducts, even microscopic amounts of contamination can have a disastrous impact. Contamination can render whole batches or materials unusable, with obvious cost, time, and productivity implications. That's why products must conform to the standards of cleanliness required to safeguard both intermediates and the final product.

The tiered portfolio of Thermo Scientific™ Nalgene™ containers provides bioproduction facilities with a range of high-quality sterile storage and transport options while addressing particulate level (USP <788>), endotoxin level, and sterility requirements. By choosing the “level of clean” required for your application, you can support quality and regulatory compliance.

When only the cleanest will do, Thermo Scientific™ Nalgene™ Platinum Clean ultralow particulate containers offer the lowest levels of particulates and endotoxins. They are certified to contain less than one-third of the allowable particulate limits specified in USP <788>. These sterile products come ready-to-use with robust triple-layer packaging for cleanroom use. Compliance with cGMP regulations helps reduce the risk of drug recall post-launch. In addition to a validated level of clean, Thermo Fisher Scientific offers a reliable, continuous supply chain to help minimize delays in project timelines.

How clean is clean

The Nalgene container tiers of clean help meet the different application requirements of bioproduction facilities. All containers are supplied with supporting literature binders, forced extraction studies, and quality certificates, providing products to help meet your required standards.

Table 1. Tiered portfolio.

Tier	Product qualities
Standard clean	<ul style="list-style-type: none"> • Available sterile or nonsterile • Manufactured from high-quality resins • Dimensionally optimized design • Features handles, volume graduations, and leakproof* closures
Certified clean	<ul style="list-style-type: none"> • SAL of 10^{-6} inside and outside of the container • Compliant with USP <788> • <0.5 EU/mL endotoxin • Produced in clean room • Triple-layer packaging (2 heat seals and 1 carton liner)
Platinum certified clean	<ul style="list-style-type: none"> • SAL of 10^{-6} inside and outside of the container • Below one-third of the allowable USP <788> particulate limits • <0.25 EU/mL endotoxin • Washed with WFI (water for injection) and inspected, assembled, and packaged in Class 5 (100) cleanrooms with Class 4 (10) hoods and full gowning for operators** • Triple-layer packaging (2 heat seals and 1 carton liner)

* Our guarantee for a leakproof seal is subject to our standard product warranty, as set forth in the **Thermo Fisher Scientific Terms and Conditions of Sale**. Our products are leakproof under use with our required specifications at ambient temperature and pressure when used with their corresponding closures, when handled properly and secured by the user properly. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned application.

** Not all Platinum Certified Clean products require WFI wash to meet particulate claims



Getting the right level of clean

Critical pharmaceutical and biopharmaceutical products that may be injected into a patient need to conform to strict regulations, including USP <788>. Nalgene Platinum Clean containers have undergone a strict washing procedure, which means the containers are certified to contain less than one-third of the allowable particulate limits specified in USP <788>.

Nalgene Platinum Clean containers are manufactured to have a fraction of the permissible particulate contamination. This helps ensure there is minimal contribution of particulate load to the final product, allowing for any product batch-to-batch variation and accommodating standard deviation errors in assay testing. Nalgene Platinum Clean containers help customers protect their products, quality, and patients while maintaining productivity.

While the importance of minimizing contamination risk cannot be overstated, choosing the most appropriate level of clean for the application is also budget-conscious. Where contamination risks are low, simply switch to a more cost-effective level. The technical specialists at Thermo Fisher Scientific are happy to provide guidance on which product to use.

As a trusted collaborative supplier with facilities across the globe, Thermo Fisher Scientific provides customers with a single point of direct contact to route inquiries to appropriate support personnel. These include industry and regulatory specialists with vast knowledge of different clean parameters, validation options, and certifications. In addition, we can help with troubleshooting or managing purchasing lead times.



Availability

Nalgene containers are available in a range of materials.

Table 2. Range of container materials.

Tier	PETG	PC	HDPE
Standard clean	x	x	x
Certified clean	x	x	Custom solution available
Platinum clean	x	x	x

Applications

Whether you are working in cell culture, or biopharmaceutical or vaccine production, there is a Nalgene clean container to suit your required level of clean, helping minimize contamination risks and maintaining both clean room and product integrity. For detailed guidance on your application of interest, contact your Thermo Fisher Scientific specialist.

Table 3. Applications.

Tier	Application examples
Standard clean	<ul style="list-style-type: none">• Buffer preparation
Certified clean	<ul style="list-style-type: none">• Cell culture media storage• Human genetics final product and final fill and finish• Bulk drug substance storage• Sampling from bioreactor
Platinum clean	<ul style="list-style-type: none">• Final drug substance• Oligonucleotides/chemistry for gene therapeutics• Sterile media• Human genetics stability studies• Bulk drug substance storage





Dedicate your time to manufacturing, not cleaning

To further meet your cleanliness requirements, Thermo Scientific™ Custom Processing Services can clean glass or plastic containers, stoppers, closures, or other components up to 50 L in size. All of the cleaning services and packaging are performed in our ISO 9001–registered facility using certified Class 10 packaging areas in Class 100 clean rooms with documented traceability and GMP compliance.

Our cleaning services are designed to alleviate contamination concerns when they are used downstream in production for bulk drug storage and when filtration is not possible. These include:

- **Particulate washing service**—resulting in product with less than one-third of the allowable particulates according to USP <788>, and endotoxin levels of <0.25 EU/mL
- **Packaging services**—double or triple bagging in the quantity and configuration of your choice
- **Sterilization services**—with option of a validated sterility assurance level (SAL) of 10^{-6} according to USP <71>
- **Depyrogenation service**—containers processed to meet endotoxin levels according to USP <85>
- **Low total organic carbon (TOC) services**—helping ensure <10 ppb TOC
- **Silanization service**—inhibits adherence to container surface, for maximum recovery of contents



PETG

PETG containers have robust gas-barrier properties and offer low permeability to gases such as O₂ and H₂O₂.

- Suitable for storage in conditions from -70°C to 70°C
- White, low-density polyethylene (LDPE)-lined, radiation-stable polypropylene (PP) closure

Ordering information

Thermo Scientific™ Nalgene™ PETG Certified Clean Biotainer™ Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
125 mL	38 mm	52 mm	105 mm	5/100	16410591
500 mL	38 mm	77 mm	176 mm	5/70	16400591
1,000 mL	48 mm	98 mm	201 mm	5/35	16430591
2,000 mL	48 mm	116 mm	265 mm	20/20	16450591
2,000 mL	48 mm	116 mm	265 mm	5/20	16460591
5,000 mL	48 mm	166 mm	299 mm	1/6	16420601
5,000 mL	48 mm	166 mm	299 mm	1/6	16430601

* With polyethylene handle.

Thermo Scientific™ Nalgene™ Square PETG Certified Clean Media Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
30 mL	20 mm	38 mm	64 mm	6/72	16420581
60 mL	24 mm	41 mm	82 mm	6/72	16430581
125 mL	38-430	52 mm	108 mm	6/48	10702107
250 mL	38-430	59 mm	144 mm	6/48	16450581
500 mL	38-430	73 mm	178 mm	4/24	16460581
1,000 mL	38-430	92 mm	219 mm	2/24	10310155
2,000 mL	53B	116 mm	271 mm	1/12	10289804

Thermo Scientific™ Nalgene™ Square PETG Platinum Clean Media Bottles					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20 mm	22 mm	46 mm	52/416	16450611
20 mL	20 mm	30 mm	65 mm	84/504	16460611
250 mL	38-430	59 mm	144 mm	12/48	16410611
1,000 mL	38-430	92 mm	219 mm	5/35	16430611
2,000 mL	53B	116 mm	271 mm	5/20	16440611

PC

The robustness and impact resistance of PC at cold temperatures make PC bottles and carboys ideal for freezing all of your high-value products.

- White, silicone-lined, radiation-stable PP closure
- Recommended temperature range of –100°C to 100°C
- Validation vials available in 5 mL and 20 mL sizes

Ordering information

Thermo Scientific™ Nalgene™ PC Certified Clean Biotainer™ Bottles and Carboys					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
125 mL	38 mm	52 mm	105 mm	5/50	16420591
1,000 mL	48 mm	98 mm	201 mm	5/35	16440591
2,000 mL	38 mm	116 mm	265 mm	5/20	16470591
5,000 mL	38 mm	166 mm	299 mm	1/6	16480591
5,000 mL	48 mm	166 mm	299 mm	1/2	16490591
10,000 mL	48 mm	255 mm	337 mm	1/2	16400601
10,000 mL	48 mm	255 mm	337 mm	1/2	16410601
20,000 mL	48 mm	255 mm	495 mm	1/3	16440601

* With attached handle.

Thermo Scientific™ Nalgene™ PC Platinum Clean Biotainer™ Bottles and Carboys					
Volume	Closure size	Outer diameter (OD)	Height with closure	Quantity per pack/case	Cat. No.
5 mL	20 mm	22 mm	46 mm	52/416	16470631
20 mL	20 mm	30 mm	69 mm	84/504	16480631
125 mL	38 mm	52 mm	105 mm	5/50	16400631
1,000 mL	48 mm	98 mm	201 mm	5/35	16420631
2,000 mL	38 mm	116 mm	265 mm	5/20	16440631
10,000 mL	48 mm	255 mm	337 mm	1/2	16450631
					16460631

HDPE

HDPE containers offer excellent chemical resistance, and the wide range of chemical compatibilities makes them a great option for storage of harsh materials.

- Support storage conditions of –100°C to 120°C
- LDPE-lined, radiation-stable PP closure (sizes 10 L and above with white PP closures)

Ordering information

Thermo Scientific™ Nalgene™ Certified Platinum Clean HDPE Bottles and Carboys						
Description	Volume	Closure size	Optical density (OD)	Height with closure	No. per pack/case	Cat. No.
Narrow-mouth bottle	30 mL	20-415	34.3 mm	61 mm	12/72	16470601
	250 mL	24-415	61 mm	133 mm	12/72	16470611
	500 mL	28-415	72.6 mm	170.4 mm	12/48	16480611
	1 L	38-430	91.4 mm	215.9 mm	6/24	16490611
Wide-mouth bottle	250 mL	43-415	61 mm	99.3 mm	12/72	16400621
	500 mL	53-415	72.6 mm	168.2 mm	12/48	16410621
	1 L	63-415	91.44 mm	199.2 mm	6/24	16420621
Carboy with integrated handles	10 L	83B	250.2 mm	389 mm	1/6	16450621
	20 L		284.2 mm	501.7 mm	1/4	16460621
	33 L		381 mm	546 mm	1/1	16470621

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