



## Nalgene clean containers

Protecting your products,  
processes, and quality

# 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 enable quality and regulatory compliance.

When only the cleanest will do, Thermo Scientific™ Nalgene™ Platinum Clean 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. Complete 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 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 confidence that products meet your required standards.

**Table 1. Tiered portfolio.**

| Tier                     | Product qualities  |
|--------------------------|--|
| Standard clean           | <ul style="list-style-type: none"><li>• Available sterile or nonsterile</li><li>• Manufactured from high-quality resins</li><li>• Dimensionally optimized design</li><li>• Features handles, volume graduations, and leakproof* closures</li></ul>   |
| Certified clean          | <ul style="list-style-type: none"><li>• SAL of <math>10^{-6}</math> inside and outside of the container</li><li>• Compliant with USP &lt;788&gt;</li><li>• &lt;0.5 EU/mL endotoxin</li><li>• Produced in clean room</li><li>• Triple-layer packaging (2 heat seals and 1 carton liner, both qualified as sterile barriers)</li><li>• Double-walled carton</li></ul>  |
| Platinum certified clean | <ul style="list-style-type: none"><li>• SAL of <math>10^{-6}</math> inside and outside of the container</li><li>• Below one-third of the allowable USP &lt;788&gt; particulate limits</li><li>• &lt;0.25 EU/mL endotoxin</li><li>• 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</li><li>• Triple-layer packaging (2 heat seals and 1 carton liner, both qualified as sterile barriers)</li><li>• Double-walled carton</li></ul> |

\* 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 at ambient temperature and pressure when used with their corresponding closures. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned applications.

## 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 trusted collaborative partners 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  |      |
| 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, minimizing 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"><li>• Buffer preparation</li></ul>   |
| Certified clean | <ul style="list-style-type: none"><li>• Cell culture media storage</li><li>• Human genetics final product and final fill and finish</li><li>• Bulk drug substance storage</li><li>• Sampling from bioreactor</li></ul>                     |
| Platinum clean  | <ul style="list-style-type: none"><li>• Final drug substance</li><li>• Oligonucleotides/chemistry for gene therapeutics</li><li>• Sterile media</li><li>• Human genetics stability studies</li><li>• Bulk drug substance storage</li></ul> |

## 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**—ensuring <10 ppb TOC
- **Silanization service**—inhibits adherence to container surface, for maximum recovery of contents

Find out more at [thermofisher.com/uspclean](https://thermofisher.com/uspclean)