

Thermo Scientific Nalgene Certified Clean PETG Containers Technical Information

Biologically Tested, Leakproof, Sterile and Clean

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This document presents technical information for Thermo Scientific Nalgene Certified Clean PETG Containers. While the information contained within this document is extensive, we advise that you verify these products based on your applications.

Clean Room Manufacturing

Nalgene® Certified Clean PETG Containers are manufactured in a cleanroom certified to the ISO 14644-1 Class 7 standard.

Certified Clean Containers

Nalgene Certified Clean PETG Containers are “lot-to-lot” tested and certified using liquid particle count analysis for particulate control as specified in the following international compendia:

- USP <788>
- EP 2.9.19
- JP 14th edition Part 1, Section 24

Liquid Particle Count Limits - Light Obscuration Test

Particle Size	≥10µm	≥25µm
Container working volume ≤ 100 ml	6,000	600
Container working volume > 100 ml	25/ml	3/ml

Sterility Assurance Level (SAL)

We follow ANSI/AAMI/ISO 11137 guidelines in establishing an irradiation dose level to support a 10⁻⁶ SAL for Nalgene Certified Clean PETG Containers. Sterilization Dose Audit testing in accordance with the ISO 11137 Guideline is performed on a quarterly basis to determine the continued validity of the sterilization dose.

Shelf Life

Microbial aerosol challenge testing has been conducted on product to support a 5-year sterility and performance claim.

Biological Compliance

Test Method	Results
USP Class VI	Pass
EP – Modified Abnormal Toxicity Test	Pass
MEM Elution Cytotoxicity Assay (WI-38 Cell Line)	Pass
Hemolysis Test – Direct Contact Method	Pass
USP <661> physicochemical test	Pass
Non-pyrogenic (LAL Gel-clot)	Pass

Resin Materials

PETG Bottle – polyethylene terephthalate copolyester
HDPE Closure – high density polyethylene, natural resins utilized in the production of these containers are of virgin stock and are free of animal-derived components (ADCF).

Drug Master Files (DMF)

DMF are maintained by our resin suppliers.

- PETG resin - DMF # 9987
- HDPE resin - DMF # 1646

Validation Binder

The Nalgene PETG validation binder is available under confidential disclosure. To initiate receipt of a copy, please submit your request to nunc.nalgene.na@thermofisher.com.

Regulatory/Quality Systems

Thermo Fisher Scientific Rochester, NY and Fairport, NY facilities operate under a quality system in compliance with the ISO 13485:2003 standard. Our ISO registrar is the British Standards Institute (BSI). Both facilities are FDA registered.

- Rochester, NY: Reg. No. 1314344
- Fairport, NY: Reg No. 3004548426

We manufacture Class I Medical Devices (design exempt) in compliance with the cGMP (QSR).

NOTE: Nalgene PETG containers are not registered Medical Devices.

General Chemical Resistance

Classes of Substances at 20°C	PETG	HDPE
Acids, dilute or weak	G	E
Acids, strong and concentrated	N	G
Alcohols, aliphatic	G	E
Aldehydes	F	G
Bases	N	E
Esters	N	G
Hydrocarbons, aliphatic	G	G
Hydrocarbons, aromatic	N	N
Hydrocarbons, halogenated	N	N
Ketones	N	N
Oxidizing agents, strong	F	F

E: No damage after 30 days of constant exposure.

G: Little or no damage after 30 days of constant exposure.

F: Some effect after 7 days of constant exposure.

N: Immediate damage may occur. Not recommended for continuous use.

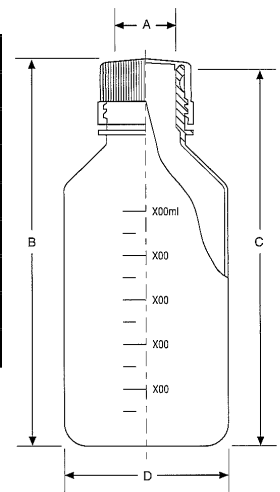
Product Dimensions

Cat. No. 382019	-0030	-0060	-0125	-0250	-0500	-1000	-2000
Nominal Volume (ml)	30	60	125	250	500	1000	2000
Brim Capacity (ml)	45	80	175	320	610	1225	2380
(A) Bottle Neck I.D. (mm)	14	18	28	28	28	28	39
(B) Bottle Height w/clsr. (mm)	63	83	108	145	178	219	271
(C) Bottle Height w/o clsr. (mm)	60	80	104	140	173	215	265
(D) Bottle Width (Square)(mm)	38	40	52	59	73	92	116
Neck Finish (mm)	20-415	24-415	38-430	38-430	38-430	38-430	53B
Bottle Weight w/clsr. (g)	13.5	22	52.5	65	116	187	350

For all sizes of Cat. No. 382019, bottle neck design is protected by US Trademark Reg. No. 2857283

Square Bottle with arched shoulders design is protected by US Trademark Reg. No. 2857279

Note: All measurements and weights are nominal.



Packaging Specifications

The Nalgene Certified Clean PETG Container packaging is designed for cleanroom applications. Bottle and closure are secured with heat-shrink bands providing a tamper-evident seal. The bands include a perforated “tear strip” for easy removal.

Assembled bottles and closures with heat-shrink band are placed in ISO Class 4 cleanroom-grade polyethylene impulse heat-sealed sleeves to further assure product integrity prior to use. Sleeves are labeled with catalog number, product description, lot number, use before date, and gamma radiation dot indicator and packed in a double poly-lined case prior to gamma irradiation.



Heat shrink band - provides tamper evident seal

Heat sealed sleeve - low particulate cleanroom packaging sleeves include product identification (product description, catalog number, lot number, use by date)



Gas Transmission Rate

Analysis conducted on representative 500ml expanded volume PETG bottle and 38-430 HDPE closure with an application torque of 27.4 in. lb.

Gas	Transmission Rate (cc/package - 24hr)
O ₂	0.167
CO ₂	0.242
H ₂ O Vapor	0.013

Transmission rates at 23°C and 60% RH

Trace Metal Analysis

The tables below summarize the trace metal content for PETG and HDPE resin by Inductively Coupled Plasma - Atomic Emission Spectrophotometer (ICP-AES). Results expressed as parts per million by weight (ppm). Duplicate determinations reported. Estimated detection limits are provided (bold emphasis), ND signifies that the element was not detected, and N/A signifies test result not available.

PETG

Al	B	Ba	Be	Ca	Cd	Co	Cr	Cu	Fe	K	Li	Mg
ND	(0.06)	ND	ND	0.2	ND	ND	(0.04)	(0.04)	0.2	ND	ND	0.04
ND	(0.06)	ND	ND	0.2	ND	ND	(0.03)	(0.04)	0.2	ND	ND	0.04
0.3	0.05	0.005	0.001	0.06	0.02	0.03	0.03	0.03	0.02	10	6	0.001

Mn	Mo	Na	Ni	P	Pb	Sb	Si	Sn	Sr	Ti	V	Zn
46	ND	3	ND	40	ND	ND	ND	ND	ND	17	ND	0.2
46	ND	3	ND	41	ND	ND	ND	ND	ND	17	ND	0.2
0.005	0.05	0.3	0.2	3	0.2	0.3	0.2	0.4	0.04	0.03	0.03	0.006

HDPE

Al	B	Ba	Be	Ca	Cd	Co	Cr	Cu	Fe	K	Li	Mg
7	0.1	ND	ND	66	ND	ND	(0.03)	0.07	0.2	ND	N/A	20
7	0.2	ND	ND	64	ND	ND	(0.06)	(0.04)	0.4	ND	N/A	19
0.02	0.01	0.005	0.002	0.02	0.01	0.01	0.02	0.01	0.02	1	-	0.001

Mn	Mo	Na	Ni	P	Pb	Sb	Si	Sn	Sr	Ti	V	Zn
(.004)	ND	(0.9)	ND	17	ND	ND	(0.2)	ND	N/A	10	ND	0.1
(.008)	ND	(0.9)	ND	16	ND	ND	(0.4)	ND	N/A	9	ND	0.1
0.003	0.01	0.3	0.05	0.3	0.1	0.2	0.2	0.2	-	0.003	0.01	0.007

Recommended Application Torques

Torque must be properly applied in measured amounts to the HDPE closure and PETG bottle to assure leakproof sealing. To maintain the closure/bottle seal and minimize back-off during shipment, closures should be tightly applied using the following guidelines. Closure and bottle threads must be dry when torque is applied to the system. Because different applications will require different torques for the same closure/bottle system, it is recommended that users determine these values on their own filling and capping lines.

Closure Size, mm	Minimum Torque in-lb / cm-kg	Maximum Torque ¹ in-lb / cm-kg
20-415	10 / 11	14 / 16
24-415	12 / 13	17 / 19
38-430	27 / 31	33 / 38
53B	38 / 43	53 / 60

¹This number should not be exceeded.

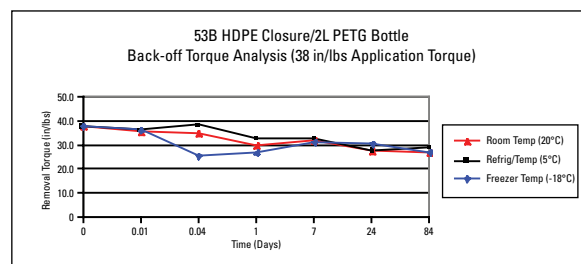
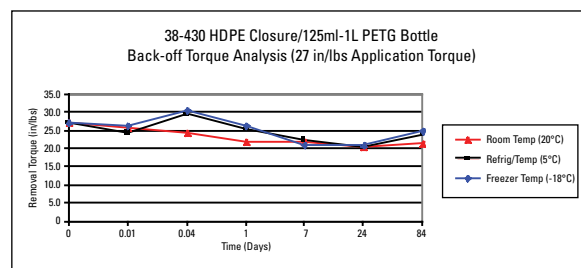
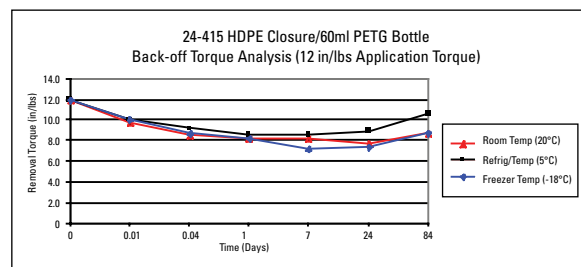
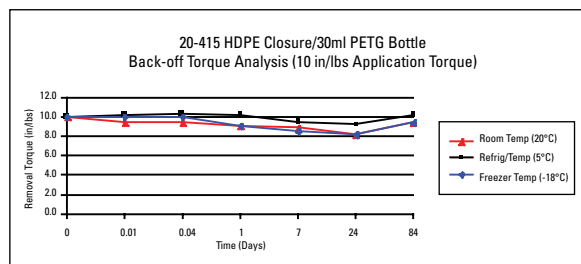
Leakproof Service

Designed and manufactured to work as a system, Nalgene Certified Clean PETG Containers are guaranteed leakproof. The unique closure and bottle design requires no liner or gasket to provide repeatable leakproof performance. Bottles have a molded-in semi-buttress thread finish which virtually eliminates stripping or thread jumping by over-torque. Closures have a molded-in seal ring, which mates against the beveled inner edge (chamfer) of the bottle neck forming a leakproof valve seal as the closure is tightened. Under our quality inspection system, bottles and closures are continually monitored during manufacturing to ensure quality performance. Closures and bottles are randomly selected during production for testing and assembled to minimum application torque to ensure a minimum air pressure of 2 psig for 2 minutes performance. Leak testing is performed at higher psig levels on select products. For more information, email Technical Support nunc.nalgene.na@thermofisher.com in North America or nunc.nalgene.eu@thermofisher.com in Europe.

Back-off Torque Analysis Over Time

PETG Bottles with HDPE Closure were evaluated for torque degradation over time. Products were subjected to three environmental conditions, including freezer (-18°C), refrigerated (5°C), and room (20°C) temperatures. Each chart represents the storage conditions for samples that were tightened to minimum application torques. This data is presented as a case study to support customer packaging applications. Complete minimum and maximum back-off torque studies are available in the validation binder. Customers are advised to perform independent testing of Nalgene products to verify results based on their applications.

Back-off Torque Analysis - Min. Application Torque



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