

Certificate of Analysis



Article no.	Retrace Code/Batch/Lot no.	Date of Manufacture
818063604	10182139	2025-06-05

Article description

DURAN® PURE bottle, amber, GL 45, 250 ml

Expiry Date

2030-06-05

DURAN PURE Product Certificate

The articles listed under "article number" are hereby confirmed to have been produced using a quality system conforming to ISO 9001 and comply with the DWK Life Sciences quality standards.

Product Material

The specified glass bottles are manufactured from DURAN® glass. DURAN® glass is classified as a Borosilicate 3.3 glass as defined by ISO 3585 and a "Type I, Class A low-expansion borosilicate glass" as defined by ASTM-E438.

Declaration of Product Conformity

DURAN® glass bottles are compliant with the requirements of the following guidelines, laws and regulations:

The dimensions correspond to the standard ISO 4796-1.

Prior to delivery, all production batches are subjected to statistical quality inspections corresponding to the standard DIN ISO 2859 -1. We herewith confirm that this lot passed the statistical quality inspection according to ISO 2859-1.

DURAN® – Glass type 1 Composition

SiO ₂	B ₂ O ₃	Na ₂ O/K ₂ O	Al ₂ O ₃
81 %	13 %	4 %	2 %

DURAN® - Chemical and physical properties

Coefficient of expansion	Acid resistance	Acid resistance	Hydrolytic resistance	Alkalis resistance
$3.3 \times 10^{-6} \text{ K}^{-1}$	Class S 1 (DIN 12116)	$\leq 100 \text{ } \mu\text{g Na}_2\text{O per dm}^2 \text{ (ISO 1776)}$	Class HGB 1 (ISO 719) / Class HGA 1 (ISO 720)	Class A 2 (ISO 695)

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In-process inspections according to drawing and specification

Drawing number for this product: **0335620-GZA-01694-B**

Related product specification: **Product Specification DURAN PURE bottle, amber 25ml - 20000ml (Doc ID 39242, 007/07.2024)**

Number of units per pallet: **280**

Statistical inspections according to property groups

Weight / Body diameter / Wall thickness / Overall height / Body residual stress / Decoration

Final Inspection

Sampling plan is based on DIN ISO 2859-1, AQL and Attributive properties: Level II

Extent of random samples: **125**

Directive conformity

Due to its high hydrolytic resistance, DURAN® is a neutral glass respectively glass type 1 and consequently fulfills the requirements of the US-American and European Pharmacopoeia (USP and Ph.Eur.).

DURAN® is certified for food and pharmaceutical applications.

We herewith confirm that the referenced DURAN PURE bottle is USP, Ph.Eur. and JP conform according to the following analytical measurement.

Standard	Testing	Unit	Mean value	Limit
Ph.Eur. (3.2.1)	Surface Glass Test	in ml c[HCl] 0.01 mol/L per 100 ml test solution	0.02 ± 0.01	≤0.30
	Hydrolytic resistance of glass grains	in ml c[HCl] 0.02 mol/L per 1 g of the glass sample	0.03 ± 0.01	≤0.1
	Arsenic	ppm As	<0.01	≤0.1
USP <660>	Surface Glass Test	in ml c[HCl] 0.01 mol/L per 100 ml test solution	0.02 ± 0.01	≤0.30
	Hydrolytic resistance of glass grains	in ml c[HCl] 0.02 mol/L per 1 g of the glass sample	0.03 ± 0.01	≤0.1
	Arsenic	µg/g As	<0.05	<0.1
JP <7.01>	Soluble Alkali Test (Method 1 - containers not to be fused)	in ml c[H ₂ SO ₄] 0.01 mol/L per 5 g of the glass sample	0.06 ± 0.01	≤2.0

(analytical measurement carried out by an external laboratory, SCHOTT AG in Mainz, Germany.)

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Transmission

The ambering procedure creates a layer of ambered glass on the outside surface of the bottle by an ion-exchange process. During the procedure the inner surface is protected and remains a clear borosilicate 3.3, type 1 glass.

Light transmission is less than 10 % in the wavelength region between 290 nm and 450 nm and meets the requirements of USP <660>, <671> and EP / Eur. Ph. 3.2.1. Spectral Transmission for Colored Glass Containers.

DWK Inspection and Release site:

DWK Life Sciences GmbH
Hattenbergstrasse 10
D-55122 Mainz

Issued by: 
Mariska Jefferson
Quality Manager

Issuance
date: 2025-06-23

Approved by: 
Alexander Cross
Vice President Global Quality

Approval
date: 2025-06-23