

# Certificate of Conformity



Article no.	Retrace Code/Batch/Lot no.	Date of Manufacture
218013651	10176671	2024-12-04

## Article description

DURAN® Laboratory bottle, clear, graduated, GL 45, with screw-cap and pouring ring (PP), 250 ml

## DURAN® 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. The specified glass products are manufactured from DURAN® glass.

DURAN® glass is classified as a Borosilicate 3.3 glass as defined by ISO 3585:1998.

## 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 <sub>2</sub>	B <sub>2</sub> O <sub>3</sub>	Na <sub>2</sub> O/K <sub>2</sub> O	Al <sub>2</sub> O <sub>3</sub>
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)	$\leq 100 \mu\text{g Na}_2\text{O per dm}^2$ (ISO 1776)	Class HGB 1 (ISO 719) / Class HGA 1 (ISO 720)	Class A 2 (ISO 695)

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## Directive Conformity

Due to its high hydrolytic resistance, DURAN® is a neutral glass respectively glass type I and consequently fulfills the requirements of the following pharmacopoeias:

- USP <660> Containers - Glass
- EP (3.2.1) Glass containers for pharmaceutical use

The arsenic content in DURAN® Glass is less than 0.1 ppm acc. to EP (3.2.1) and 0.1 µg per g acc. USP <660> / Arsenic <211>.

DURAN® is compliant with JP <7.01> Test for Glass Containers for Injections (Soluble Alkali).

DURAN® is certified for food applications.

The confirmations and information in this certificate apply solely to goods originating from DURAN®. For further processed products these details are not binding.

## Statement on BSE/TSE for products manufactured from DURAN® glass:

We hereby confirm that DURAN® glass consists of raw material without any biological origin or genetically modified organism (GMO). No materials of animal origin are used or added during the manufacturing process.

The manufacturing of DURAN® glass involves minimum melting temperatures of 1500 °C for several hours, where all the raw materials are melted together. After forming, the glass products are tempered in an oven at more than 400 °C before being slowly cooled. Due to the high temperatures, we can act on the assumption that any and all biological substances are destroyed during production.

Therefore, DURAN® glass can be considered as free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

Please note that analysis of the raw materials and/or finished goods for presence of the above mentioned substances is not performed on a routine basis.

## BSE/TSE statement for DURAN® components manufactured from synthetic plastic polymers

We confirm that the raw material used in the manufacture of the referenced product is not of animal origin. Accordingly, transmission of animal spongiform encephalopathy agents via the mentioned components is extremely improbable. We therefore state that these materials and the product is to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

Certified by:

Mariska Jefferson  
Quality Manager

Download date: 2025-06-11