

## DECLARATION OF CONFORMITY

### Pharmaceutical Glass Container

Form 13.05.01.01 Version 03

**Distributor:** Fermetech

**Product Code:** 72722301830 **Product Description:** 100ml Amber Dropper Bottle

**Reference Drawing:** E020/00/18

**Batch Number:** A40000846 **Quantity:** 1,876,392

**Manufacturing Date:** 02.09.2022 **Expiry Date:** 07.09.2027

#### Declaration:

We hereby declare that the product specified above complies with the requirements of ISO 9001/15378 and is suitable for pharmaceutical use. All testing was performed according to technical specifications, applicable standards and "Defect Evaluation list for containers made from moulded glass", Vol. 14. The product meets all quality parameters and safety requirements for its intended use.

#### Product Specifications

**Material:** Type 3 Moulded Glass (Pharmaceutical Grade) **Temperature Resistance:**

- Operational Temperature: up to 121°C (autoclaving conditions)
- Single-use Sterilization: 160°C (2-3 hours with dry heat)
- Maximum Heat Resistance: up to 500°C (dry heat, not recommended for repeated use)

#### Safety Parameters:

Parameter	Test Method	Result	Specification
Arsenic Release*	Ph.Eur./USP	< 0.1 ppm	Max 0.1 ppm
Heavy Metal Content*	Ph.Eur./USP	<100 ppm	Max 100 ppm
Light Transmission	Ph.Eur./USP	0.4%	Max 10%
Hydrolytic Class (powdered glass)	Ph.Eur./USP	0.56 ml 0.02 N HCl	Max 0.85 ml 0.02 N HCl
Hydrolytic Resistance (inner surface)	Ph.Eur./USP	3.4 ml 0.01 N HCl	Max 4.8 ml 0.01 N HCl

#### Surface Treatment

**Surface Coating:** T5 CE-Coating (Conforming)

#### Dimensional Specifications

Characteristic	Unit	Min	Nominal	Max	Actual	Standard Deviation
Through Bore Diameter	-	-	-	-	Conforming	-
Height	mm	109.60	110.70	111.80	110.80	0.19
Bore Diameter	mm	10.50	10.65	10.80	10.68	0.03
Body Diameter (middle)	mm	46.40	47.00	47.60	46.68	0.13
Weight	g	-	-	-	101.86	0.38
Brimful Capacity	ml	107.00	110.00	113.00	110.49	0.43

#### Quality Control

**Visual Inspection:** All units conform to approved appearance standards and defect evaluation criteria

#### Compliance Statement

We certify that the product described herein has been tested and meets all applicable quality and safety standards. This product is suitable for pharmaceutical applications within the parameters specified above.

**Released by:** Fermetech Quality Department

**Declaration Date:** 11.03.2025 / **Document ID:** A40000846-DOC

*This is an electronically generated document that is valid without a physical signature. Note: Arsenic release and heavy metal content are tested on a periodic basis according to sampling plan. This declaration is valid for the specific batch number indicated above.*