PRODUCT DATA SHEET

LLG-EPA threaded bottle 60 ml, clear 1st hydrolytic class, 140 x 27.5 mm, pack of 100

Cat. No.: 6.267 126

Dear valued Customer,

we state, that our sample vials (cat.no. 24 09 0927) are manufactured from borosilicate glass. They match our technical conditions of delivery for special glass tubes for manufacturing of pharmaceutical packings.

1. Hydrolytic stability:

Borosilicate glass tubes in flint and amber glass are classified as Type I according to:

- Eu.Ph. Ed. 9
- U.S.P. Rev. 41
- DAB 2017

The vials are classified as 1st. hydrolytic class.

The alkali release measured according to USP 41 for glass type I on powdered glass are typically within the following range:

Clear glass:	0,35 ± 0,05 ml 0,02 N H_2SO_4 / 10 g Glas
Amber glass:	0,35 ± 0,05 ml 0,02 N H_2SO_4 / 10 g Glas

2. Arsen

Tests (according to USP 41 and Eu.Ph. Ed. 9) of manufactured vials showed, that the content of arsenic was far below the limit of value.

3. Light protection:

Amber vials fulfill the requirements for the guaranty of light protection of Eu.Ph. Ed. 9, DAB 2017 and USP 41 for vials with wall thickness according to ISO 9187 or ISO 8362

4. Heavy metals:

The content of heavy metals (Pb, Cd, Hg, Cr(VI)) is considerably below the limit of values the US and EC regulations. Limit of value prescribed on art. 11 of stipulations 94/62 (CE=100ppm)

5. DIMENSIONAL AND VISUAL PROPERTIES

The above-mentioned tubing conforms to the agreed technical specification and has been controlled according to the documented standards (procedures, criteria and methods).

6. BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY (TSE)

Our clear and amber glass tubing and the associated packing materials contain no nonconforming components of animal origin.

Meckenheim, 25.10.2023

This document was sent online and is valid without signature

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