

Translated English of Chinese Standard: YBB00292005-2-2015

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YBB

Injection Vials Made of Middle Borosilicate Glass Tubing

中硼硅玻璃管制注射剂瓶

The Standard is applicable to injection vials made of middle borosilicate glass tubing containing directly-dispensed injections, sterile powders for injection and concentrated solutions for injection.

[Appearance] TAKE appropriate amount of this product; in the light of natural light, visually INSPECT from front. It shall be colorless and transparent or brown and transparent; the surface shall be clean and smooth, and there shall be no obvious glass defects; no cracks are allowed on any part.

[Identification]* (1) Coefficient of linear thermal expansion: TAKE appropriate amount of this product, DETERMINE according to *Tests for Coefficient of Mean Linear Thermal Expansion* (YBB00202003-2015) or *Tests for Coefficient of Linear Thermal Expansion* (YBB00212003-2015). It shall be $(3.5 \sim 6.1) \times 10^{-6} \text{ K}^{-1}$ (20 ~ 300 °C).

(2) Content of boron oxide: TAKE appropriate amount of this product, DETERMINE according to *Determination of Boron Oxide* (YBB00232003-2015). The content of boron oxide shall not be less than 8 %.

[Hydrolytic resistance of glass grains at 121 °C] TAKE appropriate amount of this product, DETERMINE according to *Test and Classification for Hydrolytic Resistance of Glass Grains at 121 °C* (YBB00252003-2015). It shall comply with Grade 1.

[Hydrolytic resistance of glass grains at 98 °C] TAKE appropriate amount of this product, DETERMINE according to *Test and Classification for Hydrolytic Resistance of Glass Grains at 98 °C* (YBB00362004-2015). It shall comply with Grade HGB1.

[Hydrolytic resistance of interior surfaces] TAKE appropriate amount of this product, DETERMINE according to *Test and Classification for Hydrolytic Resistance of Interior Surfaces at 121°C* (YBB00242003-2015). It shall comply with Grade HC1.

[Acid resistance]* TAKE appropriate amount of this product, DETERMINE according to the first method of *Tests for Resistance to Attack of Glass by Boiling Hydrochloric Acid* (YBB00342004-2015), it shall comply with Grade 1; or DETERMINE according to the second method of *Tests for Resistance to Attack of Glass by Boiling Hydrochloric Acid* (YBB00342004-2015), the amount of alkaline oxide leaching shall not exceed 100 µg/dm².

[Alkali resistance]* TAKE appropriate amount of this product, DETERMINE according to *Tests for Resistance to Attack of Glass by Mixed Alkali Aqueous Solution* (YBB00352004-2015), it shall not be lower than Grade 2.

[Internal stress] TAKE appropriate amount of this product, DETERMINE according to *Test for Stress* (YBB00162003-2015). The optical path difference caused by the maximum permanent stress after annealing shall not exceed 40 nm/mm.

[Heat resistance] TAKE appropriate amount of this product, PLACE it in an oven, HEAT to 180 °C in 30 minutes and KEEP at constant temperature for 2 hours, REMOVE it immediately, it shall not be broken.

[Freezing resistance] TAKE appropriate amount of this product, INJECT 1/2 of the nominal capacity of water into the freezer. The temperature is controlled at -41 °C ± 2 °C. REMOVE after 24 hours, immediately PLACE it in the water at 40 °C ± 1 °C; REMOVE after 1 minute, it shall not be broken.

[Leaching amount of arsenic, antimony, lead, cadmium]* TAKE appropriate amount of this product, DETERMINE according to *Tests for Leaching Amount of Arsenic, Antimony, Lead and Cadmium* (YBB00372004-2015). In per liter of leachate, arsenic shall not exceed 0.2 mg, antimony shall not exceed 0.7 mg, lead shall not exceed 1.0 mg, and cadmium shall not exceed 0.25 mg.

[Vertical axis deviation] TAKE appropriate amount of this product, DETERMINE according to *Test for Vertical Axis Deviation of Bottles* (YBB00192003-2015). It shall comply with the specifications of Table 1.

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