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NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

YBB 00082005-2015

Aluminum Caps for Injection Bottles

注射剂瓶用铝盖

Aluminum Caps for Injection Bottles

This Standard applies to unsterilized aluminum caps for injection bottles.

[Appearance] Take an appropriate amount of this product and look directly at it in a bright natural light place. It shall be clean and free of residual lubricant, burrs and damage.

[Mechanical properties of aluminum part materials] * The tensile strength of the material shall be 130~180 N/mm²; and the elongation shall be no less than 2.0%.

Tensile strength refers to the maximum tensile load on a unit initial cross-section in a tensile test until it breaks. Elongation refers to the ratio of the increase in the distance between the marks to the initial gauge length when the specimen breaks in the tensile test, expressed as a percentage.

Take an appropriate amount of aluminum sheet with the same batch number; and cut it into a specimen as shown in Figure 1 by a tool with a width (b) of 12.5 mm, an original gauge length (L_0) of 50 mm, a parallel length (L_c) of 75 mm, and a transition arc radius (r) of at least 20 mm. It is tested on a tensile device at a test speed of 10 mm/min \pm 2 mm/min. The specimen shall stand at temperature of 23°C \pm 2°C and relative humidity of 50% \pm 5% for more than 4 hours; and the test shall be carried out under these conditions.

The elongation shall be calculated as follows:

$$\varepsilon_t = \frac{L - L_0}{L_0} \times 100\%$$

Where:

ε_t – elongation, in %;

L_0 – distance between the original marks of the specimen, in mm;

L - distance between marks when the specimen is broken, in mm.

[Convex edge] Take appropriate amount of this product, measure by the vernier caliper, accurate to 0.1mm. The convex edge shall be no more than 3% (Figure 2).

Tear-off Aluminum Cap

[Sterilization resistance] Take an appropriate amount of this product; rinse it with water; and bake it in an oven at 180°C for 1 hour. There shall be no apparent change in the surface; and the surface layer shall be free from bulging or detachment.

[Compatibility] Take an appropriate amount of this product after baking in a 180°C oven for 1 hour; cover it on a suitable bottle with marked-capacity of water (with a rubber stopper); and seal it with a capping device. It shall be properly compatible, and no fracture or abnormal deformation shall occur.

[Coating firmness] (applicable to the coated aluminum cap on the outer surface) Take an appropriate amount of this product; bake it in a 180°C oven for 1 hour; wipe the surface by degreasing cotton soaked in 80% ethanol solution for 30 seconds; and wipe the surface by degreasing cotton soaked in 70% isopropyl alcohol solution for 30 seconds; the coating shall be free of any abrasion.

Attachment-I: Inspection Rules

1. Product inspection is divided into full inspection and partial inspection.
2. In one of the following situations, a full inspection shall be carried out according to the requirements of the standard.
 - (1) Product registration.
 - (2) The product is re-manufactured after a major quality accident occurs.
 - (3) Supervise random testing.
 - (4) Resumption of production after the product has been discontinued.
3. After the product is approved to register, the pharmaceutical packaging material production and use enterprises can conduct inspections for items other than "*" in accordance with the requirements of the standard, provided that the origin of the raw materials and the production process have not changed.
4. The inspection of appearance, convex edge, opening force, sterilization resistance, compatibility and coating firmness shall be carried out in accordance with the provisions of *Sampling Procedures for Inspection by Attribute - Part I: Sampling Schemes Indexed by Acceptance Quality Limit (AQL) For Lot-by-Lot Inspection* (GB/T 2828.1-2012). The inspection items, inspection level and acceptance quality limit are shown in Table 3.

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