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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

YBB 00402003-2015

Aluminum-Plastics Combination Caps for Infusion Bottles

输液瓶用铝塑组合盖

Aluminum-Plastics Combination Caps for Infusion Bottles

This Standard is applicable to the aluminum-plastics combination caps for non-sterilized glass infusion bottles.

【Appearance】 take an appropriate amount of this product; directly visually examine in a bright place with natural light. It shall be clean, free of residual lubricant, burrs, damage, and injection flash. The plastic parts shall be fully integrated with the aluminum parts.

【Mechanical properties of the aluminum part materials】* the tensile strength shall be 100~180N/mm²; elongation shall be no less than 2.0%.

Tensile strength refers to the maximum tensile load on the initial cross-section per unit in the tensile test until the test specimen is broken. Elongation refers to the ratio of the increase in the distance between graticules to the initial graticule (expressed in percentage), in the tensile test, when the specimen is broken.

Take an appropriate amount of aluminum sheet with the same batch number; use the tool with width (b) of 12.5mm, original gauge (L_0) of 50mm, parallel length (L_c) of 75mm, transition arc radius (r) of at least 20mm to cut the specimen as shown in Figure 1. Conduct the test on the tensile device; the test speed is 10mm/min $\pm$ 2mm/min. The specimen shall stand for 4h above at the temperature of 23°C $\pm$ 2°C, and relative humidity of 50% $\pm$ 5%; and test shall be performed under the above conditions.

Figure 1 -- Specimen Diagram for Mechanical Property Test

Elongation shall be calculated as per the following formula:

Where:

Figure 3 – Opening Force Diagram

Figure 4 – Type-ZD Aluminum Part Tear-Sheet
Tearing Force Test Device

【Opening quality】 take an appropriate amount of this product through the opening force test, and removing the plastic parts; visually examine; the opening position on the aluminum part shall be free of damage.

【Conformability】 take an appropriate amount of this product; cover it onto the bottle filled with nominal capacity of water (add rubber stopper); seal with capping-machine; it shall match properly.

【Resistance to sterilization】 take an appropriate amount of this product; cover it onto the bottle filled with nominal capacity of water (add rubber stopper); seal with capping-machine; after that place into the steam sterilizer; maintain for 30min at $121^{\circ}\text{C}\pm 2^{\circ}\text{C}$, including maintaining for 5min at $130^{\circ}\text{C}\pm 2^{\circ}\text{C}$. After sterilization, the plastic part of the bottle cap can withstand 130°C steam sterilizing temperature without deformation or discoloring; the surface of the aluminum part shall be free of any obvious changes. The bottle cap shall be free of breaking or abnormal deformation.

【Coating fastness】 (applicable to the aluminum cap with coating on the outside surface) take an appropriate amount of this product; maintain for 30min at $121^{\circ}\text{C}\pm 2^{\circ}\text{C}$, including steam sterilizing for 5min at $130^{\circ}\text{C}\pm 2^{\circ}\text{C}$; remove the plastic part; wipe the surface with absorbent cotton dipped in 80% ethanol solution for 30s; then wipe the surface with absorbent cotton dipped in 70% isopropanol solution for 30s. The coating shall be free of any abrasion.

Annex I -- Inspection Rules

1. The product inspection is divided into full inspection and partial inspection.
2. In any of the following cases, a full inspection shall be carried out in accordance with the requirements of the standard.

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