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Aluminium-plastics Combination Caps for Antibiotics Bottles

抗生素瓶用铝塑组合盖

Aluminium-plastics Combination Caps for Antibiotics Bottles

This Standard applies to unsterilized aluminium-plastics combination caps for antibiotics bottles.

[Appearance] Take an appropriate amount of this product and make a visual inspection in a bright place with natural light. They should be clean and free of lubricant residue, burrs, damage and injection molding flash. Plastic parts should be completely integrated with aluminum parts.

[Mechanical properties of aluminum parts materials] * The tensile strength should be 100~180 N/mm². Elongation shall not be less than 2.0%.

Tensile strength refers to the maximum tensile load endured by the initial unit cross-section during the tensile test until fracture. Elongation refers to the ratio of the increase in distance between the marking lines to the initial gauge length when the specimen breaks during the tensile test, expressed as a percentage.

Take an appropriate amount of aluminum sheets from the same batch number. Use a tool with a width (b) of 12.5 mm, an original gauge length (L₀) of 50 mm, a parallel length (L_c) of 75 mm, and a transition arc radius (r) of at least 20 mm to cut the specimen as shown in Figure 1. Test on tensile apparatus. The test speed is 10 mm/min±2 mm/min. The specimen should be placed at a temperature of 23±2°C and a relative humidity of 50%±5% for more than 4 h. Conduct the test under these conditions.

Figure 4 -- Diagram of the tearing force test device for ZD or OD aluminum tear sheet

[Opening quality] Based on the opening force test, remove the appropriate amount of this product from the plastic parts. Perform visual observation. Openings in aluminum parts should not be damaged.

[Compatibility] Take an appropriate amount of this product and cover it on a suitable bottle containing water with the marked capacity (add a rubber stopper). Cap with capping device. It should be matched appropriately.

[Sterilization resistant] Take appropriate amount of this product. Cap it on a suitable bottle containing water with the marked capacity (add a rubber stopper). Cap with capping device. After capping, place in steam sterilizer, at $121^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 30 min, including $130^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 5 min. After sterilization, the plastic parts of the bottle cap can withstand a steam sterilization temperature of 130°C without deformation or discoloration. There should not be any noticeable changes in the surface of the aluminum parts. The bottle cap should be free from breakage and abnormal deformation.

[Coating firmness] Take an appropriate amount of this product (the outer surface is coated). After steam sterilization at $121^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 30 min, including $130^{\circ}\text{C}\pm 2^{\circ}\text{C}$ for 5 min, remove the plastic parts. Wipe the surface with absorbent cotton soaked in 80% ethanol solution for 30 s. Then wipe the surface with absorbent cotton soaked in 70% isopropyl alcohol solution for 30 s. The coating should be free of any wear.

Attachment 1 -- Inspection rules

1. Product inspection is divided into full inspection and partial inspection.
2. When any of the following situations occurs, a full inspection shall be carried out in accordance with the requirements of the standard.
 - (1) Product registration.
 - (2) Reproduction after a major quality incident occurs on the product.
 - (3) Supervise random inspections.
 - (4) Resumption of production after the product is discontinued.
3. After product approval and registration, enterprises that produce and use pharmaceutical packaging materials can conduct inspections for items other than "*" in accordance with the requirements of the standard, provided there are no changes in the origin of raw materials, additives, production processes, etc.
4. Inspection of appearance, convex edge, opening force, opening quality, compatibility, sterilization resistance and coating fastness shall be carried out according to "Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection" (GB/T 2828.1-2012). Inspection items, inspection levels and acceptance quality limits are shown in Table 2.

NOTE: Items with "*" must be inspected at least once every six months.

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