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National Drug Packing Container (Material) Standard

YBB 00162004-2015

Bromobutyl rubber plungers and liners for pen-injectors

笔式注射器用溴化丁基橡胶活塞和垫片

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Bromobutyl rubber plungers and liners for pen-injectors

This standard applies to bromobutyl rubber plungers and liners for pen-injectors sleeves.

[Appearance] TAKE several products; MAKE visual inspection from frontside in the bright natural light. The surface color shall be uniform; it shall be free from stains, impurities, bubbles, cracks, lack of plastic, roughness, rubber thread, rubber fragment, sponge-like, or burr; it shall be free from incompleteness or jagging due to trimming operation; AND it shall be free from obvious mark due to die.

[Identification] * (1) TAKE appropriate amount of this product; CUT it into small particles; WEIGH 2.0 g; PLACE it into crucible; ADD 2.0 g of sodium bicarbonate to uniformly cover the sample; PLACE it on the electric furnace; slowly HEAT it until it is carbonized; LET it cool naturally; PLACE it in the high temperature furnace at 300 °C to heat it until it is totally ashed; TAKE it out; LET it cool naturally; ADD 10 mL of water to dissolve it; FILTER it; TAKE 1.5 mL of filtrate; PLACE it into the test tube; ADD nitric acid to acidize it; ADD 1 drop of silver nitrate test solution; AND it shall produce yellow precipitate.

(2) TAKE appropriate amount of this product; MAKE determination in accordance with the method 4 of the packaging material infrared spectroscopy (YBB00262004-2015), AND the results shall be consistent with the control map.

[Puncture chip] (Liner) liner pretreatment: TAKE a few liners; ADD water (ml) the volume of which is twice the total surface area (cm²) of the liner; MAKE it boil for 5 min; USE water to flush it for 5 times; PLACE the liner into the conical flask; ADD water the volume of which is twice the total surface area (cm²) of the liner to cover the liner; USE aluminum foil or silicon borate beaker to cover the conical flask mouth; PLACE it into the high pressure steam sterilizer for heating; INCREASE the temperature to 121 °C ± 2 °C; MAINTAIN this temperature for 30 minutes; COOL it to room temperature; TAKE it out; BAKE it at 60 °C for 60 minutes; STORE it in a sealed glass vessel to prepare for use.

FILL water into the 50 pen-injector sleeves fitted with a plunger to half of its volume; USE the liner under test and aluminum cap (with hole at middle) to seal it; USE 50 pen-injector sleeves equipped with the liner having known number of puncture chip numbers to repeat this procedure. Alternatively PUNCTURE the rubber liner in the sequence of the liner under test AND then the liner having known number of puncture chip. During puncturing, PLACE the pen-injector sleeve perpendicularly on a stable base; MAKE the liner end upwards; FILL water into the injector sleeve and REMOVE the water from the injection needle (outer diameter 0.4 mm subcutaneous injection needle, as shown in Figure 1 and Table 1); HOLD the injector sleeve vertically to puncture the liner; INJECT 1 ml of water into the flask; before each puncturing, USE acetone or methyl-isobutyl ketone to wipe the injection needle; REPLACE the injection needle after 20 times of puncturing, until all the liners are punctured for one time; TAKE off the liner under test; USE fast filter paper to filter all the water in the flask; ENSURE that there is no chip remaining in the flask; under normal conditions, KEEP the distance from the eyes and the filter paper at 25 cm; USE naked eyes to fast observe the number of chips on the fast filter paper; MAKE record; MAKE same operation for the liners

Nonvolatile matter: precisely MEASURE 100 ml of test solution and blank solution, respectively; PLACE them respectively into the evaporation dish which had been dried to constant weight; EVAPORATE it dry in water bath; DRY it at 105 °C to constant weight; AND the difference between the two must not be more than 4.0 mg.

Heavy metal: precisely MEASURE 10 ml of test solution; ADD 2 ml of acetate buffer (pH 3.5); MAKE reference to the (four general rules 0821 of “Chinese Pharmacopoeia” 2015 version); AND the heavy metal content shall not be more than one millionth.

Ammonium ion: precisely MEASURE 10 ml of test solution; ADD 2 ml of alkaline potassium mercuric iodide test solution; PLACE it for 15 min; AND it shall not have color; if it has color, COMPARE it with the control solution which is prepared by adding 8 ml of blank solution and 2 ml of alkaline potassium mercuric iodide test solution into the ammonium chloride solution (TAKE 31.5 mg of ammonium chloride; ADD appropriate amount of ammonia free water to dissolve and dilute it to 1000.0 ml), AND its color shall not be deeper (0.0002%).

Zinc ion: TAKE the test solution; USE the filter membrane having a pore size of 0.45 µm to filter it; precisely MEASURE 10 ml of filtrate; ADD 1 ml of 2 mol/L hydrochloric acid and 3 drops of potassium ferrocyanide test solution (WEIGH 4.2 g of potassium ferrocyanide trihydrate; USE water to dissolve it and dilute it to 100 ml; SHAKE it uniformly to obtain this test solution, which shall be prepared before use); MIX it; AND it shall be free from turbidity; however, if there is turbidity, COMPARE it with the control solution which is prepared by adding 7 ml of blank control solution, 1 ml of 2 mol/L hydrochloric acid and 3 drops of potassium ferrocyanide test solution into 3.0 ml of standard zinc solution (WEIGH 44.0 mg of zinc sulfate heptahydrate; USE newly boiled and cooled water to dissolve and dilute it to 1000.0 ml; AND this product shall be prepared before use); AND it shall not be deeper (0.0003%).

Conductivity: Within 5 hours of preparation of the test solution; USE the conductivity meter to make determination, AND the conductivity of the blank solution shall not exceed 3.0 µS/cm (20 °C ± 1 °C); AND the conductivity of the solution under test shall not exceed 40.0 µS/cm. However, if the determination is not made at 20 °C ± 1 °C, the temperature shall be corrected.

[Biological test] pyrogen*: TAKE this product; ADD sodium chloride injection in accordance with the proportion of irregular shape; PLACE it into the high pressure steam sterilizer at 115 °C ± 2 °C; MAINTAIN for 30 minutes; MAKE determination in accordance with the pyrogen inspection method (YBB00022003-2015); AND it shall comply with requirements.

Acute systemic toxicity test:** TAKE this product; ADD sodium chloride injection in accordance with the proportion of irregular shape; PLACE it into the high pressure steam sterilizer at 115 °C ± 2 °C; MAINTAIN for 30 minutes; MAKE determination in accordance with the acute systemic toxicity inspection method (YBB00042003-2015); AND it shall comply with requirements.

Hemolysis:** TAKE this product; MAKE determination in accordance with the hemolysis inspection method (YBB00032003-2015); AND the hemolysis rate shall comply with requirements.

Appendix I inspection rules

1. Product inspection is divided into full item inspection and partial item inspection.

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