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# YBB

NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA

## YBB 00082004-2015

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**Bromobutyl rubber plungers for prefilled syringes**

预灌封注射器用溴化丁基橡胶活塞

## Bromobutyl rubber plungers for prefilled syringes

This standard applies to brominated butyl rubber plungers for prefilled syringes. Plunger types are either snap-fit type (PSL) or threaded type (PT).

**[Appearance]** Take a few of this product. In a bright place with natural light, visually check it from front side. The surface color shall be uniform. There shall be no stains, impurities, bubbles, cracks, lack of glue, roughness, rubber hair, glue chipping, sponge, burrs. There shall be no defects or jaggedness caused by edge removal. There shall be no obvious molding mark. If there is pouring mouth, it shall not project from the surface of the plunger.

**[Identification]** \* (1) Weigh 2.0 g of this product. Cut it into small particles. Place it in a crucible. Add 2.0 g of sodium bicarbonate to cover the specimen evenly. Place it on an electric furnace. Slowly heat to carbonize it. Let it cool. Place it in a muffle furnace at 300 °C to burn it until completely ash it. After taking out, cool it to room temperature. Add 10 ml of water to dissolve it. Filter it. Take 1.5 ml of the filtrate. Place it in a test tube. Add nitric acid. Add 1 drop of silver nitrate test solution. It shall produce light yellow precipitate.

(2) Take an appropriate amount of this product. Follow the 4<sup>th</sup> method of the “Determination method for packaging materials by infrared spectrometry” (YBB 00262004-2015). It shall be basically consistent with the control spectrum.

**[Matching of plunger and push rod] [Plunger lubricity] [Plunger sliding performance] [Plunger tightness]** Check it according to the method under the “Assembly of pre-filled syringe (with injection needle)” (YB 00112004-2015). It shall comply with requirements.

**[Ash content]** Take 1.0 g of this product. Follow the “Determination method of ash content” (YBB 00262005-2015) to make determination. The residual residue shall not exceed 50%.

**[Volatile sulfide]** \* Take this product and determine it according to the “Determination method of volatile sulfide” (YBB 00302004-2015), which shall meet the requirements.

**[Insoluble particles]** Take 10 of this product. Add 50 ml of water for particle inspection. Follow the medicinal rubber stopper item under the “Determination method of insoluble particle of packaging materials” (YBB 00272004-2015). There shall be no more than 60 particles that are larger than 10 µm particles per 1 ml. There shall be no more than 6 particles that are larger than 25 µm particles per 1 ml.

**[Chemical properties]** Preparation of test solution: Take a number of complete

shall not exceed one millionth.

**Ammonium ion:** Precisely take 10 ml of the test solution. Add 2 ml of alkaline potassium mercury iodide test solution. Let it stand for 15 min. It shall not have color development. If color is developed, when compared with the control solution which is prepared by 2.0 mL of ammonium chloride solution (add an appropriate amount of ammonia-free water into 31.5 mg of ammonium chloride to dissolve and dilute it to 1000.0 ml), 8 ml of blank extraction solution, 2 ml of alkaline potassium mercury iodide test solution, it shall not be deeper (0.0002%)

**Zinc ion:** Take the test solution. Use a 0.45  $\mu\text{m}$  filter membrane to filter it. Precisely take 10 ml of the 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 it, which shall be prepared before use) to mix it. It shall not be turbid. If it is turbid, it shall be compared with the control solution which is prepared by 3.0 ml of the standard zinc solution (weigh 44.0 mg of zinc sulfate heptahydrate; use the freshly boiled and cooled water to dissolve and dilute it to 1000.0 ml; this product shall be prepared before use), 7 ml of blank control solution, 1 ml of 2 mol/L hydrochloric acid, 3 drops of ferrocyanide potassium chloride test solution; the color shall not be deeper (0.0003%).

**Conductivity:** Within 5 hours of the preparation of the test solution, use a conductivity meter to measure it. Use water to rinse the measuring electrode (bright platinum electrode or platinum black electrode) for several times. Take the blank solution to rinse the electrode at least 2 times. The measured conductivity of the blank solution shall not to exceed  $3.0 \mu\text{S}/\text{cm}$  ( $20^\circ\text{C} \pm 1^\circ\text{C}$ ). Then use the test solution to rinse the electrode for at least 2 times. Measure the conductivity of the test solution, which shall not exceed  $40.0 \mu\text{S}/\text{cm}$ . If the measurement is not performed at  $20^\circ\text{C} \pm 1^\circ\text{C}$ , it shall correct the temperature.

**[Biological test] Pyrogen \*** Take this product. Add sodium chloride injection according to the irregular shape ratio. Place it in a high-pressure steam sterilizer at  $115^\circ\text{C} \pm 2^\circ\text{C}$  for 30 minutes. Make determination according to the "Pyrogen inspection method" (YBB 00022003-2015). The results shall meet the requirements.

**Acute systemic toxicity test \*\*** Take this product. Add sodium chloride injection according to the irregular shape ratio. Place it in a high-pressure steam sterilizer at  $115^\circ\text{C} \pm 2^\circ\text{C}$  for 30 minutes. Make determination according to the "Acute systemic toxicity test method" (YBB 00042003-2015). The results shall meet the requirements.

**Hemolysis \*\*** Take this product and make determination according to the "Hemolysis test method" (YBB 00032003-2015). The hemolysis rate shall meet the requirements.

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