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NATIONAL STANDARD OF THE
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YBB 00042005-2015

Halogenated Butyl Rubber Stopper for Injection

注射液用卤化丁基橡胶塞

Halogenated Butyl Rubber Stopper for Injection

This Standard is applicable to chlorobutyl or bromobutyl rubber stoppers that are in direct contact with the injection.

[Appearance] Take several such products, check by Table 1 accordingly; it shall meet the requirements.

[Identification] * (1) Take 2.0g of this product; cut into small particles; place in the crucible; add 2.0g of sodium bicarbonate to cover the specimen evenly; place it into the electric furnace; slowly heat to carbonization; cool off; then place on 300°C muffle furnace to heat till completely ashing; take it out; then cool off to the room temperature; add 10mL of water to dissolve; filter; take 1.5mL of successive filtrate; place into the test tube; add nitric acid to acidify; add 1 drop of silver nitrate test solution; then generate white or light yellow precipitate.

(2) Take appropriate amount of this product; determine according to the Fourth Method of Test for Infrared Spectrum of Packaging Materials (YBB00262004-2015); it shall be basically consistent with the reference spectrum.

[Puncture coring] Take 10 pieces of this product; determine according to the First Method of Test for Rubber Stopper, Pads and Puncture Coring for Injection (YBB00332004-2015); the number of the coring shall not exceed 20 particles.

[Puncture force] Take 10 pieces of this product; determine according to the First Method of Test for Rubber Stopper, Pads and Puncture Force for Injection (YBB00322004-2015); the average puncture force shall not exceed 75N; while the puncture force of each rubber stopper shall not exceed 80N; no rubber stopper shall be pushed into the bottle during the puncture period.

[Sealing and retain ability of puncture outfit] Take 10 pieces of this product; place into a high-pressure steam sterilizer (not soaked in water); hold it at 121°C±2°C for 30min; cool off to the room temperature; take another 10 matching glass injection bottles; add water to the marking capacity; tighten with the above rubber stopper; add the matching aluminum cover and gland. Use the puncture outfit shown in Figure 1 of Test for Rubber Stopper, Pads and Puncture Force for Injection (YBB00322004-2015) to vertically puncture the puncture site of the rubber stopper; the puncture outfit pierces the rubber stopper; hand the bottle upside down; the puncture outfit suspends 0.5kg of heavy object; the puncture outfit shall keep for 4h without pulling out; the puncture site has no leakage.

[Ash] Take 1.0g of this product; determine according to the Rubber – Determination of Ash (YBB00262005-2015); the residual residue shall not exceed 45%.

check accordingly (the First Method in General Rules 0821 of Volume 4 of *Chinese Pharmacopoeia* 2015 Edition); the contained heavy metal shall not exceed one in a million.

Ammonium ion: Accurately take 10mL of test-liquid; add 2mL of alkaline potassium iodide test solution; stand for 15min; no color appears; if color appears, it shall be no deeper (0.0002%) than the control solution prepared by adding 8mL of blank solution and 2mL of alkaline potassium iodide test solution to the 2.0mL of ammonium chloride solution (take 31.5mg of ammonium chloride; add appropriate amount of ammonia-free water to dissolve and dilute till 1000.0mL).

Zinc ion: Take test-liquid; filter by filter membrane with pore size of 0.45μm; accurately take 10mL of successive filtrate; add 1mL of 2mol/L hydrochloric acid and 3 drops of potassium ferrocyanide test solution (take 4.2g of potassium ferrocyanide trihydrate; use water to dissolve and dilute to 100mL; shake up; then obtain this product; it shall be prepared for ready-use) to mix; it is no turbidity; if it is turbid; it shall be no deeper (0.0003%) than the control solution prepared by adding 7mL of blank solution, 1mL of 2mol/L hydrochloric acid and 3 drops of potassium ferrocyanide test solution to 3.0mL of standard zinc solution (take 44.0mg of zinc sulfate heptahydrate; use the boiled and cooled water to dissolve and dilute to 1000.0mL; obtain this product; it shall be prepared for ready-use).

Conductivity: Determine by the conductivity meter within 5h of the preparation of the test-liquid. The conductivity of the blank solution shall not exceed 3.0μS/cm (20°C±1°C); while the conductivity of the test-liquid shall not exceed 40.0μS/cm. If the determination is not performed at 20°C±1°C; then the temperature shall be corrected.

[Biological test] Pyrogen * Take this product; add sodium chloride injection according to the proportion of irregular shape; place into the high-pressure steam sterilizer; keep for 30min at 115°C±2°C; determine according to Pyrogen Test Method (YBB00022003-2015); it shall meet the requirements.

Test for acute systemic toxicity ** Take this product; add sodium chloride injection according to the proportion of irregular shape; place into the high-pressure steam sterilizer; keep for 30min at 115°C±2°C; determine according to Test for Acute Systemic Toxicity (YBB00042003-2015); it shall meet the requirements.

Hemolysis ** Take this product; determine according to the Hemolysis Test Method (YBB00032003-2015); the hemolysis rate shall meet the requirements.

Annex I: Inspection Rules

1. The product inspection can be divided into the full-item inspection and partial-item inspection.

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