YB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

YBB 00052005-2015

Halogenated butyl rubber stopper for injectable sterile powder

注射用无菌粉末用卤化丁基橡胶塞

Halogenated butyl rubber stopper

for injectable sterile powder

This standard applies to chlorinated or brominated butyl rubber stoppers (excluding dry stopper for freezing purposes) that are in direct contact with injectable sterile powder.

[Appearance] TAKE several of this product, PERFORM inspection in accordance with Table 1, it shall comply with requirements.

[Identification]* (1) WEIGH 2.0 g of the 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 the electric stove, slowly HEAT it to carbonization, LET it cool, PLACE it in the muffle furnace to heat it to 300 °C until completely ashed. After removal, COOL it to room temperature, ADD 10 ml of water to dissolve, FILTER it, CONTINUE taking 1.5 ml of filtrate, PLACE it in a test tube, ADD nitric acid, ADD 1 drop of silver nitrate solution, it shall produce white or pale yellow precipitate.

(2) TAKE appropriate amount of this product, MAKE determination in accordance with the method IV of Packaging materials infrared spectrometry (YBB00262004-2015), it shall be basically consistent with the control map.

[Punch chip] TAKE appropriate amount of this product, MAKE determination in accordance with the method II of Injection stopper and gasket chip determination method (YBB00332004-2015). The number of chips shall not exceed 5.

[Puncture force] TAKE 10 of this product, MAKE determination in accordance with the method II of Rubber stopper for injection and the gasket puncture force measurement method (YBB00332004-2015). The force required to puncture the stopper is not more than 10 N.

[Adhesiveness between rubber stopper and container] TAKE 10 of this product, PLACE it in a beaker, ADD water, BOIL for 5 minutes, REMOVE it, DRY it at 70 °C for 1 hour. PREPARE for use. In addition, TAKE 10 matching injection bottles, ADD water to the marked capacity. USE the above stopper to plug it tightly, ADD the matching aluminum cap, PRESS the cap. PLACE it in an autoclave at 121 °C ± 2 °C for 30 minutes, COOL it to room temperature, ALLOW it to stand for 24 hours. Inversely PLACE the above sample, PLACE it in a container with a 10% methylene blue solution with a suction device, VACUUM it to a vacuum of 25 kPa, MAINTAIN this pressure for 30 minutes,

and cooled water to dissolve and dilute it to 1000.0 mL, this product shall be prepared before use), ADD 7 ml of blank solution and 1 ml of 2 mol/L hydrochloric acid and 3 drops of potassium ferrocyanide test control solution for comparison, it shall not be deeper (0.0003%).

Conductivity: Within 5 hours of preparation of the test solution, USE a conductivity meter to measure that: The conductivity of the blank solution shall not exceed 3.0 μS/cm (20 °C ± 1 °C). The conductivity of the test solution shall not exceed 40.0 μS/cm. If the measurement is not performed at 20 °C ± 1 °C, the temperature shall be corrected.

[Biological test] pyrogen* TAKE this product, ADD it into the sodium chloride injection at irregular shape ratio, PLACE it in an autoclave at 115 °C ± 2 °C for 30 minutes. MAKE determination in accordance with the pyrogen test method (YBB00022003-2015), the results shall comply with requirements.

Acute systemic toxicity test ** TAKE this product, ADD it into the sodium chloride injection at irregular shape ratio, PLACE it in an autoclave at 115 °C ± 2 °C for 30 minutes. MAKE determination in accordance with the Acute systemic toxicity test method (YBB00042003- 2015), the results shall comply with requirements.

Hemolysis** TAKE this product, MAKE determination in accordance with Hemolysis test method (YBB00032003-2015), the hemolysis rate shall meet the requirements.

Attachment: Inspection rules

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

2. When one of the following situations occurs, the full item inspection shall be conducted in accordance with the standard requirements.

(1) Product registration.

(2) Reproduction after major product quality accidents.

3. In the case of one of the following situations, it shall perform inspections other than those marked with “**”.

(1) Supervise random inspection.

(2) Production resumes after production suspension.

4. After product approval and registration, if the production and use enterprises of pharmaceutical packaging materials do not change their raw material production areas, additives, production processes, etc., they may perform inspections other than those items marked with “*” and “**” in accordance with

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