Criteria for vascular prosthesis

(August 10, 1970)
(MHW Ministerial Announcement No. 298)

In accordance with provisions in Article 42, Paragraph 2 of the Pharmaceutical Affairs Act (Act No. 145 of 1960), the criteria for vascular prosthesis shall be established as follows and applied from August 10, 1970.

Criteria for vascular prosthesis

I Definition

Vascular prosthesis is a product used as a substitute for blood vessels and made by "knitting" or "plain weaving" polymer fibers of "poly(tetrafluoroethylene)" or "saturated polyester" or by "stretching" of "poly(tetrafluoroethylene)."

(partially revised by MHW Announcement No. 151 of 1979)

II Quality and test methods of vascular prosthesis

(1) Physical tests

A Appearance

Vascular prosthesis is clean, seamless, and free from holes and weaving irregularities potentially causing problems for use when examined with a loupe of 10x magnification.

B Heat resistance

Boil a piece of vascular prosthesis 17 cm in length with about 100 mL of water for 10 minutes, place in a container already containing 30 mL of water, autoclave at 121°C for 20 minutes, and cool. Repeat the above operation further twice, and determine the dimensions and elasticity: No changes are observed.

(2) Chemical tests

A Dissolved amount

Collect 3 pieces of vascular prosthesis each weighing about 1 g, weigh accurately each, place in 100 mL each of water, 3% acetic acid solution, and 2% sodium hydrogen carbonate solution, and heat at 37°C for 24 hours. Collect the pieces of vascular prosthesis, wash with water, dry, and weigh: The difference between amounts of each piece before and after the dissolved amount test is not more than 0.1%.

B pH, heavy metals, and potassium permanganate-reducing substances

Place a piece of vascular prosthesis weighing 1.0 g in 100 mL of water in a container, heat at 37°C for 24 hours, remove the piece, and use the remaining solution as the test solution in the following tests. The test solution meets the requirements for the tests.

(A) pH

Perform the test with 20 mL each of the test solution and water as directed in pH Determination under the General Tests, Processes and Apparatus of the Japanese Pharmacopoeia (hereinafter referred to as "JP") (MHW Ministerial Announcement No. 58 of March 1986): The difference in pH between these solutions is not more than 1.0.

(B) Heavy metals

Perform the test with 10 mL of the test solution as directed in Method 1 of the Heavy Metals Limit Test in the JP. Prepare the control solution with 1.0 mL of Standard Lead Solution.

(C) Potassium permanganate-reducing substances

To 10 mL of the test solution in a glass-stoppered Erlenmeyer flask, add 20 mL of 0.002 mol/L potassium permanganate solution and 1.0 mL of dilute sulfuric acid, and boil for 3 minutes. After cooling, add 0.1 g of potassium iodide, and titrate with 0.01 mol/L sodium thiosulfate solution (indicator: 5 drops of starch TS). Perform the blank test in the same manner, using 10 mL of water instead of the test solution. The difference in mL of potassium permanganate solution required between the tests is not more than 2.0 mL.

(3) Biological tests

Cut a piece of vascular prosthesis weighing about 20 g into small pieces of about 1 cm^2, wash with a neutral detergent, water, and distilled water for injection in this order, and place these in a 500 mL glass container meeting the requirements for Soluble alkali test under the Test for Glass Containers for Injections in the JP. To the container, add 125 mL of saline solution, close tightly by melting glass of the opening or with a suitable stopper, proceed with extraction at 121°C for 1 hour, allow to stand until the temperature falls to room temperature, and use this solution as the test solution.

Separately, prepare the blank solution in the same manner.

A Pyrogen test

Perform the test as directed under Pyrogen Test in the JP: The test solution meets the requirement for the test.

B Acute toxicity test

Use male mice of inbred strain or from a closed colony, weighing 17 to 23 g, and inject intravenously each of the test solution and the blank solution into 10 mice at 50 mL/kg. Observe the animals for 5 days after injection: No death occurs.

(partially revised by MHW Announcements No. 74 of 1971, No. 42 of 1978, No. 211 of 1997)

Revised text (Excerpt) (MHW Ministerial Announcement No. 42 of March 6, 1978)

To products manufactured or imported until March 5, 1978, the provisions then in force shall remain applicable.

Revised text (Excerpt) (MHW Ministerial Announcement No. 211 of September 30, 1997)

It shall be applied from October 1, 1997.