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Tests for hydrolytic resistance of interior surfaces

121℃内表面耐水性测定法

Tests for hydrolytic resistance of interior surfaces

This method is suitable for the determination and grading of the water resistance of the inner surfaces of various types of pharmaceutical glass containers, using titration methods.

This method is a surface test method. Inject test water into the test container to the specified capacity. Heat it under specified conditions. Measure the degree of water corrosion of the container and grade it by titrating the etching solution.

Reagents: Test water

The test water must not contain heavy metals (especially copper). If necessary, the dithizone limit test method can be used to test it [see GB 12416.1-90 Pharmaceutical glass containers - Hydrolytic resistance - Test method and classification (Normative)]. Its conductivity shall not exceed 0.1 mS/m, at 25 °C ± 1 °C. The test water shall be boiled, in an aged beaker, for more than 15 minutes, to remove dissolved gases, such as carbon dioxide. The test water shall be neutral to methyl red. That is, when adding 4 drops of methyl red indicator solution to 50 ml of water, it produces an orange-red color, which is equivalent to pH5.5±0.1. This water can also be used for blank test. Test water can usually be stored in a beaker, which has a ground glass stopper, for 24 hours, without changing its pH value.

Instruments: High-pressure steam sterilizer, burette, beaker, flask (Note: New beakers and flasks need to be subject to aging treatment, that is, fill purified water to the top of the bottleneck; then repeatedly process them according to the hot-pressing conditions in the measurement method, until the purified water is neutral to methyl red).

Tested products: The number of test containers depends on the capacity of the container, the volume of the extract solution required for one titration, the number of titration results required, which can be calculated according to Table 1.

Determination method: The cleaning process of the tested container shall be completed within 20 ~ 25 minutes, to remove debris or dirt. Use purified water, to thoroughly clean each container at least 2 times, at ambient temperature. Fill with purified water for later use. Empty the container before use, rinse once with purified water and test water in turn. Then drain the

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