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PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

YBB 00252003-2015

**Test and Classification for Hydrolytic Resistance of
Glass Grains at 121°C**

玻璃颗粒在 121°C 耐水性测定法和分级

Test and Classification for Hydrolytic Resistance of Glass Grains at 121°C

This Method applies to the test and classification for hydrolytic resistance of all kinds of pharmaceutical glass materials.

This Method is a material test method: take a certain amount of glass grains of a specified size; place in a specified container; add a specified amount of water; heat under the specified conditions; use titrant extracting liquid to measure the degree of attack of glass grains by water and classify it.

[Test water] Test water shall not contain heavy metals (especially copper); if necessary, it may use dithizone limit test method for testing; its conductivity shall not exceed 0.1 mS/m at $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$. Test water shall be boiled for more than 15 minutes in a beaker that has been undergone ageing treatment, so as to remove the gases including carbon dioxide. Test water shall be neutral to methyl red, that is, adding 4 drops of methyl red indicating liquid (take 0.025 g of methyl red sodium; add water to dissolve and dilute to 100 mL) into 50 mL of water; the colour of water turns orange red (pH 5.4 ~ 5.6). This water can be used for blank tests. Test water can be generally stored in a ground-glass stoppered flask for 24 h without changing its pH value.

[Apparatus] Pressure steam sterilizer, conical flasks, beakers (Note: Glass containers shall be made of borosilicate glass having an average coefficient of linear thermal expansion about $3.3 \times 10^{-6} \text{K}^{-1}$; new glass containers must go through ageing treatment, that is, add an appropriate amount of water into a glass container; repeat the treatment under the thermal compression conditions as specified in the test procedures, until water turns neutral to methyl red before using), drying oven, hammer, grinding bowl and pestle made of hardened steel (Figure 1), a set of stainless steel sieves (including sieve-A with a mesh size of 425 μm , sieve-B with a mesh size of 300 μm , and sieve-O with a mesh size of 600 ~ 1000 μm).

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