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National Drug Packing Container (Material) Standard

YBB 00242003-2015

Test and classification for hydrolytic resistance of interior surfaces at 121 °C

121 °C 内表面耐水性测定法和分级

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Test and classification for hydrolytic resistance of interior surfaces at 121 °C

This method is applicable to the determination and classification of hydrolytic resistance of interior surfaces of various types of medicinal glass containers by titration method.

This method is a surface test method. The test water is injected into the test container to a prescribed capacity AND heated under the specified conditions. The degree of water erosion of the container is measured by titration of the etching solution AND classified.

Test water: The test water shall not contain heavy metals (especially copper), if necessary, it may use the dithizone limit test method to perform testing; when the conductivity is $25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, it shall not exceed 0.1 mS/m . Test water shall be boiled in the aged beaker for 15 minutes or more to remove carbon dioxide and other gases. Test water shall be natural when adding the methyl red, that is, if the 50 ml of water is added by 4 drops of methyl red indicator solution (methyl red sodium 0.025 g, dissolved in water and diluted to 100 ml), the water color will change into orange red (pH 5.4 ~ 5.6). The water can be used for blank testing. Test water can usually be stored in a flask with a glass stopper for 24 hours without pH change.

Instrument and device: pressure steam sterilizer, burette, beaker, and flask (note: glass containers shall be made by the borosilicate glass having an average linear thermal expansion coefficient of about $3.3 \times 10^{-6}\text{ K}^{-1}$. The new glass containers shall be subjected to aging treatment before use, that is, adding appropriate amount of water into the glass container, treating it repeatedly in accordance with the hot pressing conditions in the determination method, until the water is in neutral to methyl red.

Product under test: The number of the product under test depends on the capacity of the container, the volume of the extract required for the primary titration, and the number of titration results required, as calculated in Table 1.

Table 1 Number of containers required for the determination of hydrolytic resistance by titration method

Capacity (ml) (equivalent to filling volume)	Minimum number of container required for one titration (pieces)	Volume of extract required for one titration (ml)	Number of titrations
≤ 3	10	25.0	1
$> 3 \sim 30$	5	50.0	2
$> 30 \sim 100$	3	100.0	2
> 100	1	100.0	3

Determination method: The product under test shall be cleaned within 20 ~ 25 min to remove the debris or dirt. At room temperature, USE water to thoroughly clean each container for at least 2 times; FILL it full of water to prepare for use. EMPTY the container before use; USE water and test water to flush it respectively for one time; MAKE the container be completely dried.

TAKE the product under test which is cleaned; ADD test water to 90% of its full capacity; as for the small capacity container such as ampoules, FILL the water to the shoulder of the container; USE an inverted beaker (subjected to aging treatment) or other appropriate material to cover the opening. PLACE the product under test into the pressure steam sterilizer;

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