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YBB 00322004-2015

Test for Penetration Force of Injection Closures

注射剂用胶塞、垫片穿刺力测定法

Test for Penetration Force of Injection Closures

This standard applies to the test for penetration force of injection closures.

Penetration force refers to the maximum force value of puncture devices penetrating rubber stoppers or liners in a penetration test, expressed in N.

Method I

Scope of application: applying to injection rubber stoppers of appropriate specifications.

[Apparatus] Material testing machine: the apparatus can make the puncture devices move vertically at $200 \text{ mm/min} \pm 20 \text{ mm/min}$; during the movement, the reactive force of the puncture devices can be recorded, precision is $\pm 2 \text{ N}$; in the axial direction, there shall be an appropriate position to place the injection bottles, so that the marked positions in the stoppers of the injection bottles can be penetrated vertically.

Injection bottles: matching with the stoppers to be tested; having a loading capacity more than 50 mL (including 50 mL); 10 pieces.

Aluminum caps or aluminum-plastic combination caps: matching with the stoppers to be tested; 10 pieces.

Manual cap tightener: matching with the rubber stoppers to be tested; 1 set;

Metal puncture device: a stainless steel (e.g. 1Cr18Ni9Ti) long needle -- its dimensions are as shown in Figure 1 -- total 2 pieces.

be penetrated vertically.

Injection bottles: matching with the stoppers to be tested; having a loading capacity less than 50 mL (including 50 mL); 10 pieces.

Aluminum caps or aluminum-plastic combination caps: matching with the stoppers to be tested; 10 pieces.

Manual cap tightener: matching with the rubber stoppers to be tested; 1 set;

Injection needles (conforming to GB 15811-2001): outer diameter is 0.8 mm; bevel angle type L (long type); bevel angle is $12^{\circ} \pm 2^{\circ}$; 10 pieces. Prior to use, use acetone or methyl isobutyl ketone to scrub.

[Determination method] Unless specified otherwise, pretreat the rubber stoppers as follows: estimate the total surface area A of 10 rubber stoppers to be tested (cm^2); place the rubber stoppers in an appropriate glass container; add water (mL) of two times of the total surface area $2A$ of the rubber stoppers; boil for 5 minutes $\pm$ 15 seconds; use cold water to wash for 5 times; place the washed rubber stoppers in the conical flask; add water (mL) of two times of the total surface area $2A$ of the rubber stoppers to be tested; use aluminum foil or one borosilicate beaker to cover the mouth of the conical flask; place in the pressure steam sterilizer to heat; within 30 minutes, raise the temperature to $121^{\circ}\text{C} \pm 1^{\circ}\text{C}$; maintain for 30 minutes; then, within 30 minutes, cool to room temperature; take out; dry for 60 minutes in the hot air at 60°C ; take out; place the rubber stoppers in a sealed glass container for use.

Take 10 matched injection bottles; add respectively water of the nominal capacity; mount the pretreated rubber stoppers to be tested; put on the aluminum or aluminum-plastic combination caps; use the manual cap tightener to seal. Fix one injection needle on the material testing machine; place the injection bottles in the material testing machine; open the aluminum or aluminum-plastic combination cap; expose the marked positions of the rubber stoppers; puncture the marked positions of the rubber stoppers vertically at the speed of 200 mm/min; record the maximum force value applied to penetrate through the rubber stoppers. Change one injection needle to repeat the above-mentioned procedures until all rubber stoppers are punctured once.

[Expression of results] Express it by using the maximum force value applied to penetrate through the rubber stoppers.

Method III

Scope of application: used for injection liners.

[Apparatus] Material testing machine: the apparatus can make the puncture devices move vertically at $200 \text{ mm/min} \pm 20 \text{ mm/min}$; during the movement, the

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