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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0031-2008

Silicone tubes and elastomeric parts for infusion and transfusion

输液、输血用硅橡胶管路及弹性件

Issued on: October 17, 2008 **Implemented on: January 1, 2010**

Issued by: National Medical Products Administration

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1 Scope

YY/T 0031 is the material and component standard for the silicone tubing and elastomeric parts used in infusion and transfusion sets: the injection sites, the pump segments and the flexible sections that a roller pump squeezes or a needle pierces. It specifies what such parts have to be, covering the composition and physical properties of the silicone, the resealing behaviour after puncture, the resistance to the mechanical work a pump does on the tube, the extractables and the biological safety. Silicone is chosen for these positions precisely because it tolerates repeated deformation and puncture, and the standard is what turns that general property into a verifiable specification. The standard carries Amendment 1 of 2020. For a set manufacturer, this is what the incoming component is certified against.

This Standard specifies the general requirements and test methods for silicone tubes for infusion and transfusion (hereinafter referred to as "the tubes") and elastomeric parts. The products to which this Standard is applicable include (but are not limited to): -- Reusable in vitro transfer lines for intravenous infusion; -- Disposable silicone rubber elastic parts in blood treatment products, such as pump tubing, valves or seals for flow control devices, injection parts; -- Silicone rubber elastic parts for disposable infusion apparatus, such as silicone rubber reservoirs for injection parts and infusion pumps; -- Pump tubes, valves, and injection parts in disposable pressure infusion lines. This Standard does not include silicone rubber catheters and artificial heart- lung machine pump tubes inserted or implanted in the human body.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 528, Rubber, vulcanized or thermoplastic - Determination of tensile stress-strain properties (GB/T 528-1998, eqv ISO 37:1994)

GB/T 529, Rubber, vulcanized - Determination of tear strength (trouser, angle and crescent test pieces) (GB/T 529-1999, eqv ISO 34-1:1994)

GB/T 3512, Rubber, vulcanized or thermoplastic - Accelerated ageing and

Annex A

(normative) Steam resistance test A.1 Principle For silicone rubber products that are expected to undergo steam sterilization, use a specimen that is obtained with same production process and is in accordance with GB/T 528, after subjecting to the saturated steam at specified temperature to the specified time, to determine the reduction rate of physical properties before and after this process. A.2 Test instruments Pressure steam sterilizer (temperature control accuracy is within ±2°C). A.3 Steps A.3.1 Conduct the breaking strength test and the break elongation test to the specimen according to the provisions of GB/T 528. A.3.2 Use 100°C water to inject into the pressure steam sterilizer. Then hang the unstretched specimen in the sterilizer to make the specimen spacing not less than 5cm, the distance between the specimen and the wall not less than 10cm. Quickly heat to 121°C and remain the constant temperature for 2h. After the specified time, when it is immediately cooled to 100°C, take out the specimen. Hang at room temperature for 4h±0.5h. Then conduct the breaking strength test and the break elongation test to the specimen according to the provisions of GB/T 528. A.4 Result expression Calculate the percent reduction of the performance according to the following formula: Where, eta - The percent reduction of the performance; A - The determined value of specimen performance after hot steam treatment;