YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0581.2-2024

Infusion access adapter - Part 2: Needleless access adapters

输液连接件 第2部分：无针连接件

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1 Scope

YY/T 0581.2 is the product standard for the needleless connector, the valve on an intravenous line that lets a syringe or set be attached without a needle. It is Part 2 of the Chinese infusion access adapter series. The needleless connector exists to remove sharps injuries from infusion practice, and it introduced a problem of its own: an internal valve that has to seal reliably, be disinfectable on its external surface, and not trap fluid where bacteria can grow, since it sits directly on the patient's bloodstream. Those properties, together with flow, pressure resistance and the number of activations the device survives, are what the standard controls. For a manufacturer or an importer of needleless connectors seeking Chinese registration, this is the standard the type testing follows.

This document specifies the requirements for disposable needleless access adapters (hereinafter referred to as access adapters) and describes the corresponding test methods. This document applies to self-closing and disposable needleless access adapters intended for non-puncture use. Products that are supplied as a whole with access adapters and intravascular indwelling devices (for example, intravenous indwelling needles) shall refer to this document for implementation. The anti-backflow valve specified in YY 0585.4 is not included in the scope of this document. Switches specified in YY 0585.2 are not included in the scope of this document.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 1962.2-2001 Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment - Part

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 liquid displacement The flow state of the liquid in the system (access adapter) at the moment the infusion device is pulled out from the access port. with the provisions of A.1 in Appendix A, the contamination index shall not exceed 90.

5.2 Connection Strength When tested in accordance with the provisions of A.2, the connections between the access adapters and all components shall be able to withstand a static tensile force of at least 15 N for 15 s.

5.3 Volume Flow When tested in accordance with the provisions of A.3, the volume flow shall not be less than the nominal value, which is expressed in (mL/min).

5.4 Leakage When tested in accordance with the provisions of A.4, there shall be no water or air leakage.

5.5 Access Port

5.5.1 Assembly fitness The access port shall be able to connect with the external conical lock fitting that complies with GB/T 1962.2.When tested in accordance with the provisions of A.5.1, there shall be no water or air leakage at the connection.

5.5.2 Separating force When tested in accordance with the provisions of A.5.2, the access port and the standard external conical fitting shall not separate.

5.6 Conical fitting The conical fittings of the access adapters shall be external conical lock fittings that comply with GB/T 1962.2.

5.7 Liquid displacement

5.7.1 Positive displacement For nominal "positive displacement" access adapters, when tested in accordance with the provisions of A.6, each time the syringe is removed from the access port, the volume of liquid outward discharged from the access adapters shall be greater than

0.01 mL.

5.7.2 Neutral displacement For nominal "neutral displacement" access adapters, when tested in accordance with the provisions of A.6, each time the syringe is removed from the access port, the volume of liquid outward discharged from the access adapters or inward back-flowed of the access adapters shall be

0.01 mL.

5.7.3 Negative displacement For nominal "negative displacement" access adapters, when tested in accordance with the provisions of A.6, each time the syringe is removed from the access port, the volume of liquid inward back-flowed of the access adapters shall be greater than

0.01 mL.

5.8 Tubing of Access Adapters (if any)

5.8.1 Transparency The transparency of the extracorporeal tubing on the access adapters shall facilitate the observation of blood return and bubbles.

5.8.2 Stop clamp If there is a tubing connecting between the access port and the conical fitting, there should be a stop clamp on the tubing that can reliably block the fluid lines.

5.9 Inner Cavity Volume When tested in accordance with the provisions of A.7, the inner cavity volume of the access adapters shall not be greater than the nominal value. NOTE. this is not applicable if the access port is integrated with other devices.

6 Chemical Requirements

When tested in accordance with the provisions Appendix B, the access adapters shall comply with the requirements of GB 8368.

7 Biological Requirements

GB 8368 applies.

8 Evaluation of Microbial Ingress

The design of the access adapter products shall be conducive to clinical disinfection, thereby preventing microorganisms from entering the sterile liquid channel, so the access adapters shall be evaluated for microbial ingress. NOTE. YY/T 0923 provides guidance on the evaluation of microbial ingress on access adapters.

9 Packaging

GB 8368 applies.

Appendix A

(normative) Physical Test A.1 Particle Contamination The test is carried out in accordance with the provisions of GB 8368.The volume of the flushing fluid shall be at least 50 times the inner cavity volume of the test sample. A.2 Connection Strength Subject the access adapter under test and all components to an axial static tensile force of 15 N for 15 s to test whether the connections of the components can withstand the applied force. A.3 Volume Flow In accordance with the provisions of Appendix E in YY 0285.1-2017, make the following modifications to the test instrument.

---The 6% (Luer) external conical fitting (Assembly 6 in Figure E.1 of YY 0285.1-2017) is modified into a 6% (Luer) external conical lock fitting. Or test in accordance with the method specified by the manufacturer. A.4 Leakage A.4.1 Before the test begins, place the entire system at the test temperature for state adjustment. Then, follow the operating procedures in the instructions for use, and use a 5 mL syringe that complies with the provisions of GB 15810 to inject 5 mL of purified water inside through the access port each time. A total of 30 injections or the number of injections specified by the manufacturer (whichever is greater) are given, with the last connection time being 24 h or the time specified by the manufacturer (whichever is greater). NOTE. in accordance with the instructions for use, this simulated injection process also includes the process of disinfecting the access port before each injection. After completing the above process, remove the syringe from the access port. A.4.2 At (23 1) C and (40 1) C, pass a pressure of 200 kPa from the end of the conical fitting to the inside for 15 min and check whether the access adapter manifests any liquid leakage. A.4.3 Fill the access adapter with purified water, in which bubbles have been removed. After passing the conical fitting through a transparent vacuum-resistant tubing of an appropriate length, connect it to a vacuum device. It is subjected to a pressure of 20 kPa for 15 seconds at (23 1) °C and (40 1) °C. Check whether air enters the access adapter system. A.4.4 For nominal "hydrodynamic injection" access adapters, at (23 1) C and (40 1) C, pass the manufacturer's nominal maximum pressure from the access port of the access adapter to the inside for 30 s. Check the access adapter manifests any liquid leakage. A.5 Access Port A.5.1 Fitness A.5.1.1 Follow A.4.1. A.5.1.2 Assemble in accordance with