YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1653-2020

Administration sets for use with infusion pumps

输液泵用管路

Issued on: February 21, 2020 **Implemented on: January 1, 2021**

Issued by: National Medical Products Administration

Table of Contents

1 Scope

YY/T 1653 is the product standard for the administration set used with an infusion pump, the disposable line that the pump squeezes to move fluid. It is a different product from a gravity giving set even where it looks identical: the pump's accuracy depends on the tubing's dimensions and its elastic recovery under repeated occlusion, so a set that is not matched to the pump delivers a dose that drifts from the setting. That coupling between a consumable and an instrument is what the standard exists to control, along with the connector, filtration and particulate requirements common to infusion products. For a manufacturer or an importer of pump-specific administration sets for the Chinese market, this is the standard the product specification and registration testing follow.

This Standard specifies the terms and definitions, requirements, test methods, marking and manual for administration set use with infusion pump. This Standard applies to administration set use with infusion pump. This Standard does not apply to administration set use with the following special infusion pumps: -- Infusion pump for ambulatory use; -- Volumetric infusion pump whose maximum speed is less than 20 mL/h, and drip-rate infusion pump whose maximum speed is less than 20 drops/min; -- Infusion pump that is specially used for diagnostics or similar purposes; -- Internal infusion pump; -- Extracorporeal circulation infusion pump for blood; -- Implantable device or single-use infusion pump; -- Emergency pump; -- Nutrition pump, flushing pump, etc.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 8368-2005, Infusion sets for single use, gravity feed (ISO 8536-4:2004, MOD)

GB 9706.27-2005, Medical electrical equipment - Part 2: Particular requirements for the safety of infusion pumps and controllers (

IEC 60601-2- 24:1998, IDT)

3.9 SVclass administration set The administration set use with infusion pump that uses the test unit that is specified in Appendix A for the robustness verification.

3.10 MVclass administration set The administration set use with infusion pump that uses the infusion pump that is specified by the manufacturer for the robustness verification.

3.11 Administration set change interval The service time of the administration set that is specified by the manufacturer.

4 Robustness identification marking

The marking of UVclass administration set is as follows: Administration set for UVclass pump The marking of SVclass administration set is as follows: Administration set for SVclass pump The marking of MVclass administration set is as follows: Administration set for MVclass pump - configurable infusion pump information - administration set change interval (see 6.5.2)

Note 1: UVclass administration set may not be marked [see 5.8.1g)].

Note 2: The configurable infusion pump information shall usually include the manufacturer and model information. If it is marked as a series model, all models in the entire series shall pass verification or evaluation.

5 Requirements

5.1 Transparency The liquid path of the administration set shall be transparent, with visible gas- water interface.

5.2 Particulate pollution The surface of the liquid channel shall be smooth and clean, and shall not exceed the pollution index.

a) Text description of the contents, such as "Administration set for disposable pumps";

b) Use the graphic symbols that are given in YY 0466.1-2016 to indicate that the fluid path is aseptic;

c) The administration set has no heat source, or the administration set has no bacterial endotoxin (if the administration set is provided as part of the infusion set, it can be expressed as that the infusion set has no heat source, or the administration set has no bacterial endotoxin);

d) The liquid path is for one-time use only, or equivalent text, or graphical symbols that comply with YY 0466.1-2016;

e) Instructions for use, including warnings;

f) Lot number, start with the word "LOT", or use graphic symbols of YY 0466.1-2016;

g) Robustness identification marking (see Chapter 4); if there is no marking, the administration set is considered to be a UVclass administration set;

h) Manufacturer, supplier name or logo and address;

i) Year and month of expiration and the corresponding text or graphical symbols in accordance with YY 0466.1-2016. If the area is too small to give all the information and/or symbols, it shall at least be marked with the markings/requirements that are specified in

f) and i). In this case, the information that is required by this article needs to be given on the larger shelf or multi-unit container.

5.8.2 Shelf or multi-unit container The shelf or multi-unit container shall be marked with at least the following information:

a) Text description of the contents, such as "Administration set for disposable pumps";

6.5 Robustness test

6.5.1 SVclass administration set robustness 6.5.1.1 4 h test The 4 h test operation is as follows: 1) Unless otherwise specified by the manufacturer, the test temperature shall be in the range of 23 °C ± 2 °C; the test humidity shall be in the range of 60% ± 15%; the atmospheric pressure shall be in the range of 860 hPa ~ 1 060 hPa; 2) Take an unused administration set and install it on the test unit (see Appendix A); 3) Build the test platform as shown in Figure 1; use the grade-3 water for analysis laboratory; 4) Adjust and record the motor speed of the test unit, so that the actual flow rate reaches the range of 25 (1 ± 10%) mL/h; start the test after it stabilizes; 5) Perform a measurement every 10 minutes; calculate the flow rate Q, in milliliters per hour (mL/h); see Formula (1); Where: Wj -- sampling volume at the end of the test time T, in grams (g); Wk -- sampling volume at the beginning of the test time T, in grams (g); T -- test time, in minutes (min). d -- density of water (

0.998 g/mL at 20 °C). 6) Infuse to 60 min; calculate the average flow rate r of 6 measurements; the flow rate change A within 60 min shall meet the requirements of 5.5.1; the calculation of average flow rate r is shown in Formula (2): 2) Take an unused administration set and install it on the test unit (see Appendix A); 3) Build the test platform as shown in Figure 1; use the grade-3 water for analysis laboratory; 4) Adjust and record the motor speed of the test unit, so that the actual flow rate reaches the range of 25 (1 ± 10%) mL/h; start the test after it stabilizes; 5) Perform a measurement every 10 minutes; calculate the flow rate Q, in milliliters per hour (mL/h); see Formula (6); Where: Wj -- sampling volume at the end of the test time T, in grams (g); Wk -- sampling volume at the beginning of the test time T, in grams (g); T -- test time, in minutes (min). d -- density of

water (

0.998 g/mL at 20 °C). 6) Infuse to 60 min; calculate the average flow rate r of 6 measurements; the flow rate change A within 60 min shall meet the requirements of 5.5.1; the calculation of average flow rate r is shown in Formula (7): The calculation of flow rate change A is shown in Formula (8): 7) Use this test motor speed setting to run continuously for another 12 hours; 8) After 12 hours of continuous operation, measure it every 10 minutes; calculate the flow rate Q. Infuse to 60 minutes; compare the average flow rate R of 6 measurements and the average flow rate r in 6); the flow rate change C shall meet the requirements of 5.5.1. The calculation of flow rate change C is shown in Formula (9): change the continuous running time of 7) to

1.5 times the administration set change interval. The flow rate change shall meet the requirements of 5.5.2.

6.6 Chemical test

6.6.1 Test liquid preparation Take 450 cm of the set and other components whose surface area is 100 cm2. Disassemble the components that are in contact with the liquid medicine in the sterilized liquid path of the supply state; separate them according to the same material. Disintegrate each component, so that both the inner and outer surfaces can be immersed in water; put it into a 250 mL wide-mouth flask; add 200 mL of distilled water that meets the requirements of the "Pharmacopoeia of the People's Republic of China" (2015 edition); cover it; place at (37±1) °C for 24 h. Take another 250 mL wide-mouth flask; add 200 mL of distilled water that meets the requirements of the "Pharmacopoeia of the People's Republic of China" (2015 edition); cover it; place it at (37±1) °C for 24 h. This liquid is used as a blank control liquid according to the test operation in GB 8368-2005.

6.6.2 Test procedure The test shall be performed in accordance with the provisions of GB 8368-2005; the test liquid that is specified in

6.6.1 shall be used.

6.7 Biological test The test shall be performed in accordance with the provisions of GB 8368-2005.