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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY 0585.4-2009

Fluid lines for use with pressure infusion equipment and accessories for single use - Part 4: Check valves

压力输液装置用一次性使用液路及其附件

第 4 部分：防回流阀

(ISO 8536-12:2007 Infusion equipment for medical use
Part 12: Check valves, MOD)

Issued on: December 27, 2009 **Implemented on: June 01, 2009**

Issued by: China Food and Drug Administration

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Foreword

The Part modified and adopted ISO 8536 12:2007 “Infusion equipment for medical use - Part 12: Check valves”.

The general title of YY 0585 is “Fluid lines for use with pressure infusion equipment and accessories for single use”, including the following parts:

Part 1: Fluid lines;

Part 2: Accessories;

Part 3: Filters;

Part 4: Check valves.

In this Part, Annex A is normative, Annex NA is informative.

This Part was proposed by China Food and Drug Administration.

This Part shall be under jurisdiction of the China National Standards Technical Committee of Infusion Equipment for Medical Use (SAC/TC106).

Main drafting organization of this Part: Shandong Quality Supervision and Inspection Center for Medical Devices.

Main drafters of this Part: Wan Min, Song Jinzi, Yao Xiujun, Wu Ping.

Fluid lines for use with pressure infusion equipment and accessories for single use – Part 4: Check valves

1 Scope

This Part of YY 0585.4 applies to sterile check valves for gravity feed infusion sets and/or pressure feed infusion sets for single use.

Note: The basic requirements in this Part also applies to the built-in check valves.

2 Normative references

The provisions in following documents become the provisions of this Part of YY 0585 through reference in this Part. For dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Part, 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 1962.2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings (GB/T 1962.2-2001, ISO 594-2:1998, IDT)

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

GB/T 6886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing (GB/T 16886.1-2001, ISO 10993-1:1997, IDT)

YY 0466 Medical devices - Symbols to be used with medical device labels labeling and information to be supplied (YY 0466- 2003, ISO 15223:2000, IDT)

ISO 8871-1 Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 1: Extractables in aqueous autoclavates

ISO 8871-2 Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization

3 Terms and definitions

8.1 Sterilization

It shall comply with GB 8368.

8.2 Pyrogen

It shall comply with GB 8368.

8.3 Biological compatibility

When evaluating the biological compatibility of check valves, it shall be performed according to GB/T 16886.1.

9 Packaging

It shall comply with GB 8368.

10 Labels

10.1 Single packages

The single package containers shall indicating the following information:

a) Text description of the contents;

b) The graphic symbols given in YY 0466, indicating that the check valve is sterile;

c) The check valve has no pyrogen or the check valve has no bacterial endotoxin;

d) The check valve is for single use only, or equivalent texts, or graphic symbols that comply with YY 0466;

e) Instructions for use, including warnings, such as checking whether the protective cover is off;

f) The lot number starts with the word "batch (LOT)", or adopts the graphic symbols given in YY 0466;

g) The words of "Safe for pressure infusion devices"[1];

h) The identification marks that comply with Chapter 4 (such as YY 0585.4/ ISO 8536-12-CV-P);

i) The letter "P" that represents the pressure, its size shall be bigger than the

[1] The name and type of pressure feed infusion sets shall be given by the manufacturer.

At (23 ± 2)°C and (40 ± 2)°C respectively, SUBJECT the check valve to a water pressure of 200kPa in the counterflow direction for 15min. Check for leakage through the check valve.

A.6 Volumetric flow rate

CONNECT the check valve with the infusion set, according to the specifications of GB 8368.

NOTE: If the requirements of 6.6 are not met, the infusion sets without the check valve shall be tested.

A.7 Blocking performance

It shall perform two tests: one with distilled water, one with 40% glucose.

When performing tests, the check valve shall be performed at least three tests under the states of horizontal position, vertical position and reverse vertical position.

The check valve shall be connected to the test system shown in Figure A.1.

For the check valve that is permanently installed in the fluid line, the pipe shall be cut off, a three-way switch with the tube shall be installed. It can also decline the liquid level of the test solution in the pipe, and make a liquid level mark.

FILL the entire system with the required test solution, avoid air bubbles, and then perform the following steps:

a) Switch position 1

If necessary, use switch position 1 to stabilize the feed rate[2] of the pump.

b) Switch position 2

KEEP the switch of the infusion set pipe on, there shall be a flow through the check valve for 2min.

c) Switch position 3

It shall observe:

- the pressure of the pump and the check valve pipe indicated on the pressure gauge is rising;

- the water level in the tube is moving toward the outlet end and the fluid drops

[2] It is recommended to apply pressure to the system with a feed rate of 0.3mL/h.

	Standard, and a footnote 1 is added to explain this modification	used at 10°C. In addition, the test temperature in all other provisions is (23 ± 2)°C
A.7a)	ADD a footnote, recommending a feed rate of 0.3mL/h	The technical requirements of international standard draft requires to test at this rate. After verification, it is considered that it necessary to recommend this feed rate, to help obtain comparable results
A.8.1	MODIFY (23 ± 3)°C in the international standard TO (23 ± 2)°C	Compared with A.5, adjust the tolerance of the test temperature to ± 2°C is reasonable

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