



**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0585.4-2024

**Fluid lines for use with pressure infusion equipment and
accessories - Part 4: Anti-reflux valves**

压力输液设备用一次性使用液路及其附件 第4部分：防回流阀

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Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents. This document is Part 4

of YY 0585 Fluid lines for use with pressure infusion equipment and accessories for single use. YY 0585 has been published in the following parts. -- Part

1 Scope

YY 0585.4 is Part 4 of the Chinese standard for single-use fluid lines used with pressure infusion equipment, covering the anti-reflux valve. In a line where several fluids join a common path under pressure, the valve is what stops one infusion pushing back into another's line, a failure that both interrupts the drug that should be flowing and delivers a bolus later when the pressure changes. Its requirements are therefore cracking pressure, back-pressure resistance and reliability over the life of the set. As a YY standard without the /T suffix, compliance in China is compulsory. For a manufacturer or an importer of infusion sets and their components for the Chinese market, this is the governing standard for the valve.

This document specifies the performance requirements for single-use check valves for use with gravity infusion and/or pressure infusion sets.

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for referenced documents with dates, only the versions corresponding to the dates are applicable to this document; for referenced documents without dates, the latest versions (including all amendments) are applicable to this document.

GB 8368 Infusion sets for single use - Gravity feed (GB 8368-2018, ISO 8536- 4.2010, MOD)

3 Terms and definitions

The following terms and definitions apply to this document. The pressure that opens the check valve (3.2) in the flow direction. A check valve (3.2) that requires a pressure greater than 2 kPa in the flow direction to open.

4 Marks

The marks shall comply with the provisions of Chapter

5 Materials

The selection of materials shall ensure that the check valve meets the requirements specified in Chapter 6~Chapter 8. If rubber materials are used, they shall comply with the requirements specified in ISO 8871-1 and ISO 8871-2.

6 Physical requirements

If the inlet and/or outlet of the check valve is not directly connected to the pipeline, there shall be a connection fitting that complies with the provisions of YY/T 0916 (all parts). The check valve shall have a protective cover to protect it from contamination from the surrounding environment and to avoid puncture and damage to the packaging. The protective cover shall be secure but easy to remove.

7 Chemical requirements

GB 8368 applies.

8 Biological requirements

The biocompatibility of the check valve shall be evaluated according to GB/T 16886.1.

9 Labeling

If the area of a single packaging is too small to provide all the information and/or symbols, the information may be reduced to

e) and f). In this case, the information required by this paragraph shall be given on the label of the next larger shelf or multi-unit packaging. The label on the shelf or multi-unit packaging shall contain at least the following information.

10 Packaging

GB 8368 applies.

11 Disposal

Information on the safe and environmentally sound disposal of single-use check valves shall be given in the accompanying documents.