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

YY 0329-2024

Replacing YY 0329-2009

Leukocyte reduction filters for single use

一次性使用去白细胞滤器

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document replaces YY 0329-2009 "Disposable Leukocyte Removal Filter". Compared with YY 0329-2009, except for structural adjustments and In addition to editorial changes, the main technical changes are as follows:

- Changed the tightness test conditions (see 6.1.2, 5.1.2 of the.2009 edition);
- Changed the protective device (set) (see 6.1.6, 5.1.6 of the.2009 edition);
- Changed biocompatibility (see 6.3.1, 5.5 of the.2009 edition);
- Sterility has been changed (see 6.3.2, 5.3.1 of the.2009 edition);

- Changes to bacterial endotoxins (see 6.3.3, 5.3.2 of the.2009 edition);
- Changed the residual white blood cell count (see 6.4.1, 5.4.1 of the.2009 edition);

1 Scope

YY 0329 is the mandatory standard for the single-use leukocyte reduction filter used in transfusion. Removing white cells from a blood component before it is transfused prevents febrile reactions, reduces HLA alloimmunisation and lowers the risk of transmitting cell-associated viruses, and universal leukoreduction is standard practice in most blood services. The filter's performance is expressed as the residual leukocyte count it achieves together with the recovery of the component that matters, red cells or platelets, since a filter that removes white cells by also removing the product is no use. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of leukoreduction filters, this is the governing standard.

This document specifies the classification and naming, materials, requirements, marking and packaging of single-use leukocyte removal filters and describes the corresponding tests. method. This document applies to single-use leukocyte removal filters (hereinafter referred to as "leukocyte removal filters").

Note. The leukocyte removal filter can be connected to a blood transfusion device, a blood collection/blood component separation system, and is used to remove leukocytes from blood and blood components.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories

GB 8369.1 Disposable blood transfusion sets Part

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Classification and naming

Leukocyte-removal filters are divided into whole blood, red blood cell and platelet leukocyte-removal filters according to the blood components they filter. The leukocyte removal filter for whole blood and red blood cells that meets the requirements of this document is marked. RFYY 0329-2024. The leukocyte removal filter for platelets that meets the requirements of this document is marked. PFYY 0329-2024.

5 Materials

The materials used to manufacture leukocyte depletion filters shall meet the requirements of Chapter 6.

6.1 Physical properties

6.1.1 Appearance When tested with normal or corrected vision, the outer shell of the leukocyte removal filter should be smooth and free of obvious mechanical impurities, foreign matter, cracks, welding or adhesion.