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Blood flow products for single use - General specification

一次性使用血路产品 通用技术条件

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Blood flow products for single use - General specification

1 Scope

This Standard specifies the general technical conditions for blood flow products for single use.

This Standard applies to the blood flow products for single use and the auxiliary pipelines connected to them, including the products composed of liquid flow and pressure monitoring pipeline (hereinafter referred to as "blood flow").

2 Normative references

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

GB 8369 (all parts), *Transfusion sets for single use*

GB/T 14233.1-2008, *Test methods for infusion, transfusion, injection equipment for medical use - Part 1: Chemical analysis methods*

GB/T 14233.2, *Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods*

GB/T 16886.1, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

GB/T 19633.1, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

YY/T 0316, *Medical devices - Application of risk management to medical devices*

YY 0581.1, *Infusion access adapters - Part 1: Needle access adapters (Heparin plugs)*

YY 0581.2, *Infusion access adapter - Part 2: Needleless access adapters*

YY/T 0615.1, *Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

YY/T 0923, *Needleless access ports for fluid lines and blood lines - Test method for microbial ingress*

YY/T 1288-2015, *Nylon blood filter nets for transfusion equipment for single use*

YY/T 1556, *Test methods for particle contamination of infusion, transfusion and injection equipment for medical use*

ISO 18250-8:2018, *Medical devices - Connectors for reservoir delivery systems for health care applications - Part 8: Citrate-based anticoagulant solution for apheresis applications*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

There are no terms and definitions that need to be defined in this document.

4 General requirements

It shall use the established risk assessment procedures to design the blood flow products. When transporting, storing, installing, using and maintaining blood flow products in accordance with the manufacturer's instructions, under normal and single failure conditions, use risk management procedures in accordance with YY/T 0316. Blood flow products shall not present risks that are not reduced to acceptable levels and are associated with their intended use.

Manufacturers may not be able to comply with all the requirements identified in this document, then manufacturers shall specifically consider additional risk control measures.

See Annex A for the design and evaluation requirements of blood flow products.

5 Materials

The pipelines directly or indirectly in contact with blood shall be made of materials that meet relevant standards. Leachables from the blood flow due to chemical or physical effects of anticoagulants and/or maintenance fluids, blood and blood components shall be within specified limits.

NOTE: See bibliography for relevant material standards for blood flow products.

6 Design

6.1 Protective cover

flow of fluids or gases.

NOTE: Use a liquid or gas with a pressure of 50kPa to verify the flow stop function of the stop clip.

6.6 Pressure monitoring joint/sensor protector

6.6.1 Appearance

The machine end of the pressure monitoring joint/sensor protector shall be transparent. Blood contamination can be checked visually during use.

6.6.2 Barrier properties

Pressure monitoring joints/sensor protectors on the blood flow shall prevent microorganisms from entering the pipeline. When tested in accordance with Annex B, the filtration rate of the pressure monitoring joint/sensor protector for particles above 0.5μm in the air shall not be less than 90%.

NOTE 1: The YY/T 1551 series of standards provide test methods for evaluating bacterial retention performance.

NOTE 2: This test is not required if the barrier material is non-breathable.

6.6.3 Pressure transfer performance

The pressure monitoring joint/sensor protector shall have adequate pressure transmission performance. When the test is carried out according to B.2, the time required for the pressure monitoring joint/sensor protector to transmit 10kPa air pressure shall not exceed 3s.

6.6.4 Blood blocking

The filter material in the pressure monitoring joint/sensor protector can effectively block the liquid. When tested according to B.3, under the hydraulic pressure of 40kPa for 40s, there shall be no evidence of liquid penetration.

7 Requirements

7.1 General

Blood flows are designed to maintain high quality blood or blood components. The blood flow is sterile and pyrogen-free under the expected conditions of use. It has properties (such as transparency, softness, strength, fatigue resistance, sterilization adaptability) that are compatible with its clinical use.

7.2 Physical properties

7.2.1 Appearance

The hose on the blood flow shall be plasticized evenly without kinks. Its transparency shall allow detection of air bubbles in the bloodstream with normal or corrected vision.

7.2.2 Tightness

Seal each end of the blood flow. Immerse it in water at 20°C~30°C. Access the air pressure of 50kPa or 1.5 times the maximum working pressure stated by the manufacturer. Maintain 2min. There shall be no evidence of leakage.

NOTE: The blood flow with special requirements (if it needs to bear negative pressure), depends on the specific situation.

7.2.3 Connection firmness

Each connection of the blood flow (excluding the protective sleeve) shall be able to withstand a static axial tension of 15N. It shall last 15s without breaking and falling off.

7.2.4 Particulate pollution

Blood flows shall be produced with minimal particulate contamination. Liquid passage surfaces shall be smooth and clean. When tested according to the method specified in YY/T 1556, the pollution index shall not exceed 90.

NOTE: The volume of flushing fluid can be adjusted according to the product structure and intended use.

7.2.5 Color code

When the blood flow is divided into arterial blood flow and venous blood flow, there shall be a clear color mark within 100mm of the end of the pipeline. The arterial blood flow shall be red. The venous blood flow shall be blue.

7.3 Chemical properties

7.3.1 Guide for test solution preparation

The preparation conditions of the chemical performance test solution shall represent the most severe conditions for the clinical use of the product. Design the reasonable and feasible extraction ratio, extraction temperature and extraction time. Prepare the blank control solution in the same way.

The leaching method prioritizes the use of recycling methods. It shall represent the maximum flow rate at which the product is intended to be used.

If the product contains containers or other components that are inconvenient to prepare the test solution in a cyclic manner, the test solution can be prepared according to the requirements in GB/T 14233.1-2008. Prepare the blank control solution in the same

If ethylene oxide is used for sterilization, when inspected according to Chapter 9 of GB/T 14233.1-2008, the residual amount of ethylene oxide in blood flow products shall meet the requirements specified in the product standard.

NOTE: The ethylene oxide residue index of blood flow products needs to be established on the basis of biological evaluation.

7.5 Biological properties

7.5.1 General requirements

Blood flow products shall be biologically evaluated according to GB/T 16886.1.

7.5.2 Sterile

Blood flow products shall be supplied sterile and shall meet the requirements of YY/T 0615.1.

7.5.3 Bacterial endotoxin

Blood flow products shall control bacterial endotoxin content in corresponding product standards. Carry out the test according to the test method given in GB/T 14233.2. It shall not exceed 20EU/set.

7.5.4 Hemocompatibility of blood flow in the fluid state

If applicable, the mechanical force-mediated hemocompatibility of the blood flow shall be evaluated.

If applicable, the blood flow shall be evaluated for residual blood components and blood component damage under normal conditions of use.

NOTE: See YY/T 1620 and YY/T 1631 for the design evaluation test protocol.

8 Packaging, marks

The manufacturer of the blood flow shall provide evidence that its single package complies with GB/T 19633.1.

NOTE: See also YY/T 0313.

Annex A

(informative)

Design and evaluation requirements

A.1 General

The following aspects are considered in the design of blood flow products:

a) Ensure that the blood or blood components maintain the required high quality.

b) As far as possible to ensure safe and efficient collection, testing, storage, separation and transfusion of blood, especially the risk of minimization due to:

- Contamination, especially microbial contamination;

- Air embolism;

- Interaction between the blood flow and the blood.

c) When used in conjunction with other devices, the guaranteed function is applicable.

A.2 Pump tubing

Manufacturers shall evaluate pump tubing in three areas:

- Matching with the supporting equipment to obtain accurate flow rate;

- or the shedding of particles during the use of the pump tube, refer to ISO/TR 19727 to design and evaluate the test plan;

- Durability, to ensure target flow rate is maintained throughout the process.

A.3 Residual amount of adhesive

The adhesive residue index shall be established on the basis of toxicological evaluation.

For blood flow products using cyclohexanone as a binder, see YY/T 1658 for the evaluation method of cyclohexanone residue.

A.4 Dissolution amount of plasticizer

For blood flow products using plasticizers, the plasticizer dissolution index shall be established on the basis of toxicological evaluation.

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