YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.20

C 31

YY/T 0316-2017

Replacing YY 0326.1-2002, YY 0326.2-2002 and YY 0316.3-2005

Plasmapheresis centrifuge apparatus for single use

一次性使用离心式血浆分离器

Issued on: May 02, 2017 **Implemented on: April 01, 2018**

Issued by: China Food and Drug Administration

Table of Contents

Plasmapheresis centrifuge apparatus for single use

1 Scope

This Standard specifies the requirements for plasmapheresis centrifuge apparatus for single use (hereinafter referred to as centrifuge apparatus) to ensure that it is compatible with the matching centrifugal automatic plasma collection machine.

The plasma collected and stored by the centrifuge apparatus specified in this Standard is used for the preparation of blood products and cannot be used for clinical blood transfusion.

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/T 1962.1 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirement

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 6682 Water for analytical laboratory use - Specification and test methods

GB 8369 Medical transfusion sets for single use

GB 14232.1 Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers

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

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

YY/T 0328 A.V. fistula needle sets for single use

YY 0321.3-2009 Single-use filter for anaesthesia

5 Physical requirements

5.1 Plasma centrifuge bowl

5.1.1 Appearance

5.1.1.1 The centrifuge bowl shall be transparent.

5.1.1.2 Observe the interior surface of the centrifuge bowl with normal vision or corrected vision under natural light, it shall be clean and smooth, and there shall be no obvious spots or impurities.

5.1.2 Particulate contamination

The centrifuge bowl shall be produced under the conditions of the minimum particulate contamination. When tested according to A.1, the contamination index shall not exceed 90.

5.1.3 Airtightness

When the centrifuge bowl is tested according to Annex A.2, it shall be able to withstand the pressure of 8 kPa for 10 s without any signs of gas leakage.

5.1.4 Connection strength

The joints (excluding the protective sleeve) of the centrifuge bowl shall be able to withstand the static tension of not less than 15 N for 15 s.

5.1.5 Frictional heat

When the centrifuge bowl is tested according to A.3, the water temperature shall not exceed 37 °C.

5.1.6 Noise

The centrifuge bowl is operated at a speed of 7000 r/min, and when the average noise of the test centrifuge is not more than 60 dB when idle, use a sound level meter (A weighting) to measure 4 points in front, back, left, right at 1 m away from the center of the centrifuge bowl, the average noise shall not exceed 70 dB.

5.1.7 Blood residual amount

When the centrifuge bowl is tested according to A.4, the residual amount in the bowl shall not exceed 5.0 mL.

5.1.8 Separated plasma hemoglobin content

the tubing. When tested according to A.2 of YY 0321.3-2009, the pressure monitor connector shall have a filtration rate of not less than 90 % for particles larger than 0.5 μm in air.

5.2.8.2 Ventilation

The pressure monitor connector shall be sufficiently ventilated. When tested according to B.3, the time required for the pressure monitor connector to transfer 10 kPa air pressure shall not exceed 3 s.

5.2.8.3 Blood blocking

The filter material in the pressure monitor connector can effectively block the blood. When tested according to B.4, at a hydraulic pressure of 40 kPa above the atmospheric pressure for 40 s, there shall be no signs of liquid infiltration. The mechanical end surface of the pressure monitor connector shall be transparent, and it may visually inspect the blood for contamination during use.

5.2.8.4 Adaptability

The pressure monitor connector shall be tightly coupled with the pressure monitor of the matching plasma collection machine. It shall not fall off naturally and shall be easily disassembled. The conical fitting with taper in the joint shall meet the requirements specified in GB/T 1962.1 or GB/T 1962.2.

5.2.9 Pump tubing[2)]

5.2.9.1 Flow

The anticoagulant flow and the blood flow shall be compatible with the state of use of the matching centrifugal automatic plasma collection machine. When tested according to B.5, the anticoagulant flow and the blood flow shall meet (1 ± 0.1) mL/lap (peristaltic pump).

5.2.9.2 Elasticity

The pump tubing part of the tubing shall have good elasticity. When the water temperature is 23 °C ± 2 °C, and tested according to B.6, the flow reduction rate shall be less than 5 % after operating for 1 h.

5.2.10 Locating clip[3)]

[2)] The pump tubing refers to a hose installed in the peristaltic pump of the centrifugal plasma collection machine.

[3)] The locating clip is a plastic piece that is mounted on the pump tubing to limit the displacement of the pump tubing.

conjunction with the centrifuge bowl as specified in 5.1.

The plasma container shall be transparent or translucent, colorless, soft, sterile, non-pyrogenic, non-toxic and not easily broken under the conditions of use. It shall be compatible with the contents when stored under normal conditions. The plasma container shall meet the requirements for final sterilization, and shall not adhere during the sterilization process and in the storage life at a temperature not exceeding 40 °C.

The whole process of manufacture, assembly and storage of plasma containers shall be carried out under the clean and hygienic conditions specified by the relevant national laws and regulations. Various effective preventive measures shall be taken throughout the manufacturing process to reduce the risk of microbiological or foreign substance contamination.

5.3.2 Sterilization

5.3.2.1 The plasma container shall be sterilized by a validated method.

5.3.2.2 The sterilization method shall not adversely affect the material of the plasma container, and shall not loosen the connections, reduce the heat-seal strength of the plastic material, and cause significant deformation of the plasma container.

5.3.2.3 The manufacturer shall be able to provide evidence of the effectiveness of the sterilization process used to national authorities.

5.3.3 Input tubing

5.3.3.1 The plasma container shall have an input tubing for the collection of plasma. The input tubing shall be equipped with an interface matched with the centrifuge bowl. Assemble the centrifuge bowl interface according to the manufacturer's instructions, the joint shall be able to withstand a pressure of 8 kPa for 10 s without any signs of leakage.

NOTE: For centrifuge apparatus supplied as a set (a set of four), the test does not require an assembly operation, and the test is carried out directly on the manufacturer's assembled product.

5.3.3.2 The input tubing shall be isolated from the outside without breaking in normal use.

5.3.3.3 After the plasma container has been filled with water to nominal capacity and sealed, the input tubing connected to the plasma container shall form a seal. The connection is resistant to leakage and is able to withstand a pull of 20 N applied to the tubing for 15 s without leakage. The tension shall be applied at right angles to the edge of the joint and in the direction of the longitudinal axis

If the plasma container is sterilized with ethylene oxide, the ethylene oxide residue shall not exceed 10 μg/g.

NOTE: GB/T 14233.1-2008 and GB/T 16886.7 specify the test methods and release control of ethylene oxide residues. The use of breathable materials that are easily accessible to ethylene oxide on single packages (such as using composite package bags with a dialysis paper on one side and a plastic film on the other side, or adding dialysis paper on perforated package bags) can effectively reduce ethylene oxide residue.

7 Biological requirements

7.1 Centrifuge bowl

7.1.1 Biocompatibility

The biological evaluation of the centrifuge bowl shall be carried out according to GB/T 16886.1. The evaluation results shall show that there is no biological hazard.

7.1.2 Sterility

The sterile supply assembly of the centrifuge bowl shall meet the requirements of YY/T 0615.1.

7.2 Plasma tubing

7.2.1 Biocompatibility

The biological evaluation of the plasma tubing shall be carried out according to GB/T 16886.1. The evaluation results shall show that there are no biological hazards.

7.2.2 Sterility

The sterile supply assembly of the plasma tubing shall meet the requirements of YY/T 0615.1.

7.3 Plasma container

GB 14232.1 applies.

7.4 Bacterial endotoxin

The bacterial endotoxin content of the centrifuge apparatus shall meet the requirements for the plasma collection equipment in human plasma for the production of blood products in the Pharmacopoeia of the People's Republic of China (2010 Edition) (Part 3).

d) instruction that use is prohibited if any visible signs of deterioration is found by naked eyes;

e) instruction that ventilation is not required;

f) instruction that the plasma container is for single use only;

g) use instructions of plasma containers;

h) name and address of manufacturer and/or supplier;

i) batch number;

j) if appropriate, the label may also include information that the plasma container should not be used to collect plasma after the period of use or the expiration date, as well as information related to product codes.

9.2.2 Label requirements

The label of the plasma container shall meet the following requirements:

a) the printing on the label does not penetrate into the plastic material of the plasma container;

b) the printing on the label remains clear and recognizable when in use.

9.3 Transport packaging

The transport packaging box of the centrifuge apparatus (or assembly) shall have at least the following symbols:

a) name and address of manufacturer and/or supplier;

b) product name and model;

c) quantity, weight;

d) volume (length × width × height);

e) single use and sterile;

f) production batch number;

g) sterilization batch number;

h) period of use or expiration date;

i) graphical signs related to storage and transportation.

Annex A

(normative)

Physical test method for centrifuge bowl

A.1 Particulate contamination test

A.1.1 Preparation of test solution

TAKE 5 centrifuge bowls, respectively INJECT 200 mL of flushing fluid (distilled water filtered through a membrane with a pore size of 0.2 μm) from the inlet of the centrifuge bowl, SEAL the inlet and outlet with protective sleeves, PLACE them in the special centrifuge, ADJUST the centrifuge speed to 7000 r/min, after centrifuge for 5 min, FLIP up and down 5 times. Respectively COLLECT 200 mL of eluent from the outlet of the centrifuge bowl, and COLLECT a total of 1000 mL as the eluent.

TAKE another 1000 mL of flushing fluid as the blank control solution.

NOTE: It shall avoid environmental pollution during the test process. The arbitration method is to centrifuge using a plasma collection machine matched with the test centrifuge bowl.

A.1.2 Test method

According to the method specified in GB 8369, CHECK the total number of particulates of the 5 centrifuge bowls in the eluent and the number of particulates in the blank control solution, and CALCULATE the contamination index.

A.2 Airtightness test

SEAL the outlet of the centrifuge bowl, INTRODUCE a pressure of 8 kPa higher than the atmospheric pressure to the inlet of the centrifuge bowl for 10 s, CHECK whether the pressure gauge indicates signs of gas leakage (the limit is that the pressure reduction does not exceed 0.1 kPa). Then ROTATE the upper and lower bodies of the centrifuge bowl 180 degrees relative to each other, and REPEAT the above steps.

A.3 Frictional heat test

A.3.1 Principle

This method is to simulate the working state of the centrifuge bowl, evaluate the frictional heat generated by high-speed centrifugation by measuring the increase in water temperature at the inlet and outlet.

result of colorimetric determination of the hemoglobin solution with of a known concentration, and then calculate the hemoglobin content in the separated plasma.

A.5.2 Samples

The test sample is the plasma collected and separated by the centrifugal apparatus specified in this Standard. If it is frozen plasma, it shall be melted before test.

A.5.3 Reagents

A.5.3.1 O-toluidine solution

WEIGH 0.2 g of o-toluidine to DISSOLVE in 60 mL of glacial acetic acid, ADD water to 100 mL, STORE in refrigerator. If the color becomes dark, it shall be re-prepared.

A.5.3.2 1% (volume fraction) hydrogen peroxide solution

Freshly diluted by 30 % hydrogen peroxide solution.

A.5.3.3 Acetic acid solution

10 % (volume fraction) acetic acid solution.

A.5.3.4 Hemoglobin (Hb) standard stock solution

TAKE 5 mL of human anticoagulant whole blood with a collection time of no more than 24 h in a plastic tube, ADD 5 mL of sodium chloride injection solution with a concentration of 9 g/L, CENTRIFUGE at 1200 g for 5 min, ASPIRATE the supernatant and DISCARD it; REPEAT the above steps three times. The remaining red blood cells (about 4 mL) are added with 5 mL of water for injection, gently shaken for 5 min, centrifuged at 800 g for 10 min. pipette the Hb solution into another plastic tube. MEASURE the Hb content on a hemocytometer. According to the Hb content, use 9 g/L sodium chloride injection solution to adjust the Hb concentration to 10 g/L, which is Hb standard stock solution. STORE the Hb standard stock solution in small sample tubes (Doff tube) with a lid and keep it frozen.

A.5.3.5 Hemoglobin (Hb) use standard solution

The Hb standard stock solution is naturally melted and diluted to 100 mg/L using sodium chloride solution with a concentration of 9 g/L. It may also use 9g/L sodium chloride solution to dilute the commercially available Hb standard solution to 100 mg/L.

Annex B

(normative)

Physical test method for plasma tubing

B.1 Particulate contamination test

B.1.1 Preparation of test solution

TAKE 5 sets of plasma tubing. Under a hydrostatic head of 1 m, MAKE 500 mL of flushing fluid (distilled water filtered through a membrane with a pore size of 0.2 μm) flow through 5 sets of plasma tubing respectively, COLLECT A total of 2500 mL as the eluent.

TAKE another 2500 mL of flushing fluid as the blank control solution.

NOTE: It shall avoid environmental pollution during the test process. The arbitration method is to centrifuge using a plasma collection machine matched with the test centrifuge bowl.

B.1.2 Test method

According to the method specified in GB 8369, CHECK the total number of particulates of the five sets of plasma tubing in the eluent and the number of particulates in the blank control solution, and CALCULATE the contamination index.

B.2 Airtightness test

SEAL three of the four ends of the tubing and IMMERSE them in water at 20 °C ~ 30 °C. INLET a pressure of 50 kPa higher than the atmospheric pressure to the unsealed end of the tubing for 2 min. CHECK the signs of leakage in the tubing.

B.3 Pressure monitor connector's ventilation test

B.3.1 Cut off the pressure monitor connector, connect it with two spring-loaded sphygmomanometers (the full scale is 40 kPa) and the pressurizing device consists of 5 and 6 according to Figure B.1. At this point the pointers of the two sphygmomanometers shall be at 0.

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 3 websites:

1. https://www.ChineseStandard.us

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. https://www.ChineseStandard.net

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - https://www.ChineseStandard.us).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

3. https://www.google.com/search?tbm=bks&q=ChineseStandard.net

- SEARCH the standard ID, such as GB 4943.1-2022.
- Google Books -- Select your currency.
- Processed by Google (delivery, tax invoice etc.). Delivered in 9 seconds by Google.
- Tips: Download an unprotected True-PDF (text-editable) from Google-Books:
  1. https://play.google.com/books → 2. Sign in → Google account
  3. Find the BOOK you bought → 4. Click "3-dots" → Export
  5. Save as "*.pdf" (Save True-PDF to your local computer for offline reading/printing)

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

Accountable person and shareholder: Wayne Zheng

About Us (Goodwill, Policies, Fair Trading…): https://www.chinesestandard.net/AboutUs.aspx

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: https://www.linkedin.com/in/waynezhengwenrui/

------ The End ------