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Plastic collapsible containers for human blood and blood components

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Contents

	Page
Introduction	1
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions	2
4 Configuration and names of parts	3
5 Design.....	4
5.1 General requirement	4
5.2 Air content	5
5.3 Emptying under pressure	5
5.4 Pilot samples.....	5
5.5 Rate of collection.....	5
5.6 Collection tube (duct) and transfer tube.....	5
5.7 Blood-taking needle	6
5.8 Outlet port(s) (outlet for administration)	6
5.9 Suspension hole	6
6 Requirements.....	7
6.1 General	7
6.2 Physical requirements	7
6.3 Chemical requirements.....	9
6.4 Biological requirements	12
7 Packaging	12
8 Labelling	13
8.1 General	13
8.2 Label on blood components collapsible container	13
8.3 Label on secondary container	13
8.4 Label on shipping box.....	14
8.5 Label requirements.....	14
Annex A (normative) Chemical tests.....	15
Annex B (normative) Physical tests	21
Annex C (normative) Biological tests.....	23
Annex JA (informative) Comparison table between JIS and corresponding International Standard.....	27

Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3217 : 2005** is replaced with this Standard.

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Plastic collapsible containers for human blood and blood components

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of **ISO 3826-1** published in 2003 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions with continuous sidelines or dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies the plastics collapsible containers for collection, storage, processing, transport, separation and administration of human blood and blood components (hereafter referred to as “blood components collapsible containers”).

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 3826-1 : 2003 *Plastics collapsible containers for human blood and blood components—Part 1: Conventional containers* (MOD)

In addition, symbols, which denote the degree of correspondence in the contents between the relevant International Standard and **JIS**, are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

JIS T 3217 : 2005 may be applied until July 28 in 2014.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

JIS T 0307:2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

NOTE : Corresponding International Standard : **ISO 15223:2000** *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied* and Amendment 1:2002 (IDT)

JIS T 0993-1: 2005 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

JIS T 3212: 2011 *Sterile blood transfusion set*

NOTE : Corresponding International Standard : ISO 1135-4 *Transfusion equipment for medical use—Part 4 : Transfusion sets for single use* (MOD)

JIS T 3220:2011 *Sterile blood collection needle*

ISO 594-1:1986 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1: General requirements*

ISO 594-2:1998 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2 : Lock fittings*

ISO 1135-3:1986 *Transfusion equipment for medical use—Part 3: Blood-taking set*

3 Terms and definitions

For the purposes of this Standard, the following terms and definitions apply.

3.1 plastics container

a container used for collection, separation, storage, processing, transport or administration of blood and blood components, provided with an inlet for blood collection, an outlet for transfusion or outlet(s) of plasma and others

The container which is capable of direct collection of blood is referred to as “plastics blood collection containers.”

3.2 nominal capacity

volume or mass of blood or blood components to be collected in the plastics container, which is indicated on a label or packaging of the container

3.3 pilot sample

a tube with segment number printed on the blood collecting tube (duct) or a transfer tube so that it can be used for examination of collected blood

3.4 male and female connector

a connector capable of connection and separation between tools by a male and female taper

3.5 vent

a device used for circulating air in and out of the plastics container

3.6 auxiliary bag

a bag for collection or temporary storage of collected blood at initial stage or blood for examination

3.7 sampling port

a holder for connecting the blood collecting tube used to collect blood for examination

3.8 check valve

a valve to prevent backflow of a blood preparation

3.9 plastic sheet

film portion of the container

3.10 shelf-life

period between the date of sterilization and the expiry date, after which the blood components collapsible containers shall not be used for the collection or separation of blood

3.11 purified water

“purified water” specified in Official Monographs of Japanese Pharmacopoeia (hereafter referred to as “JP”), or water being at least equivalent thereto in quality

3.12 primary container

packaging to directly cover the blood components collapsible container, used for maintaining the sterility of blood components collapsible containers

Furthermore, if the secondary packaging is performed for this, it corresponds to a so-called “inner bag”.

3.13 secondary container

packaging to directly cover the primary container and generally containing the multiple primary container sets, for example, the 50 sets

4 Configuration and names of parts

The blood components collapsible container mainly consists of a duct and a transfer tube, and some may be attached with a separation needle or male and female connectors (including lock). A blood-taking needle, a separation needle or a connector may be further optioned. The blood-taking needle, separation needle or the connector shall be provided with a protective cap. In addition, a vent, check valve, sampling port, auxiliary bag, etc. may be attached. Some blood component collapsible containers have plural bags.

Figure 1 illustrates a typical configuration of the blood component collapsible container.

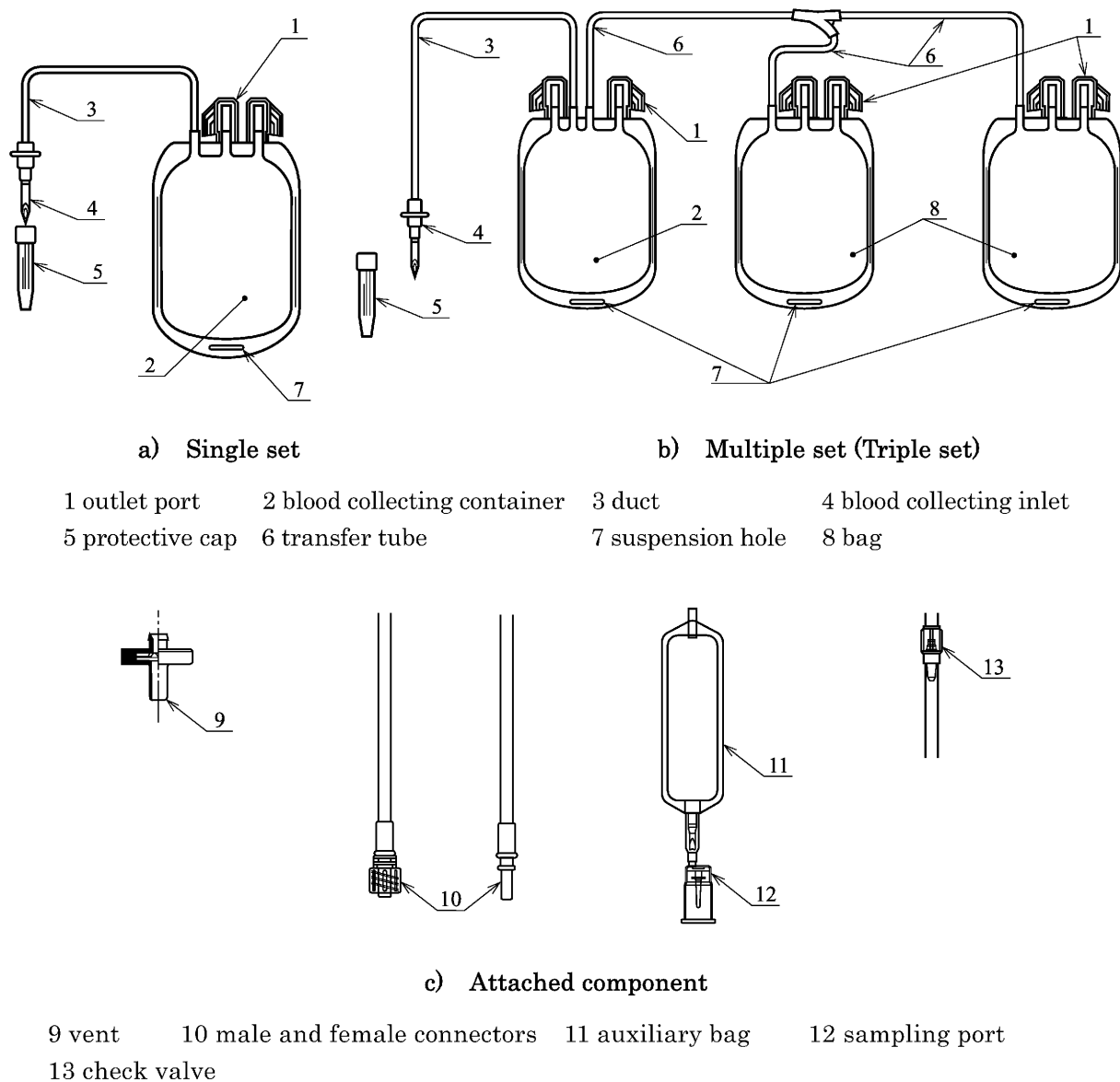


Figure 1 Configuration and names of parts of blood components collapsible container

5 Design

5.1 General requirement

The design and manufacture of the blood components collapsible container shall provide for the safe and convenient collection, storage, processing, transport, separation and administration of whole blood and blood components. The blood components collapsible container shall permit the collection of blood and the preparation of plasma or centrifuged or re-suspended cellular components with a minimal hazard of contamination by microorganisms. The blood components collapsible container shall be functionally compatible with the transfusion set specified in JIS T 3212.

5.2 Air content

Air content shall conform to the following matters.

- a) The total volume of air contained in the blood components collapsible container to be filled with an anticoagulant and/or a preservative solution shall not exceed 15 ml per container.
- b) When used in accordance with the operating procedure specified by the manufacturer and the supplier, the blood components collapsible container to be filled with an anticoagulant and/or a preservative solution shall be capable of being filled with blood without air being introduced.

5.3 Emptying under pressure

The blood components collapsible container, when filled with a volume of water at a temperature of $23\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ equal to its nominal capacity and connected to a transfusion set as specified in JIS T 3212 (with its clamp closed and without transfusion needle) inserted in an outlet port (see 5.8), shall be capable of emptying at an average flow rate of 250 ml/min or over without water leakage through the connected transfusion set when squeezed between 2 plates to an internal pressure of 50 kPa above atmospheric pressure.

5.4 Pilot samples

The blood components collapsible container to be filled with an anticoagulant and/or a preservative solution shall be designed so that pilot samples of unmistakable identity can be collected for the performance of appropriate laboratory tests without the closed system of the container being penetrated.

5.5 Rate of collection

The blood components collapsible container provided with a blood-taking needle and to be filled with an anticoagulant and/or a preservative solution shall be designed so that it is capable of being filled to its nominal capacity within 8 min when tested in accordance with a) or b) of B.2.

5.6 Collection tube (duct) and transfer tube

Collection tube (duct) and transfer tube shall be as follows.

- a) The blood components collapsible container to be filled with an anticoagulant and/or a preservative solution is provided with one or more blood collection tube(s) [duct(s)] or transfer tube(s) to allow the collection and separation of blood and blood components. If a transfer tube is present, it shall be fitted with a device which first acts as a seal and then, when broken, permits the free flow of blood components in either direction.
- b) The collection tube(s) [duct(s)] and transfer tube(s) shall be such that they can be sealed hermetically and do not collapse under normal use.

- c) The blood components collapsible container, filled with water to its nominal capacity and sealed, and the collection tube(s) [duct(s)] and transfer tube(s) connected to the blood components collapsible container, when a tensile tension of 20 N is applied to the edge of the joint for 15 s at a room temperature, shall have no leakage at the joints and the blood components collapsible container shall also conform to 6.2.7.
- d) Under visual inspection, the collection tube(s) [duct(s)] and transfer tube shall not display cracks, blisters, kinks or other defects.
- e) A part of the collection tube(s) [duct(s)] and transfer tube of the blood components collapsible container to be filled with an anticoagulant and/or a preservative solution shall be removable while keeping sterility inside the container and bear a printed number (segment number) matching that of the blood components collapsible container in order to supply a part of collected blood to blood laboratory test.

5.7 Blood-taking needle

The blood-taking needle, if the container is provided with any needles, shall be integral with the collection tube and covered by a protective cap. The protective cap shall prevent leakage of an anticoagulant and/or a preservative solution from the blood components collapsible container during storage, shall maintain the sterility of the fluid path and shall be readily removable. The protective cap shall be tamper-evident and manufactured so that either it is impossible to replace or any attempt at manipulating it is blatantly obvious. The blood-taking needle shall withstand, without working loose from the assembly, a tensile force of 20 N applied along the axis of the tubing for 15 s. The blood-taking needle may contain an anti-needle-stick device.

5.8 Outlet port(s) (outlet for administration)

Outlet port(s) (outlet for administration) shall conform to the following matters.

- a) The blood components collapsible container shall be provided with one or more outlet port(s) used for the administration of blood and blood components through a transfusion set.
- b) The port(s), which shall have a puncturable and non-resealable closure, shall allow connection of a transfusion set specified in **JIS T 3212** without leakage during conditions of use. Each outlet port shall be fitted with a hermetically sealed, tamper-evident protector to maintain the sterility of the internal surface.

5.9 Suspension hole

Suspension hole shall conform to the following matters.

- a) The blood components collapsible container shall have adequate suspension hole or means of positioning which do not interfere with use of the blood components collapsible container during collection, storage, processing, transport and administration.

- b) The suspension hole shall be capable of withstanding a tensile force of 20 N applied along the axis of the outlet port(s) for 60 min at a temperature of $23\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ without breaking.

6 Requirements

6.1 General

The blood components collapsible container shall be transparent, virtually colourless, flexible, sterile, non-pyrogenic, free from toxicity and non-frangible under conditions of use. It shall be compatible with the contents under normal conditions of use. The blood components collapsible container shall meet the requirements for terminal sterilization, and shall not become tacky during or after sterilization. The blood components collapsible container shall be stable biologically, chemically and physically with respect to its contents during its shelf-life, and shall not permit penetration of microorganisms.

Furthermore, the following matters apply when the container is filled with an anti-coagulant and/or a preservative solution.

- a) The blood components collapsible container shall be designed so that it is capable of safe and effective performance of collection, storage, processing, transport, separation and administration of blood and blood components.
- b) It shall be designed and manufactured so as not to have an adverse affect on the storage of blood and blood components.
- c) The blood components collapsible container shall be capable of minimizing the risk of contamination with microorganisms, and capable of preparing plasma or centrifuged or re-suspended cellular components.
- d) The blood components collapsible container shall have functional compatibility with the transfusion set specified in **JIS T 3212**.
- e) The blood components collapsible container shall be designed so as to be applicable to centrifuge except for that used for storage only.

6.2 Physical requirements

6.2.1 Conditions of manufacture

All processes involved in the manufacture, assembly and storage of the blood components collapsible container shall be carried out under clean and hygienic conditions. Every practicable precaution shall be taken at all stages to reduce the risk of adventitious contamination by microorganisms or foreign matter.

6.2.2 Sterilization

Sterilization shall be as follows.

- a) The blood components collapsible container shall have been sterilized by autoclaving or any other validated method.

- b) The method of sterilization used shall not adversely affect the materials or contents, nor cause any loosening of joints and deterioration of welds in the plastics material nor any major alteration in the shape of the blood components collapsible container.
- c) The manufacturer and supplier shall be able to produce evidence acceptable to the national control authority of the effectiveness of the sterilization process actually used. If required by the national control authority, positive controls to check the effectiveness of sterilization shall be included in each sterilization lot.

6.2.3 Transparency

When tested as specified in B.1, the opalescence of the suspension shall be perceptible when viewed through the blood components collapsible container as compared with a similar blood components collapsible container filled with purified water.

6.2.4 Colouration

The material of the sterilized blood components collapsible container shall not be coloured to such an extent that assessment of the colour of the blood is adversely affected.

6.2.5 Thermal stability

The blood components collapsible container, filled to half of its nominal capacity with water, shall withstand a slow freezing to and storage at $-80\text{ }^{\circ}\text{C}$ for 24 h, subsequent immersion in water at $37\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ for 60 min, and returning to room temperature. The blood components collapsible container shall meet the requirements of 5.6 c), 5.9, 6.2.7 and 6.2.8.

NOTE : The blood components collapsible container intended to be fast-frozen or irradiated shall be validated for those applications. If a refrigerant solution is used, the blood components collapsible container may be enclosed in a protective bag to avoid direct contact between the refrigerant solution and the blood components collapsible container.

6.2.6 Water vapour transmission

The blood components collapsible container, without a primary container, shall be filled to its nominal capacity with purified water, sealed and labelled ready for use. The blood components collapsible container shall then be capable of being stored for 42 days at a temperature of $4\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and a relative humidity of 60 % or lower without loss of a mass fraction of more than 2 % of water from the solution.

NOTE : The storage of certain blood components, such as platelet concentrates, may require specific gas exchange rates for oxygen and carbon dioxide.