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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 18469-2012

Quality requirements for whole blood and blood components

全血及成分血质量要求

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Table of Contents

Foreword

Chapter 4 of this Standard is mandatory and the rest are recommended. This Standard was drafted in accordance with the rules given in GB/T 1.1-2009. This Standard replaces GB 18469-2001 Standards for whole blood and blood components quality. Compared with GB 18469-2001, the main technical changes are as follows: -- Change the English name from "Standards for whole blood and blood components quality" to "Quality requirements for whole blood and blood components"; -- Adjust the framework structure of the standard, by dividing the requirements for blood into two parts. blood safety testing requirements and blood quality control requirements; -- Add the definitions of whole blood leukocytes reduced, frozen red blood cells, fresh frozen plasma methylene blue treated and removed, frozen plasma and frozen plasma cryoprecipitate reduced, frozen plasma methylene blue treated and removed, pooled platelets, irradiated blood components and freezing; -- Revise the definitions of blood product, blood components, red blood cells components, apheresis components, whole blood, red blood cells, red blood cells in additive solution, washed red blood cells, deglycerolized red blood cells, platelets, fresh frozen plasma, cryoprecipitated antihemophilic factor, concentrated leukocyte-reduced red blood cells, suspended leukocyte-reduced red blood cells, apheresis platelets, apheresis leukocyte-reduced platelets, apheresis fresh frozen plasma and apheresis granulocytes; -- Change the name of "leukocyte-reduced blood products" in GB 18469-2001 to "blood products leukocytes reduced"; -- Add quality requirements for whole blood leukocytes reduced, red blood cells in additive solution leukocytes reduced, fresh frozen plasma methylene blue treated and removed, frozen plasma and frozen plasma cryoprecipitate reduced, frozen plasma methylene blue treated and removed and pooled platelets; -- Delete the relevant content of whole blood and component blood labels and connect with other relevant national standards; -- Add quality requirements for 300 mL whole blood and corresponding blood components; Quality requirements for whole blood and blood components

1 Scope

GB 18469-2012 is the Chinese national standard on quality requirements for whole blood and blood components, in the field of health care technology. It carries no /T suffix, which in the Chinese system means compliance is mandatory: a product or a practice within its scope has to meet it to be lawfully made, sold or carried out in China. It was issued on 11 May 2012 by the Ministry of Health of the People's Republic of China; Standardization Administration of China, and has been in force since 1 July 2012. Classification: ICS 11.020, CCS C05. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This Standard specifies the quality requirements for whole blood and blood components provided by general blood stations and used for clinical transfusion. This Standard applies to whole blood and blood components provided by general blood stations and used for clinical 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 14232.1, Plastics collapsible containers for human blood and blood components - Part

3 Terms and definitions

For the purposes of this document, the terms and definitions given in GB 14232.1 and the following apply.

3.1 preservative solution A class of drugs with anticoagulants, glucose, etc. as main ingredients, used to prevent blood coagulation and maintain the activity and physiological functions of various components in the blood.

3.2 blood product A uniform product formed by mixing a certain amount of blood or blood components from qualified blood donors with a certain amount of preservative solution.

3.3 additive solution red blood cells leukocytes reduced The red blood cells components made by using a leukocyte filter to remove almost all leukocytes from red blood cells and making the number of leukocytes remaining in the red blood cells lower than a certain value; or the red blood cells components made by the remaining part after separating most of the blood plasma in the whole blood leukocytes reduced by using a multi-unit plastics container with a leukocyte filter to collect whole blood, and removing almost all leukocytes

from the whole blood through the leukocyte filter.

3.11 red blood cells in additive solution The red blood cells components made by separating most of the blood plasma from the whole blood collected in a multi-link plastics container using a specific method, and adding red blood cell additive solution into the remainder.

3.12 red blood cells in additive solution leukocytes reduced The red blood cells components made by using a leukocyte filter to remove almost all leukocytes from red blood cells in additive solution and making the number of leukocytes remaining in the red blood cells in additive solution lower than a certain value; or the red blood cells components made by using a multi-unit plastics container with a leukocyte filter to collect whole blood, removing almost all leukocytes from the whole blood through the leukocyte filter, separating most of the blood plasma in the whole blood leukocytes reduced, and adding red cell additive solution to the remainder.

3.13 washed red blood cells The red blood cells components made by using a large amount of isotonic solution to wash the whole blood and red blood cells in additive solution within the storage period by a specific method to remove almost all blood plasma components and some non-red blood cell components, and suspending the red blood cells in sodium chloride injection or red blood cells in additive solution.

3.14 frozen red blood cells The red blood cells components made by separating red blood cells from whole blood or red blood cells in additive solution within 6 days of collection using a specific method, mixing it with glycerol of a certain concentration and volume, and quickly The blood components, in solid state by quick freezing, made by separating the blood plasma from the whole blood which is stored in a refrigerated environment, preferably within 6 hours (ACD as preservative solution) or 8 hours (CPD or CPDA-1 as preservative solution) after collection, but not more than 18 hours.

3.21 fresh frozen plasma methylene blue treated and removed The blood components, in solid state by quick freezing, made by collecting the whole blood stored in a refrigerated environment, separating the blood plasma according to the requirements of 3.20, and using the methylene blue virus inactivation technology for virus inactivation before quick freezing.

3.22 apheresis fresh frozen plasma The apheresis components made by using a blood cell separator to automatically separate the blood plasma from the blood of qualified blood donors under fully closed conditions and quickly freezing it into a solid state within 6 hours.

3.23 frozen plasma and frozen plasma cryoprecipitate reduced The blood components made by separating the blood plasma from the whole blood within the valid period by a specific method and quickly freezing it into solid state; or the blood components made by separating the cryoprecipitated antihemophilic factor from fresh frozen plasma and quick freezing the remaining part into solid state.

3.24 frozen plasma methylene blue treated and removed The blood components made by virus-inactivating and quick-freezing into solid state of the blood plasma separated from the whole blood within the valid period OR the remaining blood plasma after reducing the cryoprecipitated antihemophilic factor from the fresh frozen plasma by using the methylene blue virus inactivation technology.

3.25 cryoprecipitated antihemophilic factor The blood components made by using a specific method to thaw the fresh frozen plasma within the storage period at 1 °C ~ 6 °C, separating most of the blood plasma, and quick- freezing the remaining cold insoluble substances into solid state within 1 hour.

3.26 apheresis granulocytes The apheresis components made by using a blood apheresis machine to automatically separate the granulocytes from the blood of qualified blood donors under fully closed conditions and suspending them in a certain amount of blood plasma.

4.1 Blood typing

4.1.1 The ABO blood typing test results are correct.

4.1.2 The RhD blood typing test results are correct.