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

YY/T 1617-2018

PVC calendered film for blood bags

血袋用聚氯乙烯压延薄膜

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. Publication of this document The organization does not assume responsibility for identifying these patents. This standard was proposed by the State Drug Administration. This standard is under the jurisdiction of the National Technical Committee for Standardization of Medical Infusion Devices (SAC/TC106). This standard was drafted. Shanghai Xinshang Polymer Materials Co., Ltd., Shandong Medical Device Product Quality Inspection Center, Guangzhou Renault Lite Plastics Co., Ltd., Shanghai Blood Transfusion Technology Co., Ltd. The main drafters of this standard. Zhong Weiqin, Wang Jinhong, Liu Bin, Zeng Yongjun, Liu Wei, Tang Yanfang, Deng Mingan. Polyvinyl chloride calendered film for blood bags

1 Scope

YY/T 1617 is the material standard for the calendered PVC film from which blood bags are made. The film is not a neutral container: its plasticiser migrates into the stored blood, and in the case of DEHP that migration is what stabilises the red cell membrane and extends shelf life, while also being the reason the plasticiser is under regulatory pressure worldwide. This document specifies what the film has to be, covering composition, mechanical properties, transparency, the extractables and the biological safety, together with the test methods that verify them. Blood bags are manufactured in China in enormous volume for domestic use and export. For a bag manufacturer or a film supplier, this is the specification an incoming material certificate cites and a Chinese registration relies on. It carries Amendment 1 of 2020.

This standard specifies the technical requirements, test methods and packaging, marking, and transportation of polyvinyl chloride rolled film (hereinafter referred to as calendered film) for blood bags. Shipping and storage requirements. This standard is applicable to the use of medical polyvinyl chloride resin as the main raw material, adding a certain amount of plasticizer, stabilizer and other additives. A composite material, a calendered film produced by calendering.

Note. This calendered film is mainly used in traditional blood bag and platelet ingredient storage bags.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this article. Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 1031 Product Geometry Specifications Surface Structure Contour Surface Roughness Parameters and Their Values Determination of tensile properties of plastics - Part 3. Test conditions for film and film

GB/T 4615 Determination of residual vinyl chloride content in polyvinyl chloride resin - Gas chromatography

GB/T 6682 Analytical laboratory water specifications and test methods

GB 14232.1-2004 Human blood and blood components - Plastic containers - Part 1. Traditional blood bags

GB/T 14233.1-2008 Methods of test for infusions, blood trans

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing

YY/T 1286.1 Performance of platelet storage bags - Part 1

3 Product model

Low-temperature PVC laminated film for type A traditional blood bag Polyvinyl chloride calendered film for type B traditional blood bag Polyvinyl chloride calendered film for type C platelet bag

4 Technical requirements

4.1 Production conditions The calendered film should be produced under clean and hygienic conditions, and its purification level should not be lower than the blood bag production level.

4.2 Appearance When tested according to 5.1, the calendered film should be uniform in color, black spots, focus and fish eyes should not be greater than 1 mm, greater than

0.5 mm and less than 1 mm. The black spots, focus and fish eyes should be less than 2/10m², less than 0.5mm should be less than 5/10m², no foreign objects, the surface is flat, no Wrinkles.

4.3 Roughness When tested in accordance with 5.1.2, the inner and outer surface roughness of the calendered film shall conform to the nominal value to prevent adhesion of

the blood bag made of the calendered film.

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