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

YY/T 1989-2025

**Medical devices for human assisted reproductive technology -
Determination of sucrose, glucose, trehalose and fructose in
assisted reproduction media**

人类辅助生殖技术用医疗器械 辅助生殖用液中蔗糖、葡萄糖、海藻糖、果糖的测定

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the unit responsible for the standardization of medical devices for human assisted reproductive technology. This document was drafted by: China National Institutes for Food and Drug Control and Shenzhen Institutes for Drug Control (Shenzhen Medical Device Testing Center). Hunan Provincial Institute for Drug Control and Testing, Shandong Weigao Ruisheng Medical Device Co., Ltd., Dongyun Medical Technology (Shanghai) Co., Ltd., Zhejiang Ming Yue Medical Technology Co., Ltd., and Shenzhen Weituo Biotechnology Co., Ltd. The main drafters of this document are. Huang Yuanli, Peng Jun, Liu Bang, Ke Linan, Han Qianqian, Tian Yan, Yin Hang, Han Xiaomeng, Lin Xiaozhen, and Wang Shuhan. Zhou Shumei. Medical devices for human assisted reproductive technology Sucrose, glucose, and other substances in assisted reproductive fluids Determination of trehalose and fructose

1 Scope

YY/T 1989 is an analytical method standard for the fluids used in IVF. It describes how to determine the content of sucrose, glucose, trehalose and fructose in assisted reproduction media by high performance liquid chromatography. Those four sugars are what the medium uses to feed and protect gametes and embryos, and their concentration is a release specification rather than a formulation detail, which is why the measurement needs a single agreed method rather than each manufacturer's own. In China assisted reproduction media are regulated as medical devices, so the analysis belongs to the YY/T series rather than to a pharmacopoeia. For a manufacturer of culture, handling, vitrification or thawing media,

this is the method a Chinese testing institute will use on the batch, and the one the specification should cite.

This document describes a method for determining the content of sucrose, glucose, trehalose, and fructose in assisted reproductive fluids using high performance liquid chromatography. Method 1 in this document is applicable to assisted reproductive fluids that do not contain sucrose or trehalose; Method 2 is applicable to fluids containing sucrose, glucose, or trehalose. A fluid containing one or more fructose components for assisted reproduction.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories

YY/T 0995 Medical Devices for Human Assisted Reproductive Technology. Terminology and Definitions

3 Terms and Definitions

The terms and definitions defined in YY/T 0995 apply to this document.

4.2 Reagents and Materials

4.2.1 Water, Grade I water as specified in GB/T 6682.

4.2.2 Sulfuric acid, analytical grade.

4.2.3 Glucose reference standard ($C_6H_{12}O_6$, CAS No.. 50-99-7), purity >99%, certified by the state and granted a standard substance certificate. Quasi-substances or other certified reference materials.

4.2.4 Fructose reference standard ($C_6H_{12}O_6$, CAS No.. 57-48-7), purity >99%, certified by the state and granted a standard substance certificate. Substances or other certified standard substances.

4.2.5 Sulfosalicylic acid, analytical grade.

4.2.6 Ultrafiltration centrifuge tubes, 30kDa.

4.3 Reagent Preparation 4% sulfosalicylic acid. Weigh 4.0g of sulfosalicylic acid, dissolve it in water and make up to 100mL.