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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1964-2025

Tacrolimus testing kit

他克莫司测定试剂盒

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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. This document is published... The organization is not responsible for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center), Beijing Medical... Medical Device Evaluation and Inspection Center, Beijing Chaoyang Hospital affiliated to Capital Medical University, Shandong Yingsheng Biotechnology Co., Ltd., Shimadzu Enterprise Management (China) Co., Ltd., Beijing BGI Genomics Co., Ltd., Abbott Trading (Shanghai) Co., Ltd., Shanghai Yunze Biotechnology Co., Ltd. Limited Company. The main drafters of this document are. Li Shengmin, Sun Rong, Li Pengfei, Mi Zhaoyuan, Li Changkun, Zhang Shenyan, Wu Xiaojun, Lin Weijing, and Zhao Bingfeng. Wu Kechun. Tacrolimus Assay Kit

1 Scope

YY/T 1964 is the product standard for the tacrolimus assay kit, used to keep transplant patients inside a narrow therapeutic window for their immunosuppressant. It specifies the requirements, the marking, the labelling and the instructions for use of tacrolimus assay kits, together with the packaging, transport and storage, and describes the corresponding test methods. It applies to kits for the quantitative determination of tacrolimus. Therapeutic drug monitoring assays are held to tighter precision than most immunoassays because the clinical decision follows the number directly: too little and the graft is rejected, too much and the kidney suffers. For a manufacturer or a distributor registering a tacrolimus kit in China, this is the standard the specification and the registration testing follow.

This document specifies the requirements for tacrolimus assay kits, including labeling,

marking, instructions for use, packaging, transportation, and storage. The corresponding test method. This document applies to the quantitative determination of human whole blood using chemiluminescence immunoassay, homogeneous enzyme immunoassay, immunoturbidimetry, and liquid chromatography-tandem mass spectrometry. A reagent kit containing tacrolimus.

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 191 Pictorial Symbols for Packaging and Storage

GB/T 21415 Metrological Traceability of Calibrators and Control Substances for the Measurement of Quantities in Biological Samples of In Vitro Diagnostic Medical Devices

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and Definitions

This document does not contain any terms or definitions that need to be defined.

4 Requirements

4.1 Appearance Manufacturers should specify appropriate appearance requirements based on the packaging characteristics of their products. Generally, this should include descriptions of the components and properties of the reagent kit. The requirements for internal and external packaging, labels, etc. are clearly defined.

4.2 Traceability If the kit contains calibrators, the manufacturer shall provide information on the source, assignment process, and measurement of the calibrators in accordance with GB/T 21415 and relevant regulations. Information on uncertainties and other related topics.

4.3 Filling Quantity The liquid volume should be no less than the indicated value.

4.4 Linear Kits based on mass spectrometry principles should meet requirements a), while kits based on other principles should meet requirements b).

a) Within the range of [1.0, 30.0] ng/mL, the correlation coefficient (r) >= 0.990; within the range of [1.0, 3.0] ng/mL, the absolute linear deviation should not exceed [0.990]. For values exceeding ±

0.45 ng/mL, the relative linear deviation should not exceed ±15.0% within the range of (3.0,

30.0) ng/mL.

b) Within the range of [2.0, 30.0] ng/mL, the correlation coefficient (r) >= 0.990; within the range of [2.0, 3.0] ng/mL, the specified absolute deviation is [missing value].