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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1870-2023

General requirements of liquid chromatography-mass spectrometry testing kits

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part

1.Structure and Drafting Rules for Standardization Documents" to be drafted. Please note that some contents of this document may refer to patents. Publishing of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). This document was drafted by: Beijing Institute of Medical Device Testing, Shanghai Xuhui District Central Hospital, Food and Drug Evaluation and Inspection of Shandong Province Center, Shanghai Clinical Laboratory Center, Meikang Biotechnology Co., Ltd., Shenzhen Huada Gene Co., Ltd. The main drafters of this document. Sun Xueqing, Li Shuijun, Guo Jinshuang, Ju Yi, Shen Min, Zhang Shenyan. General requirements for liquid chromatography-mass spectrometry kits

1 Scope

YY/T 1870 sets the general requirements for in vitro diagnostic kits that measure an analyte by liquid chromatography coupled to mass spectrometry. LC-MS has moved out of the research laboratory and into routine clinical testing in China, for vitamin D, immunosuppressants, steroid hormones and newborn screening, and a kit sold for that use has to be specified like any other reagent: composition, performance, stability, labelling and the test methods that demonstrate them. Because the technique separates and identifies rather than simply reacting, the performance claims a manufacturer may make and the way they must be substantiated differ from those for an immunoassay. This document is the framework a Chinese reviewer applies to any LC-MS kit registration, and the reference an analyte-specific standard builds on.

This document specifies the requirements, test methods, labels and instructions for use of liquid chromatography-mass spectrometry detection kits, packaging, transportation and

storage. This document is applicable to kits for quantitative detection of human samples (whole blood, serum, plasma, urine, etc.) by liquid chromatography-mass spectrometry (hereinafter referred to as the kit).

Note. The kit generally includes pretreatment solution, internal standard solution, calibrator, quality control product and other related components.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 21415 Metrology traceability of measuring calibrators and control substances in biological samples of in vitro diagnostic medical devices origin

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

3 Terms and Definitions

This document does not have terms and definitions that need to be defined.

4 Requirements

4.1 Appearance Manufacturers should specify appropriate appearance requirements according to the packaging characteristics of their own products. Generally, there should be the composition and properties of each component of the kit; Requirements for packaging, clear labels, etc.

4.2 Net content The net content should not be less than the marked value.

4.3 Traceability The manufacturer shall provide the source, assignment process and measurement uncertainty of the calibration products used in accordance with GB/T 21415 and relevant regulations content.

4.4 Linearity The following requirements shall be met within the linear interval given by the manufacturer.

a) The correlation coefficient (r) should not be less than 0.9900;