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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1740.3-2024

Clinical mass spectrometer - Part 3: Inductively coupled plasma mass spectrometer

医用质谱仪 第3部分：电感耦合等离子体质谱仪

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Table of Contents

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" Drafting is required. This document is part 3 of YY/T 1740 "Medical Mass Spectrometers". YY/T 1740 has been published in the following parts.

1.Liquid chromatography-mass spectrometry;

2.Matrix-assisted laser desorption ionization time-of-flight mass spectrometry;

3.Inductively coupled plasma mass spectrometer. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Clinical Testing Laboratories and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Beijing Medical Device Inspection Institute (Beijing Medical Bioprotection Equipment Inspection and Research Center), Capital Medical University Beijing Tongren Hospital affiliated to the University of Science and Technology, Zhejiang Medical Device Evaluation Center, First Medical Center of the General Hospital of the Chinese People's Liberation Army, Shandong Yingshengsheng Biotechnology Co., Ltd., Ruilaipu (Hangzhou) Medical Technology Co., Ltd., Tianjin Guoke Medical Technology Development Co., Ltd., Beijing Yixinbo Chuangsheng Technology Co., Ltd. and Mekang Biotechnology Co., Ltd. The main drafters of this document are. Li Shengmin, Liu Xiangyi, Ye Chaofu, Duan Jinyan, Cui Wenbin, Zheng Yi, Cheng Wenbo, Ma Qingwei, Shen Min, and Zhao Bingfeng.

YY/T 1740 "Medical Mass Spectrometer" is divided into 4 parts.

1.Liquid chromatography-mass spectrometry. The purpose is to specify the requirements, test methods, Labelling, instructions for use, packaging, transportation and storage.

2.Matrix-assisted laser desorption ionization time-of-flight mass spectrometer. The purpose is to specify the medical matrix-assisted laser desorption ionization time-of-flight mass

spectrometer Performance requirements, test methods, identification, labeling and instructions, packaging, transportation and storage of time-of-flight mass spectrometers.

3.Inductively coupled plasma mass spectrometer. The purpose is to specify the performance requirements of medical inductively coupled plasma mass spectrometers, Test methods, labeling, instructions for use, packaging, transportation and storage.

4.Gas chromatograph-mass spectrometer. The purpose is to specify the performance requirements and test methods of medical gas chromatograph-mass spectrometer. Method, labeling, instructions for use, packaging, transportation and storage. Medical mass spectrometers Part 3. Inductively Coupled Plasma Mass Spectrometer

1 Scope

YY/T 1740.3 is Part 3 of the Chinese clinical mass spectrometer series, covering the inductively coupled plasma mass spectrometer. ICP-MS is the instrument clinical laboratories use for trace elements: lead, cadmium, mercury and arsenic in toxicology, selenium, zinc and copper in nutrition, and increasingly for element speciation. It is regulated here as a medical device because the result goes into a patient record, which puts the burden on detection limits, linearity across the wide dynamic range these analytes span, and the control of interferences that plague the technique. The standard sets the requirements, labelling and accompanying information with the corresponding test methods. For a manufacturer or an importer of clinical ICP-MS systems for China, this is the governing standard.

9.Electrical equipment for laboratory analysis and other purposes Special requirements for automatic and semi-automatic equipment

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

GB 4793.1 Safety requirements for electrical equipment for measurement, control and laboratory use Part

GB 4793.9 Safety requirements for electrical equipment for measurement, control and laboratory use Part

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

GB/T 18268.1 Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Mass range massrange A range between the lower and upper limits of the mass-to-charge ratio that a mass spectrometer can measure. [Source: GB/T 6041-2020, 2.4, modified]

Note. The unit is expressed in u.

3.2 Mass resolution Mass resolution is expressed as the peak width at 10% of the mass peak height of an element. [Source: JJF1159-2006, 3.2, modified]

Note. The unit is expressed in u.