ICS 11.100.10
CCS C44

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0655-2024

Replacing YY/T 0655-2008

Dry chemistry analyzer

干式化学分析仪

Issued on: February 7, 2024 **Implemented on: March 1, 2025**

Issued by: National Medical Products Administration

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. This document replaces YY/T 0655-2008 Dry Chemical Analyzer. Compared with YY/T 0655-2008, except for structural adjustment and editing, In addition to the changes in performance, the main technical changes are as follows:

--- Changed "Normal working conditions of the instrument" (see 5.1,

4.1 of the.2008 edition);

--- Changed the "accuracy" requirement (see 4.3,

4.3 of the.2008 edition);

--- Changed the "precision" requirement (see 4.4,

4.4 of the.2008 edition);

--- Changed the "linear correlation coefficient" requirements (see 4.5,

4.5 of the.2008 edition);

--- Added "electrical safety" related requirements (see 4.10,

4.10 of the.2008 edition);

--- Added "Electromagnetic compatibility requirements" (see 4.11);

--- Changed the "Accuracy" test method (see 5.3,

1 Scope

YY/T 0655 is the standard a dry chemistry analyzer has to satisfy to be registered in China. Dry chemistry instruments run clinical tests on reagent strips or slides rather than in liquid reagent, which makes them the workhorse of point-of-care testing, emergency rooms and

small laboratories. The document sets the requirements for such analyzers, the marking, labelling and instructions for use they must carry, and the packaging, transport and storage conditions, and describes the corresponding test methods. It replaces YY/T 0655-2008, so a manufacturer holding an approval obtained against the 2008 text has a revised reference to work back from. For a foreign instrument maker this is the document a Chinese registration reviewer applies to the analyzer itself, separately from the standards that govern the reagents it runs.

26.Special requirements In vitro diagnostic (IVD) medical devices

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/T 18268.26 Electromagnetic compatibility requirements for electrical equipment for measurement, control and laboratory use Part

GB/T 29791.3 Information provided by the manufacturer of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Dry chemistry The liquid sample is placed on a solid phase carrier containing reagents to react, and the concentration of specific components in the sample is quantitatively determined according to the reaction results. or activity detection methods.

3.2 Dry biochemical analyzer An analyzer designed specifically for clinical chemistry tests using solid phase carrier reagents.

6 Characteristics of laboratory material heating equipment Special requirements

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