Chinastandards.org

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

chinastandards.org - PREVIEW

YY/T 1200-2024

Glucose assay kit (enzymic method)

葡萄糖测定试剂盒（酶法）

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

Issued by: National Medical Products Administration

Preview: page 1 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-1200-2024

Chinastandards.org

Table of Contents

chinastandards.org · PREVIEW

Foreword

This document was drafted in accordance with the provisions of GB/T 1.1-2020 "Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents". This document replaces YY/T 1200-2013 "Glucose assay kit (Enzymic method)". Compared with YY/T 1200-2013, in addition to structural adjustments and editorial changes, the main technical changes are as follows: - MODIFY the requirements for regent blank absorbance (see

4.3 of this document,

4.3 of the 2013 edition); - MODIFY the requirements for linearity (see

4.4 of this document,

4.4 of the 2013 edition); - MODIFY the requirements and test methods for accuracy (see

4.5 of this document,

4.5 of the 2013 edition); - MODIFY the applicable range of analytical sensitivity (see

4.6 of this document,

4.6 of the 2013 edition); - MODIFY the requirements for repeatability (see

4.7.1 of this document,

4.7.1 of the 2013 edition); - MODIFY the requirements for batch difference (see

4.7.2 of this document,

4.7.2 of the 2013 edition). Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority of this document

Preview: page 2 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-1200-2024

shall not be held responsible for identifying any or all such patent rights. This document was proposed by National Medical Products Administration. This document shall be under the jurisdiction of National Technical Committee on Medical Clinical Laboratory and In Vitro Diagnostic System of Standardization Administration of China (SAC/TC 136). Drafting organizations of this document: China Institutes for Food and Drug Control, Beijing Jiuqiang Biotechnology Co., Ltd., Maccura Biotech Co., Ltd., Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Beijing Leadman Biochemistry Co., Ltd., Abbott Trading (Shanghai) Co., Ltd., Siemens Medical Diagnostics Products (Shanghai) Co., Ltd., BIOSINO Bio-technology & Science Co., Ltd., Roche Diagnostics Products (Shanghai) Co., Ltd. Glucose assay kit (Enzymic method)

1 Scope

YY/T 1200 is the Chinese industry standard a glucose assay kit has to meet before it can be registered and sold as an in vitro diagnostic reagent. It covers kits that measure glucose in human serum, plasma or other body fluids by enzymatic methods, and sets out how such a kit is classified, the technical requirements it has to satisfy, the test methods that demonstrate them, and the rules for labelling, instructions for use, packaging, transport and storage. Glucose is the single most ordered test in a Chinese clinical laboratory, which makes this one of the reagent standards a diagnostics manufacturer meets first when entering the market. The 2024 edition replaces the previous one and is the text an NMPA reviewer will hold a registration dossier against, so a manufacturer whose validation protocol still cites the earlier edition is working to a document that is no longer current.

This document specifies the requirements, labeling and instructions for use, packaging, transportation and storage of glucose assay kits (enzymatic method), and describes the corresponding test methods. This document applies to determination of assay kits by hexokinase method and glucose oxidase method, which are used in clinical tests to quantitatively analyze the glucose concentration in body fluids such as serum, plasma, urine, and cerebrospinal fluid.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 29791.2 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

3 Terms and definitions

For the purpose of this document, there are no terms and definitions that need to be

Preview: page 3 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-1200-2024

defined.

4 Requirements

4.1 Appearance The manufacturer shall specify appropriate appearance requirements based on the packaging characteristics of its own products, and it should have requirements for the composition and properties of each component of assay kits.

4.2 Net content The net content of liquid reagents shall not be less than the labeled amount.

4.3 Reagent blank absorbance The reagent blank absorbance shall not be greater than 0.6 (wavelength given by the manufacturer, light path

1.0 cm). NOTE: Not applicable to dry analyzer assay reagents.

4.4 Linearity The linearity shall meet the following requirements:

a) the linear range of glucose concentration shall cover: [0.6, 25.0] mmol/L;

b) the linear correlation coefficient (r) shall not be less than 0.9900;

c) in the range of [0.6 ~ 5.0] mmol/L, the absolute linear deviation shall be within the range of ±

0.50 mmol/L; in the range of (5.0~25.0] mmol/L, the relative linear deviation shall be within the range of ±10.0 %.

4.5 Accuracy Select one of the following methods for verification in the following order of priority.

a) Use recognized reference materials or certified reference materials that can be used to evaluate conventional methods as samples for determination, and the relative deviation shall be within the range of ±7.0 %.

b) The recovery rate of assay kits shall be within the range of 93.0 % ~ 107.0 %.

c) Compare with the traceable analytical system specified by the manufacturer. If it is in the range of [0.6, 25.0] mmol/L, the correlation coefficient (r) shall be no less than 0.9900, and the slope shall be within the range of [0.9, 1.1]; if the sample concentration is in the range of [0.6 ~ 5.0] mmol/L, the absolute deviation shall be within the range of ±

0.35 mmol/L; if the sample concentration is in the range of (5.0 ~ 25.0] mmol/L, the relative deviation shall be within the range of ±7.0 %. 95 % of the test samples shall meet the above requirements.

4.7 Precision

4.7.1 Repeatability The coefficient of variation (CV, %) shall not be greater than 3.0 %.

chinastandards.org : PREVIEW

Preview: page 4 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-1200-2024

4.7.2 Batch difference The batch relative range (R) shall not exceed 5.0 %.

4.8 Stability Expiration date stability and thermal stability can be verified.

a) Expiration date stability: The manufacturing enterprise shall specify the expiration date of the product. Take products within a certain period of time after the expiration date to test the reagent blank absorbance, linearity, accuracy, analytical sensitivity, and repeatability, determine whether the results meet the requirements of 4.3 ~

b) Thermal stability: Under the accelerated conditions specified by the manufacturer, test the reagent blank absorbance, linearity, accuracy, analytical sensitivity, and repeatability, determine whether the results meet the requirements of 4.3 ~

4.6 and 4.7.1. NOTE 1: Generally, when the expiration date is 1 year, select products that do not exceed 1 month, when the expiration date is half a year, select products that do not exceed half a month, and so on. However, if the specified time is exceeded, the product can be accepted if it meets the requirements. NOTE 2: Thermal stability cannot be used to derive the expiration date of the product unless a derivation formula based on a large amount of stability research data is used. NOTE 3: According to the characteristics of the product, any combination of methods

b) can be selected for verification, but the selected method can verify the stability of the product to ensure that the product performance complies with this document within the expiration date.

Chinastandards.org · PREVIEW

5 Test methods

5.1 Appearance Visually inspect with normal or corrected vision under natural light, determine whether the results meet the requirements of 4.1.

5.2 Net content Measure with a universal measuring instrument, determine whether the results meet the requirements of 4.2.

5.3 Reagent blank absorbance Use designated blank samples to test the assay kit. Different methods have different wavelengths. Using the wavelength given by the manufacturer, 1 cm light path, test 2 times in a row, and calculate the average value, which is the blank absorbance. Determine whether the results meet the requirements of 4.3.

Preview: page 5 of 5 shown, 16 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/yy-t-1200-2024