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**NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA**

**GB/Z 2640-2021**

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**Injection vials made of moulded glass**

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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 of Standardization Documents"

Drafting.

This document replaces GB/T 2640-1990 "Molded Antibiotic Glass Bottles". Compared with GB/T 2640-1990, except for structural adjustment and compilation

In addition to the editorial changes, the main technical changes are as follows.

---Change the scope of application of this document (see Chapter 1, Chapter 1 of the.1990 edition);

---The normative references have been changed (see Chapter 2, Chapter 2 of the.1990 edition);

---Added terms and definitions (see Chapter 3);

---C type bottle has been added (see Chapter 4);

---Deleted the grade of the product (see 3.2 in the.1990 edition);

--- Changed the technical requirements for sutures, stones, and bubbles (see 5.1.4, 5.1.5, 5.1.6, 5.2.3, 5.2.4, and 5.2.5 of the.1990 edition);

---Increase the linear thermal expansion coefficient, lead, cadmium, arsenic, antimony leaching amount, 121 degrees C granular water resistance and borosilicate glass molded injection bottle three

Diboron oxide content, 98°C granular method water resistance, acid resistance, and alkali resistance requirements (see 5.2);

--- Changed the internal stress requirements (see 5.2, 5.1.4 of the.1990 edition);

---Change the limit deviation of the specification size (see 5.3, 4.1 in the.1990 edition);

---Deleted the size classification and appearance quality classification (7.1.2 of the.1990

edition);

---Added physical and chemical performance test methods (see 6.2);

---The factory inspection rules are changed (see 7.2.2, 7.1.2 of the 1990 edition);

--- Type inspection has been added (see 7.4);

---Added the lightweight index measurement method (see Appendix D).

This document uses the redrafting method to modify and adopt ISO 8362-4:2011 "Injection Containers and Accessories Part 4. Molded Injection Bottles".

Compared with ISO 8362-4:2011, this document has many adjustments in structure. Appendix A shows the difference between this document and ISO 8362-4:2011.

The chapter number comparison list.

Compared with ISO 8362-4:2011, this document has technical differences. Appendix B gives a list of corresponding technical differences and their reasons.

The following editorial changes have been made to this document.

---Revised the standard name to "Molded Injection Bottle";

---Informative Appendix C has been added.

## 1 Scope

This document specifies the terms and definitions, product classification, technical requirements, test methods, inspection rules and signs, packaging,

Transportation and storage.

This document applies to molded injection bottles for injections.

## 2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations

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 191 Packaging, Storage and Transportation Graphic Mark (GB/T 191-2008, ISO 780:1997, MOD)

GB/T 2828.1 Sampling Inspection Procedures by Attributes Part 1. Batch Inspection Sampling Plan Retrieved by Acceptance Quality Limit (AQL)

(GB/T 2828.1-2012, ISO 2859-1.1999, IDT)

GB/T 4546 Test method for internal pressure resistance of glass containers (GB/T 4546-2008, ISO 7458.2004, IDT)

GB/T 4548 The test method and classification of the water erosion resistance of the inner surface of glass containers (GB/T 4548-1995, eqvISO 4802-1. 1988)

GB/T 6579 Laboratory glass instrument thermal shock and thermal shock strength test method (GB/T 6579-2007, ISO 718. 1990, IDT)

GB/T 6580 Test method and classification of corrosion resistance of glass with boiling mixed alkali aqueous solution (GB/T 6580-1997, eqvISO 695.1991)

GB/T 6581 Flame emission or atomic absorption spectrometric method for determination of resistance to hydrochloric acid attack on glass at 100 degrees C (GB/T 6581-2007, ISO 1776.1985, MOD)

GB/T 6582 Particle test method and classification of water resistance of glass at 98 degrees C (GB/T 6582-1997, eqvISO 719.1985)

GB/T 8452 Vertical axis deviation test method for glass bottles and cans (GB/T 8452-2008, ISO 9008.1991, MOD)

GB/T 12416.2 Test method and classification of water resistance of glass particles at 121 degrees C

GB/T 15726 Test method for internal stress of glass instruments

GB/T 15728 Weight test method and classification of resistance to boiling hydrochloric acid for glass

GB/T 16920 Determination of the average linear thermal expansion coefficient of glass (GB/T 16920-2015, ISO 7991.1987, NEQ)

GB/T 28194 Determination of double-line normal thermal expansion coefficient of glass

GB/T 28209 Chemical analysis method for borosilicate glass

GB 31604.24 National Food Safety Standard Determination of Cadmium Migration in Food Contact Materials and Products

GB 31604.34 National Food Safety Standard Determination of Lead in Food Contact Materials and Products and Determination of Migration Amount

GB/T 35595 Method for determination of arsenic and antimony elution from glass containers

### **3 Terms and definitions**

The following terms and definitions apply to this document.

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