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Guidance for Classification and Application of Pharmaceutical Glass Containers

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Preface

This document is drafted according to the rules provided in GB/T 1.1-2020 Directives for Standardization—Part 1: Rules for the Structure and Drafting of Standardizing Documents.

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Introduction

Pharmaceutical glass containers are commonly-used packaging containers in direct contact with drugs. Pharmaceutical glass manufacturer may design, develop and name new products and formulate product standards according to the guidance, and pharmaceutical manufacturer may understand classification and performance of glass containers and select proper packages for different drugs in reference to the guidance.

After selection of glass containers, pharmaceutical manufacturer should sign a quality agreement with pharmaceutical glass manufacturer: content of quality audit; complete product standard, including appearance defect, geometric shape, dimensions, deviation, physical and chemical properties, principle of division of batches and acceptable quality level etc. Glass manufacturer will effectively monitor over variation of product quality, and timely notify customers of changes in process, formulation, manufacturing site and product standard as well as relevant research.

Guidance for Classification and Application of Pharmaceutical Glass Containers

1 Scope

This document provides the guidance for classification and application of pharmaceutical glass containers.

The guidance is applicable to glass containers in direct contact with drugs.

2 Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this document. For dated references, the corresponding editions of the date shall apply to this document. For undated references, the latest editions (including all amendments) shall apply to this standard.

Chinese Pharmacopoeia 2020

National Standard for Pharmaceutical Packaging Materials-2015-Determination of Coefficient of Mean Linear Thermal Expansion

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 **Pharmaceutical glass containers**

It refers to the glass containers with good chemical stability and transparency that are in direct contact with drugs and able to store drugs stably.

3.2 **Tubular glass containers**

After smelting by glass furnace into liquid glass conforming to the requirement for forming, the mixture or glass batch is drawn into glass tubes for manufacturing of tubular bottles that are put under secondary processing into glass containers of certain geometric shape. Tubular forming is a secondary forming process.

3.3 **Molded glass containers**

After the mixture is smelted by glass furnace into liquid glass conforming to the requirement for forming, forming equipments and molds of different shapes are used to make liquid glass into glass containers of certain shape. Molded forming is a primary forming process.

3.4 **Inner surface durability of glass containers**

It refers to the inner surface resistance to physical/chemical erosion of water, acid, alkali and other substances, and to temperature, pressure and other environmental factors when any content is packaged in glass containers.

3.5 **Delamination**

It refers to the 50μm- 200μm snowflake-shape (or flake-like) sheets falling from inner surface of glass containers due to interaction of the packaged content and glass containers.

3.6 **Light resistance**

It refers to glass container performance of protecting the packaged drugs from transmission of light of specific wavelength.

3.7 **Internal surface treatment**

It refers to the treatment process aimed to improve certain performance of internal surface of glass containers, such as neutralizing treatment and siliconizing.

3.8 **Outer surface treatment**

It refers to the treatment process of outer surface of glass containers aimed to improve pharmaceutical bottle strength and protect from scratching, such as the hot end coating and cold end coating of outer surface of glass containers.

3.9 **Neutralizing treatment**

It refers to sulfidizing and other treatment to reduce alkali metal ion release of glass inner surface.

3.10 **Siliconizing**

It refers to the process aimed to improve hydrophobicity or lubricating property of inner surface of glass containers, such as silicone oil (emulsion) treatment and solidifying of inner surface of glass containers.

3.11 **SiO_2 coating**

It is used to reduce migration of glass components. For instance, the plasma impulse chemical vapor deposition (PICVD) method may be used to enable plasma reaction of inner surface of glass containers and silicon-containing gas (hexamethyldisiloxane) and form SiO_2 coating of uniform density in the form of covalent bond.

3.12 **Glass chemical strengthening**

Pharmaceutical glass container is put into salt bath over 260℃ for hot dipping for hours, during which potassium ion in the salt bath and sodium ion in glass will be exchanged to form a strengthening layer that can improve mechanical strength of glass containers.

3.13 **The cold end coating**

To improve impact strength and resistance to friction and scratching of glass containers, compressed air is used to spray polymer onto outer surface of glass containers that are under low temperature after annealing, so as to form a thin coating.

3.14 **The hot end coating**

To significantly improve internal pressure strength of glass containers, chemical vapor deposition (CVD) method is used to spray coating material onto outer surface of the containers that are under

high temperature after forming.

4 Classification

4.1 General

Pharmaceutical glass containers are classified by material, performance, forming process, post-forming surface treatment and shape.

4.2 Classification by material

Pharmaceutical glass is classified by material into four types, namely quartz glass, borosilicate glass, aluminosilicate glass and soda-lime glass. Chemical composition of each glass type is not fixed and may vary within certain range. However, difference in chemical composition of the same type of glass is allowed. Refer to table 1 for chemical composition and main properties of various glass types.

Table 1 Classification of pharmaceutical glass by material

Chemical composition	Glass type			
	Quartz glass	Borosilicate glass	Aluminosilicate glass ③	Soda-lime glass
SiO_2 (%)	>99	Appr. 71～81	Appr. 72～75	Appr. 70
B_2O_3 (%)	/	≥5	/	<5
Al_2O_3 (%)	/	Appr. 2～7	Appr. 9～12	Appr. 0～4
Alkali metal oxide (Na_2O+K_2O) (%)	/	Appr. 4～12	Appr. 10～13	Appr. 12～16
Alkali earth metal oxide (CaO, MgO, BaO)	/	0～5	0～5	Appr. 12
Coefficient o f mean linear thermal expansion $\times10^{-6}/K^{-1}$ (20～300℃) ① ($10^{-6}/K^{-1}$)	<1	3.2～7.5	6.0～7.0	7.6～9.0
Hydrolytic resistance of glass grain @ 121℃	Type I	Type I	/	Type II
Note: Refer to the diboron trioxide determination method in general technical requirements 4009, part IV, Chinese Pharmacopoeia 2020.				
① Refer to the method for determination of coefficient of mean linear thermal expansion (YBB00202003-2015); ② Refer to the method for determination of hydrolytic resistance of glass grain under 121℃ in general technical requirements 4001, part IV, Chinese Pharmacopoeia 2020. ③ Aluminosilicate glass is generally used after chemical strengthening process.				

4.3 Classification by performance

4.3.1 Classification by hydrolytic resistance of glass inner surface

Pharmaceutical glass is classified by hydrolytic resistance of inner surface into category 1 glass, category II glass and category III glass, as listed in table 2.

Table 2 Classification of hydrolytic resistance of pharmaceutical glass containers

Glass type	Hydrolytic resistance of inner surface①
Category I glass	High hydrolytic resistance
Category II glass	High hydrolytic resistance after neutralizing treatment
Category III glass	Medium hydrolytic resistance without neutralizing treatment
① Refer to the method for determination of inner surface hydrolytic resistance in general technical requirements 4006, part IV, Chinese Pharmacopoeia 2020 for specific value of hydrolytic resistance of inner surface.	

4.3.2 Classification by light resistance

Pharmaceutical glass containers are classified into two types, namely colorless type and colored type. Colored glass, such as brown glass, has light resistance.

4.4 Classification by forming process

Pharmaceutical glass containers are classified into tubular bottle and molded bottle by the forming process.

Tubular pharmaceutical glass containers include tubular injection bottle (penicillin bottle), ampoule, pen-injector sleeve (card bottle), prefilled syringe, tubular oral liquid bottle and tubular vial.

Molded pharmaceutical glass containers include infusion bottle, injection bottle (penicillin bottle) and vial.

4.5 Classification by post-forming surface treatment

Pharmaceutical glass containers that are put under surface treatment after forming for performance improvement include glass containers of neutralizing treatment, siliconizing, SiO_2 coating, chemical strengthening, cold end coating and hot end coating.

4.6 Classification by shape

Pharmaceutical glass containers are classified by shape into ampoule, injection bottle (penicillin bottle), infusion bottle, prefilled syringe, pen-injector sleeve (card bottle), tubular oral liquid bottle and vial.

5 Guide of Application

5.1 Application and characteristics of pharmaceutical glass containers of different types

Pharmaceutical glass containers of various types have different characteristics and certain

difference in application. Main characteristics and application of glass containers of different types are listed in tables 3-8.

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