**5106 General Chapter on Pharmaceutical Glass Bottles**

**1 Scope**

This general chapter specifies the classification and requirements for pharmaceutical glass bottles.

This general chapter is applicable to pharmaceutical glass bottles containing oral or topical drugs.

**2 Classification**

Pharmaceutical glass bottles can be mainly classified in terms of glass material, forming process and color.

——in terms of glass material, it can be classified as soda-lime-silica glass bottles and borosilicate glass bottles.

——in terms of forming process, it can be classified as tubular glass bottles and molded glass bottles.

——in terms of color, it can be classified as colorless glass bottles and amber glass bottles.

**3 Requirements**

The quality of glass pharmaceutical bottles shall comply with General Chapters on Glass Containers for Pharmaceutical Packaging (General Chapters 5100) and meet the following requirements.

**3.1 Appearance**

It is used to control the appearance quality of pharmaceutical glass bottles. Carry out visual inspection by naked eyes under natural and bright light. The appearance quality shall meet the enterprise specification or quality agreements.

**3.2 Thermal Shock resistant (for molded pharmaceutical bottles)**

It is used to control the thermal stability of molded pharmaceutical bottles to prevent product breakage due to thermal shock in use. According to the Determination of Thermal Shock and Thermal Shock Endurance for Glass Containers (General Chapter 4019), soda-lime-silica glass shall not break when undertaking thermal shock test for temperature difference of 42℃ Borosilicate glass shall not break when undertaking thermal shock test for temperature difference of 60℃.

**3.3 Internal stress**

It is used to control the residual internal stress of glass after annealing, and to prevent the mechanical strength of pharmaceutical glass bottles from decreasing due to the internal stress during production and use. According to the Determination of Internal Stress for Glass Containers (General Chapter 4003). The optical path difference caused by the maximum permanent stress after annealing shall not exceed 40nm/mm.

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