**5103 General Chapter on Glass Bottles for Injection**

**1 Scope**

This General Chapter specifies the classification and requirements for glass injection bottles.

This General Chapter is applicable to glass bottles containing small volume injection, sterile powder for injection (including freeze-dried) and concentrated solution for injection (commonly known as vials).

**2 Classification**

Glass injection vials can be classified in terms of material, color and forming process.

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

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

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

**3 Requirements**

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

3.1 **Appearance**

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

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

It is used to control the thermal stability of molded injection 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 pressure resistance (for molded injection bottles)**

It is used to control the internal pressure resistance of injection glass bottles to prevent the containers from breaking due to the increase of internal pressure during production and use. According to the Determination of Internal Pressure Resistance for Glass Containers (General Chapter 4017), it shall not break under 0.6 MPa internal pressure test.

3.4 **Internal stress**

It is used to control the residual internal stress of injection glass bottles after annealing and reduce the influence of internal stress on the mechanical strength of the product. 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 40 nm/mm.

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