**5102 General Chapter on Glass Ampoules**

**1 Scope**

This General chapter specifies the classification and requirements for glass ampoules.

This general chapter is applicable to glass ampoules containing injections.

**2 Classification**

Glass ampoules are made of borosilicate glass and can be classified in terms of the color of the glass and the easy-breaking ways of ampoules.

—— In terms of color, it can be classified as colorless glass ampoules and amber glass ampoules.

—— In terms of easy-breaking way, it can be classified as easy-breaking glass ampoules with dots and easy-breaking glass ampoules with chromatic circle.

**3 Requirements**

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

**3.1 Appearance**

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

**3.2 Internal stress**

It is used to control the residual internal stress of glass ampoule after annealing and reduce the influence of internal stress on the mechanical strength of the product. According to 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.

**3.3 Breaking force**

It is used to control the easy-breaking property of glass ampoules. According to the Determination of Breaking Force for Glass Ampoules (General Chapter 4018), the range of breaking force should be within the level specified in Table 1.

Table 1 Breaking Force of Glass Ampoules

|  |  |  |
| --- | --- | --- |
| Size (ml) | Breaking Force (N) | |
| Minimum | Maximum |
| 1 | 25 | 80 |
| 2 |
| 3 |
| 5 |
| 10 | 90 |
| 20 | 100 |
| 25 |
| 30 |

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