**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 |

起草单位：中国医药包装协会 联系电话： 010-62267215

参与单位：中国食品药品检定研究院、浙江省药品化妆品审评中心、山东省医疗器械和药品包装检验研究院、天津市药品检验研究院、国家食品药品监督管理局药品包装材料科研检验中心、山西省检验检测中心、江苏省医疗器械检验所、江苏省药品监督管理局审核查验中心、苏州工业园区汇毓医药包装研究院、山东省药用玻璃股份有限公司、双峰格雷斯海姆医药玻璃（丹阳）有限公司、山东力诺特种玻璃股份有限公司、康宁药用玻璃有限公司、重庆正川医药包装材料股份有限公司、宁波正力药品包装有限公司、成都平原尼普洛药业包装有限公司、肖特药品包装（浙江）有限公司、沧州四星玻璃股份有限公司、肖特玻管（浙江）有限公司、欧璧医药包装科技（中国）有限公司、湛江圣华玻璃容器有限公司、尼普洛医药包装容器（上海）有限公司、山东威高普瑞医药包装有限公司