**5101 General Chapter on Infusion Glass Bottles**

**1 Scope**

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

This General Chapter is applicable to infusion glass bottles of large volume.

**2 Classification**

Infusion glass bottles can be classified in terms of glass material and glass color .

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

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

**3 Requirements**

The quality of infusion glass bottles 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 ensure the appearance quality of infusion glass bottles. Carry out visual inspection by naked eyes under natural and bright light. The appearance quality should meet the enterprise specification or quality agreements.

**3.2 Thermal shock resistance**

It is used to control the thermal stability of infusion glass 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-silicate glass infusion bottles should not break when undertaking thermal shock test for temperature difference of 42℃; borosilicate glass infusion bottles should not break when undertaking thermal shock test for temperature difference of 60℃.

**3.3 Internal pressure resistance**

It is used to control the internal pressure resistance of infusion glass bottles to prevent the bottles from breakage 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 after 0.6 MPa internal pressure test.

**3.4 Internal stress**

It is used to control the residual internal stress of infusion glass bottles 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 maximum optical path difference caused by permanent stress shall not exceed 40 nm/mm after annealing process.

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