**5104 General Chapter on Glass Barrel for Prefilled Syringes**

**1 Scope**

This general chapter specifies the classification and requirements for glass barrel for prefilled syringes.

This general chapter is applicable to glass barrel for prefilled syringes containing injections.

**2 Classification**

Glass barrels for prefilled syringes are normally made of borosilicate glass, and have two forms: with staked needle or with luer cone.

**3 Requirements**

The quality of glass barrel for prefilled syringes 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 barrel for prefilled syringes. 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 Internal stress**

It is used to control the residual internal stress of glass barrels for prefilled syringe 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 40nm/mm.

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