5510 General Chapter of Prefilled Syringes

1 Scope

This general chapter specifies the application requirements and product quality requirements for prefilled syringes.

This general chapter applies to sterile prefilled syringes for pharmaceutical packaging that are packaged in nest tubes. Non-sterile prefilled syringes for pharmaceutical packaging can refer to this general chapter.

2 Terms and definitions

Prefilled syringes

A container system used for filling the injectable product ready for injection, the components of which include subassembled prefilled syringe, plunger stopper, plunger rod, and booster (if any).

3 Requirements

3.1 Application requirements

Drug product manufacturers shall select and use appropriate prefilled syringes based on risk assessment to ensure the quality and safety of drug products.

3.1.1 Special focus shall be given to the critical dimensions of each component to avoid affecting the fit between the components and the sealability of the container system.

3.1.2 Special focus shall be given to the impact of silicone oil and residual tungsten in glass barrels.

3.1.3 For products using terminal sterilization process, special focus shall be given to the impact of the sterilization process on each component of the prefilled syringes.

3.1.4 Special focus shall be given to the impact of the unpacking process on the drug manufacturing environment.

3.1.5 The evaluation shall be carried out by selecting appropriate methods (e.g., physical, microbiological) according to the Guideline on Integrity of Packages Intended for Sterile Pharmaceutical Products (Guideline 9650).

3.1.6 Special focus shall be given to the accuracy of all graduation marks or indicator lines (e.g. preprinted or label) on the barrels for their intended use.

3.1.7 If the product is intended to be used in combination with preattached, copackaged or label referenced device and equipment, the drug manufacturer shall ensure that the whole combination product, including the connection system, is safe and usable.

3.1.8 Special focus shall be given to the impact of drugs on the expected performance of prefilled syringes, such as the smoothness and effectiveness of drug delivery for high-viscosity drugs.

3.2 Biological evaluation

The biological safety of prefilled syringes shall be evaluated according to the Guideline on Biological Evaluation and Test Selection of Pharmaceutical Packaging Materials and Containers (Guideline 9651).

3.3 Component and material requirements

The subassembled prefilled syringe shall comply with General Chapter of Subassembled Prefilled Syringes (General Chapter 5511), and the plunger stopper shall

comply with Section 5 of General Chapter of Rubber Closures for Pharmaceutical Packages (General Chapter 5200), as well as the requirements for particulate matter, bioburden, sterility, bacterial endotoxin or pyrogenicity in General Chapter of Rubber Closures for Packages for Injections (General Chapter 5201), when applicable.

4 Product quality control

With the purpose of ensuring the controllable quality of drugs, meeting clinical needs and safety in use, manufacturers and users of the prefilled syringes shall choose appropriate quality control items according to the real situation of production and use, and develop the enterprise specification or quality agreements. In addition to meeting the requirements for components and materials in 3.3, the prefilled syringes shall also meet the following requirements.

4.1 Compatibility between plunger stopper and plunger rod

Install the plunger rod into or onto the plunger stopper, fully insert the plunger stopper into the prefilled syringe filled with half of labelled quantity of water, expel the air, attach the protective cap, and slowly withdraw back about 3 mm. The plunger rod shall remain stable and not separate from the plunger stopper.

4.2 Sealability between plunger stopper and plunger rod

Test according to the Examination Method of Sealability for Components of Prefilled Syringes (General Chapter 4041, method 2), there shall be no liquid leakage through the plunger stopper.

4.3 Gliding properties

Install the plunger rod and plunger stopper into the syringe barrel, then fix the syringe barrel on the tensile testing machine. Push the plunger rod at a speed of 100mm/min±5mm/min or other suitable speed, the initial gliding force and the average gliding force shall comply with the enterprise specification or quality agreements.

4.4 Residual volume

Take a suitable number of the products, weigh the mass of the empty prefilled syringe using a balance with an accuracy of 0.1mg (W_0), inhale the labelled quantity of water with a temperature of 20□±5□, carefully expel all the air bubbles, wipe dry the outer surface of the prefilled syringe, and push the plunger stopper to remove the water (without draining the liquid in the needle or cone). Re-weigh the prefilled syringe (W_1), W_1-W_0 is the residual volume, which shall comply with the enterprise specification or quality agreements.

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