5202 General Chapter of Rubber Closures for Packages for Oral Preparations

1 Scope

This general chapter specifies the baseline requirements shall be complied with during the manufacturing and application of rubber closures for packages for oral preparations.

This general chapter is applicable to the rubber closures used as part of packaging systems for oral preparations.

2 Classification

According to General Chapter of Rubber Closures for Pharmaceutical Packages (General Chapter 5200), rubber closures for packages for oral preparations may be classified in terms of base material, overall structure, and pretreatment.

3 Overall Requirements

Rubber closures for packages for oral preparations shall comply with the following requirements during the periods of manufacturing and use.

Rubber closures for packages for oral preparations shall comply with the relevant provisions specified in Overall Requirements of General Chapter of Rubber Closures for Pharmaceutical Packages (General Chapter 5200).

For the design of rubber closures for packages for oral preparations, the possible effects of the formulations and processes on the sense of smell and taste should be taken into account.

4 Quality Control

For rubber closures for packages for oral preparations, the relevant tests specified in Quality Control of General Chapter of Rubber Closures for Pharmaceutical Packages (General Chapter 5200) and the following tests shall be performed.

4.1 Functional Tests

4.1.1 Sealability of closures for containers. Applied to rubber closures to be secured with fasteners, and need to be performed only after rubber closures being fitted with other assembly components. Place 10 rubber closures in a beaker, add water and boil for 5 min.Take out and dry the rubber closures at 70°C for 1 hour for later use. Fill each

of 10 matched containers for oral preparations to the nominal volume with water, then fit the above rubber closures and secure with the matched fasteners. Immerse the above test samples bottom end up in 0.1% methylene blue solution in a container with a vacuum pump, reduce the pressure by 27kPa and hold for 30 min, then restore to atmospheric pressure and hold for another 30 min. Take the test samples out, rinse the outsides of the containers with water. Any trace of methylene blue solution is observed in none of the containers. If direct observation is impossible, the solution may be taken out by a suitable method and inspected visually. The solution doesn't appear blue.

4.2 Other Tests

4.2.1 Microbial limit. Applied to the wash-free rubber closures. When necessary, perform the corresponding tests according to Guideline on Microbiological Testing of Pharmaceutical Packaging Materials (Guideline 9653).The results shall comply with the relevant specifications of enterprise standards or quality agreements.

5 Packaging and Storage

The packaging materials in direct contact with rubber closures shall comply with the relevant requirements of pharmaceutical packages. The sealed packages shall be of enough integrity, and the primary and secondary packaging as a whole should meet the requirements for protection performance during the transportation and storage.

The rubber closures should be stored in the dry, clean and well-ventilated indoor environment.

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