**4020 Determination of Vertical Axis Deviation and Circular Runout for Glass Containers**

Vertical axis deviation refers to the half of the diameter of the circle made by the center of the bottle mouth around the central axis of the bottle bottom while the bottle rotated around the central axis of the bottle bottom. It is the horizontal deviation from the center of the bottle mouth to the vertical line through the center of the bottle bottom. Circular runout refers to the maximum variation in the outer diameter while a glass ampoule rotates a single revolution around the central axis of the bottle bottom.

This method applies for the determination of vertical axis deviation for glass containers for pharmaceutical use with round shape or the bottom axis of the bottle bottom can fixed, or the determination of circular runout of glass ampoules.

**Instruments:** The technical requirements that the vertical axis deviation tester or circular runout tester shall meet: it shall ensure that while the bottle bottom of the sample is placed horizontally, the horizontal distance between the center of the bottle mouth of sample and the center of the bottle bottom of the sample can be measured. There shall be means or equipment to fix the bottle bottom or ensure that the bottle bottom is in contact with the horizontal surface. There shall also be a baseplate or reliable means to rotate the bottle, to ensure that the axis of the bottle bottom always remains stable while the bottle is rotating. There shall be columns of enough height and parallel to the axis of the bottle bottom. The column shall be able to be fitted with a measuring device (such as displacement sensor, scale, dial gauge, or reading microscope). The measuring device shall be in contact with the outer edge of the bottle mouth. There shall be a contact plane parallel to the outer edge of the bottle mouth to ensure enough contact as the axis of the bottle mouth rotates.

**Determination:** Clamp the bottom of the sample bottle securely onto the rotating disk of the horizontal stage. In determining the vertical axis deviation, make the bottle mouth contact with the measuring device and rotate the sample 360° to read the maximum and minimum values, or read the vertical axis deviation value directly. In determining the circular runout, make the measuring point (apart from the bottle mouth about 3mm) contact with the measuring device, and rotate the sample 360° to read ~~and~~ the maximum and minimum values. If a V-shaped seat used for measurement, place the sample closely to the inside of the V slot to hold it in place. Then rotate the bottle 360° to read the maximum and minimum values, or read the result of circular runout directly.

**Result Calculation and Representation**

The result of vertical axis deviation is expressed as half of the difference between the maximum and minimum values read in the above determination.

The result of circular runout is expressed as the difference between the maximum and minimum values read in the above determination.

The accuracy of the measurement shall not be less than 0.1 mm.

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