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PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

YBB 00272004-2015

**Test for Insoluble Particulate Matter of Packaging
Materials**

包装材料不溶性微粒测定法

Test for Insoluble Particulate Matter of Packaging Materials

This standard applies to the determination of the size and number of insoluble particles in pharmaceutical rubber stoppers, infusion bottles, infusion bags and inner-caps of plastic infusion containers.

This method includes the photoresist method and the microscopic count method. Unless specified otherwise, the method for determination is generally the photoresist method; when the test results of the photoresist method do not comply with the provisions, it shall use the microscopic count method for retest, and use the test results of the microscopic count method as the judging criteria.

Method I -- The photoresist method

[Principle] When particles in liquid pass through a narrow and small testing area, the incident light perpendicular to fluid direction weakens because of the blockage of particulate matter; the signal output by the sensor becomes weaker; such signal change is in direct ratio to the cross section of the particulate matter. The photoresist method for the test of insoluble particulate matter is based on this principle.

[General requirements for apparatus] The apparatus generally includes three parts -- sampler, sensor and data processor. The measured particle size range is 2 ~ 100 μm ; the test particle concentration is 0 ~ 10 000 piece/mL.

[Test environment and testing] As specified in Chinese Pharmacopoeia 2015 Edition, Part 4, General Rule 0903.

[Calibration and verification of apparatus] As specified in Chinese Pharmacopoeia 2015 Edition, Part 4, General Rule 0903.

[Method for determination]

(1) Pharmaceutical rubber stoppers: unless specified otherwise, take several rubber stoppers to be tested (of a total surface area about 100 cm^2); place into a 250 mL conical flask; add an appropriate amount of particulate matter test water (the ratio of the milliliters of particulate matter test water to the square centimeters of the total area of rubber stoppers to be tested is 1:1); use aluminum foil (or other appropriate sealing materials) to cover the opening of the conical flask; place in the oscillator (rotating horizontally and circularly, in a diameter of 12 mm $\pm$ 1 mm, at an oscillation frequency of 300 r/min $\pm$ 10 r/min) for oscillating for 20 s. Carefully remove the aluminum foil (or other appropriate

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