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National Drugs Packing Containers (Materials) Standards

YBB 00212005-2015

PVC Sheet for Solid Preparation

聚氯乙烯固体药用硬片

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PVC Sheet for Solid Preparation

This Standard applies to solid preparation that takes polyvinyl chloride (PVC) resin as main raw material, used for blister packaging of solid pharmaceuticals (tablets, capsules, etc.).

[Appearance] Take an appropriate amount of this product. Place at a bright place under natural light. Visually inspect it. It shall be in uniform color, without bumps, oil stains, foreign material, perforation, impurities. In per 100 cm², the crystal points of 1.3 mm and less than 1.3 mm must not exceed 3. There must be no crystal points over 1.3 mm.

[Identification] (1) IR* Take an appropriate amount of this product; determine according to the Fourth Method of Packaging materials - Infrared spectroscopy (YBB 00262004-2015) and it shall be consistent with the control map.

(2) Density Take about 2 g of this product. Determine according to Density measurement method (YBB 00132003-2015) and it shall be 1.35 ~ 1.45 g/cm³.

[Physical performance] Water vapor permeation Take an appropriate amount of this product. Determine according to the First Method test conditions of Water vapor transmission measurement method (YBB 00092003-2015) or the Second Method (test temperature of 23°C ± 0.5°C, relative humidity of 90% ± 2%) or the Fourth Method (test temperature of 23°C ± 0.5°C, relative humidity of 90% ± 2%). It must not exceed 2.5 g/(m² • 24h).

Oxygen permeation Take an appropriate amount of this product. Determine according to the First Method of Gas permeation measurement method (YBB 00082003-2015). It must not exceed 30 cm³ / (m² • 24 h • 0.1 MPa).

Tensile strength Take an appropriate amount of this product. Determine according to Tensile performance measurement method (YBB 00112003-2015). Test speed (without load) is 100 mm/min ± 10 mm/min. Sample is Type I. The average of longitudinal, transverse tensile strength must not be less than 44 MPa.

Impact resistance Take an appropriate amount of this product. Extract 150mm x 50mm test piece, 5 pieces in total vertically and horizontally. Place the sample at a temperature of 23°C ± 2°C and relative humidity of 50% ± 5% for over 4 hours. Carry out the test under the above conditions. Fix the sample on the falling ball impact testing machine of which the span is 100 mm. Select the steel ball and drop height according to Table 1 to make the ball free fall in the central part of the span. It is not allowed to have more than two pieces of damage at the vertical and horizontal directions.

Table 1 -- Selection of steel ball and drop height

mm

Sample thickness	Drop height	Steel ball diameter
0.20 ~ 0.30	600	25 (60 g ± 6 g)
0.31 ~ 0.40	600	28.6 (100 g ± 10 g)

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