

YBB 00072005-2015

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NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

YBB 00072005-2015

LDPE Films and Pouches for Pharmaceutical Packaging

药用低密度聚乙烯膜、袋

LDPE Films and Pouches for Pharmaceutical Packaging

This Standard is applicable to pharmaceutical films produced by casting and blowing methods with low-density polyethylene resin (LDPE) as the main raw material, and pouches made by heat sealing the films. This product is applicable to the packaging of non-sterile solid active pharmaceutical ingredient.

[Appearance] Take an appropriate amount of this product and look directly at it in a bright place with natural light. The surface shall be smooth, uniform in color, and free of perforations, foreign objects, odors, and adhesions. The heat-sealed part of the pouches shall be smooth and free of false seals.

[Identification] * **(1) Infrared spectroscopy:** Take an appropriate amount of this product and measure it according to the fourth method of infrared spectroscopy determination method for packaging materials (YBB00262004-2015). It shall be basically consistent with the reference spectrum.

(2) Density Take about 2g of this product; use absolute ethanol as the immersion solution; and measure it according to the density measurement method (YBB00132003-015). The density of this product should be 0.910~0.935 g/cm³.

[Barrier performance] Water vapor transmission rate: Take an appropriate amount of this product; and measure it according to the first method experimental condition B of the water vapor transmission rate measurement method (YBB00092003-2015), and it shall not exceed 15g/ (m²•24 h).

Oxygen gas transmission rate: Take an appropriate amount of this product and measure it according to the first or second method of the gas transmission rate measurement method (YBB00082003-2015), and it shall not exceed 4000cm³/ (m²•24h•0.1MPa).

[Mechanical properties] Tensile strength: Take an appropriate amount of this product; and measure it according to the tensile property determination method (YBB00112003-2015). The test speed (no-load): 300mm/min±30mm/min, and the specimen is Type-I. The average longitudinal and transverse tensile strength shall be no less than 10MPa.

Elongation at break: Take an appropriate amount of this product; and measure it according to the tensile property determination method (YBB00112003-2015). The test speed (no-load) is 300mm/min±30mm/min, and the specimen is Type-I. For films with a thickness less than or equal to 0.05mm, the average longitudinal and transverse elongation at break shall be no less than 130%; for films with a thickness greater than

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