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YB

PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

YBB 00172002-2015

**Laminated film and pouches (PET/Al/PE) for
pharmaceutical packaging**

聚酯/铝/聚乙烯药用复合膜、袋

Laminated film and pouches (PET/Al/PE) for pharmaceutical packaging

This product refers to the films as composited of polyester (PET), aluminum (Al) and polyethylene (PE) by a binder, as well as the pouches made by heat-sealing the above films.

This standard applies to composite films and pouches for packaging of solid pharmaceutical.

[Appearance] Take appropriate amount of this product. Use the method under the appearance item of the General rules for composite films and pouches (YBB 00132002-2015). It shall comply with the requirements.

[Identification] Take appropriate amount of this product. Use the method 4 of the Determination of packaging materials by infrared spectroscopy (YBB 00262004-2015) to make determination. The PET and PE layers shall be basically consistent with the control map, respectively.

[Barrier performance] The amount of permeated water vapor: Take appropriate amount of this product. Use the method 1, 2, or 4 of the Determination of permeated water vapor (YBB 00092003-2015) to make determination. During the test, allow the PE layer to face the lower-humidity side. The test temperature is $38\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$. The relative humidity is $90\% \pm 5\%$. It shall not exceed $0.5\text{ g} / (\text{m}^2 \cdot 24\text{ h})$.

The amount of permeated oxygen: Take the appropriate amount of this product. Use the method 1 or 2 of the Determination of the amount of permeated gas (YBB 00082003-2015) to make determination. During the test, allow the PE layer to face the low-pressure side of oxygen. It shall not exceed $0.5\text{ cm}^3 / (\text{m}^2 \cdot 24\text{ h} \cdot 0.1\text{ MPa})$.

[Mechanical properties] Peel strength of PE layer and Al layer: Use the method under the peel strength item of inner layer and sub-inner layer of the General rules for medicinal composite films and pouches (YBB 00132002-2015) to make determination. The average values of longitudinal and transverse peel strength shall not be lower than $2.5\text{ N}/15\text{ mm}$.

[Heat bonding strength] (film) Cut 4 test pieces of $100\text{ mm} \times 100\text{ mm}$. Stack the PE sides of any two test pieces. Put it on the heat sealer to heat-bond it. The heat-sealing temperature is $150 \sim 170\text{ }^{\circ}\text{C}$. The pressure is $0.2 \sim 0.3\text{ MPa}$. The time is 1 second. Use the method of the Determination of heat bonding

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