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PETROCHEMICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

YBB 00242002-2015

PA/AL/PVC cold-formed foil for solid preparation

聚酰胺/铝/聚氯乙烯冷冲压成型固体药用复合硬片

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PA/AL/PVC cold-formed foil for solid preparation

This standard applies to the composite film using the polyvinyl chloride (PVC), aluminum foil (Al), and polyamide (PA) by the adhesive through compositing operation. It is applicable to the cold stamping molding blister packaging for solid pharmaceutical (tablets, capsules, etc.).

[Appearance] TAKE appropriate amount of this product; CONDUCT visual inspection against it in bright natural light. It shall be free from perforations, foreign body, odor, adhesion, composite layer separation and significant damage, bubbles, wrinkles, dirt or other defects.

[Identification] Infrared spectrum: TAKE appropriate amount of this product; FOLLOW the method 4 of the packaging material infrared spectrum determination method (YBB00262004-2015) to determine it; AND the PA layer and the PVC layer shall be basically in consistent with the control map.

[Physical performance] Water vapor permeation amount: TAKE appropriate amount of this product. FOLLOW the method 1 test condition B OR the method 2 test condition B OR the method 4 test condition 2 of the water vapor permeation determination method (YBB00092003-2015) to determine it. During the test, LET the PVC face to the low humidity side, which shall not exceed $0.5 \text{ g}/(\text{m}^2 \cdot 24\text{h})$.

Oxygen permeation amount: TAKE appropriate amount of this product. FOLLOW the method 1 OR the method 2 of the air permeation determination method (YBB00082003-2015) to determine it. During the test, LET the PVC face to the oxygen low pressure side, which shall not exceed $0.5 \text{ cm}^3/(\text{m}^2 \cdot 24\text{h} \cdot 0.1 \text{ MPa})$.

Peel strength: TAKE appropriate amount of this product; MAKE determination in accordance with the peel strength determination method (YBB00102003-2015). The peel strength between the PA layer and the Al layer shall be not less than 8.0 N/15 mm; AND the peel strength between the Al layer and the PVC layer shall be not less than 7.0 N/15 mm. (If the composite layer cannot be peeled off OR otherwise if the composite layer breaks, the peel strength is qualified).

Heat sealing strength: TAKE appropriate amount of this product; CUT 2 small pieces of 100 mm x 100 mm; OVERLAP the PVC side with the same size aluminum foil for medical use (YBB00152002-2015); MAKE it subjected to heat sealing on the heat sealing instrument, at the heat sealing temperature of $155 \text{ }^\circ\text{C} \pm 5 \text{ }^\circ\text{C}$ and the pressure of 0.2 MPa, for 1 second. CUT a 15 mm width sample from the heat sealing part; TAKE the middle 3 strips for test. FOLLOW the heat sealing strength determination method (YBB00122003-2015) to determine it, AND the mean value of the heat sealing strength of the 6 samples shall be not less than 6.0 N/15 mm.

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