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Aluminium Foils for Medicine

药用铝箔

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Aluminium Foils for Medicine

This Standard applies to aluminium foils for solid medicine (including tablets and capsules), which are adhered to the rigid sheets made of polyvinyl chloride (PVC), polyvinylidene chloride (PVDC) or other materials. The coating of this product consists of a protective layer and an adhesive layer.

[Appearance]

Take an appropriate amount of this product (2 m each roll); use front view to carry out visual inspection under sufficient natural light. The surface shall be clean, smooth and uniform in coating; the print of words and patterns shall be correct, clear and fast.

[Pinhole degree]

Take 10 test specimens of 400 mm in length and 250 mm in width (when the width is less than 250 mm, take the width of roll); place one by one on pinhole inspection table (of 800 mm × 600 mm × 300 mm or wooden case of an appropriate volume. A fluorescent lamp of 30 W is installed inside of wooden case; one glass pane is placed on wooden case; glass pane is lined with black paper and reserved with space of 400 mm × 250 mm for the inspection of the pinholes of specimens); inspect their pinholes in the dark. Pinholes shall not be dense, continuous or periodical: within each square meter, pinholes of diameter greater than 0.3 mm are not allowed; the number of pinholes of diameter 0.1 ~ 0.3 mm shall not be greater than 1.

[Barrier performance]

Water vapor transmission is determined in accordance with test condition B of the first method, or test condition B of the second method, or test condition 2 of the fourth method as specified in the method for the determination of water vapor transmission (YBB00092003-2015). During test, apply heat seal on the side of lower humidity, not exceeding 0.5 g/(m^2·24 h).

[Welding strength of adhesive layer]

Take 2 pieces of this product of 100 mm × 100 mm; take 2 pieces of PVC rigid sheet for solid medicine (as required by YBB00212005-2015) or 2 pieces of PVC/PVDC composite rigid sheet for solid medicine (as required by YBB00222005-2015). Make the adhesive layer of test specimens face the PVC side (or the PVDC side PVC/PVDC composite rigid sheet) for lamination; place on heat seal tester. The conditions for welding include: temperature 155°C ± 5°C; pressure 0.2 MPa; duration 1 s. Take out and allow to cool after welding; cut into test specimens of 15 mm in width; take 2 test specimens in the middle; carry out determination in accordance with the method for the determination of welding strength (YBB00122003-2015) (test speed 200 mm/min ± 20 mm/min); fix PVC (PVDC) specimens to the upper clamp of tester and aluminium foils to the lower clamp of tester; start tensile tester for peeling in the direction of 180°. The mean value of welding strength shall not be lower than 7.0 N/15 mm (for PVC) or 6.0 N/ 15 mm (for PVDC).

[Adhesion of protective layer]

Chinese Pharmacopoeia 2015). The content of heavy metals shall not be greater than 0.25 millionth.

[Microbial limit]

Take specimens of this product and use sterilized metal template of opening area 20 cm^2 to press on the inner face; use sodium chloride injection to moisten sterilized cotton swab; wipe for 5 times within the template opening; use a new swab to wipe for 5 times (use 2 swabs to wipe each location for 10 times, altogether 10 locations, 100 cm^2). Cut off (or burn off) each swab after wiping; throw them into conical flask (big test tube) containing 30 mL of sodium chloride injection. After throwing all swabs into flask, immediately shake flask for 1 min and then obtain test solution. After thin-layer filtration of test solution, carry out testing by law (general rules 1105 and 1106 of the fourth edition of Chinese Pharmacopoeia 2015). The bacterial count shall not be greater than 1000 cfu/100 cm^2; the count of mould and yeast shall not be greater than 100 cfu/100 cm^2; escherichia coli shall not be detectable.

[Abnormal toxicity] *

Take 500 cm^2 of the inner surface of this product to cut into small pieces of 3 cm × 0.3 cm; add 50 mL of sodium chloride injection; place into high pressure steam sterilizer; maintain at 110°C for 30 min before taking out; cool for standby; carry out intravenous injection; carry out testing by law (general rule 1141 of the fourth edition of Chinese Pharmacopoeia 2015). They shall be as required.

[Storage]

Inner packages shall be pharmaceutical low-density polyethylene bags; they shall be stored in a clean, ventilated storeroom.

Annex

Inspection rules

1. Product inspection is classified into complete inspection and partial inspection.

2. In case of any of the following cases, complete inspection shall be carried out as required by this Standard.

(1) Product registration;

(2) Production is resumed after a significant product quality accident.

(3) Selective inspection of a supervision body;

(4) Production is resumed after a production halt.

3. If the manufacturer or user of pharmaceutical packaging materials does not change the original places of raw materials, additives and production process after a product is approved and registered, all items of inspection except those marked with "*****" may be carried out as required by this Standard.

NOTE Inspection for those items marked with "*****" shall be carried out once each half year at least.

4. See Table 1 for the dimensions and tolerances.

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