

Translated English of Chinese Standard: YBB2027-2012

www.ChineseStandard.net

Email: Sales@ChineseStandard.net

**State Food and Drug Administration
of the People's Republic of China**

**Direct contact with drug's
packaging materials and containers standard**

National Institutes for Food and Drug Control
Packaging Materials and Pharmaceutical Excipients Inspection Institute
December 2012

PA/Al/PVC Cold-formed Foil for Solid Pharmaceutical Packaging

This standard applies to the foil that is compositely made of medicinal polyvinyl chloride (PVC), aluminum (Al), and polyamide (PA) through an adhesives. It applies to solid medicines (tablets, capsules, suppositories, etc.) that is packaged with blister packs by cold-form.

[Appearance] Take appropriate amount of the sample. Under natural light, visually inspect it directly. There must not have defects such as perforation, foreign bodies, smell, adhesion, composite layer's separation and significant damage, bubbles, wrinkles, and dirt.

[Identification] Infrared spectrum*: Take appropriate amount of the sample. Determine it according to the Fourth Method of The Test Method for Infrared Spectrum in Packaging material (YBB60012012). PA and PVC shall be consistent with the contrast spectrums respectively.

[Physical Properties] Water Transmission: Take appropriate amount of the sample. It shall be determined according to Test Methods for Water Transmission's (YBB60302012) The Second Test Method's test conditions to select Option B or The Fourth Method's test conditions to select Option 2. When testing, the side of the PVC that faces to low humidity must not exceed $0.5\text{g} / (\text{M}^2 \cdot 24\text{h})$.

Gas Transmission: Take appropriate amount of the sample. It shall be determined according to Test Methods for Gas Transmission's (YBB60292012) First Method (When testing, PVC shall be faced to the low-pressure side). It must 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 the sample. It shall be determined according to Tests for Peel Strength (YBB60312012). The peel strength between PA / Al layer must not be less than $8.0\text{N} / 15\text{mm}$. The peel strength between Al / PVC layer must not be less than $7.0\text{N} / 15\text{mm}$. (If the composite layer can not be peeled off or the composite layer is fractured, then the peel strength is deemed as qualified).

Welding strength: Cut 2 slices of the sample in $100\text{mm} \times 100\text{mm}$. The PVC surface of the composite foil is superimposed to the same-size pharmaceutical packaging aluminum foil (YBB10012012). Perform the welding on heat-seal instrument. The welding temperature is $155^\circ\text{C} \pm 5^\circ\text{C}$. The pressure is 0.2Mpa . The time is 1 second. Cut 15mm -wide samples from the welding area. Take the middle 3 strips to perform the test. It shall be determined according to the Tests for Welding Strength (YBB60332012). The average value of welding strengths of 6 samples must not be less than $6.0\text{N} / 15\text{mm}$.

[Translator: This paragraph is not part of December-2012 version] **[Solvent residue]** Take appropriate amount of the sample. Cut out 0.2m^2 of the inner surface area. It shall be determined according to the Test Method for Residue of Solvent in Packaging Material (YBB60062012). The total amount of solvent residues must not exceed $5.0\text{mg} / \text{m}^2$; in which, the residue of benzene-type solvents must not be detected. The detection limit of single benzene-type solvent is $0.01\text{mg} / \text{m}^2$. [Translator: This paragraph is not included in December-2012 version]

[Vinyl chloride monomer] Take appropriate amount of the sample. It shall be determined according to Tests for Determination of vinyl chloride monomer (YBB60352012). It must not exceed one in a million.

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 2 websites:

1. <https://www.ChineseStandard.us>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. <https://www.ChineseStandard.net>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - <https://www.ChineseStandard.us>).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

About Us (Goodwill, Policies, Fair Trading...): <https://www.chinesestandard.net/AboutUs.aspx>

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

----- The End -----