

Translated English of Chinese Standard: YBB00312004-2015

[www.ChineseStandard.net](http://www.ChineseStandard.net)

Email: [Sales@ChineseStandard.net](mailto:Sales@ChineseStandard.net)

# YY / YBB

PETROCHEMICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

**YBB 00312004-2015**

---

## Test for Residual Solvent of Packaging Materials

包装材料溶剂残留量测定法

### **YBB 00312004-2015 How to BUY & immediately GET a full-copy of this standard?**

1. [www.ChineseStandard.net](http://www.ChineseStandard.net);
2. Search --> Add to Cart --> Checkout (3-steps);
3. No action is required - Full-copy of this standard will be automatically & immediately delivered to your EMAIL address in 0~25 minutes.
4. Support: [Sales@ChineseStandard.net](mailto:Sales@ChineseStandard.net). Wayne, Sales manager

**Issued on: August 11, 2015**

**Implemented on: December 01, 2015**

**Issued by: China Food and Drug Administration of PRC**

## Test for Residual Solvent of Packaging Materials

This Method applies to the determination of residual solvent of pharmaceutical packaging materials. Residual solvent of pharmaceutical packaging materials refers to organic volatile substances which are used in the raw and auxiliary materials and the production process, but are not fully removed during the production process of pharmaceutical packaging materials. The residual quantity of organic solvent in pharmaceutical packaging materials shall be as specified for each product. The types of solvent to be tested shall be determined in accordance with the characteristics of formulas and technologies of products; they are not limited to the solvents described in this Standard.

This Method is based on a gas-solid equilibrium. Take a certain area of test specimen to place into a sealed container; under certain conditions of temperature and time, the residual organic solvent of test specimens is heated to become volatile; after an equilibrium is achieved, take headspace gas quantitatively to inject into chromatograph for analysis to retain time for qualitative analysis and peak area for quantitative analysis. Determine in accordance with the method for the determination of residual solvent (general rule 0861 of the fourth edition of Chinese Pharmacopoeia 2015); the limit of residual solvent shall be as specified for all products, including the detection limit of the methods for benzene and each solvent of benzenes not greater than  $0.01 \text{ mg/m}^2$ , and it changes along with the improvement of the sensitivity of test methods.

### Chromatographic conditions and system applicability test

Chromatographic column may be capillary column or other appropriate chromatographic columns which can meet the requirements for the separation of solvent to be tested. Use the chromatographic peak of solution to be tested for calculation. The number of theoretical plates of packed column is normally not lower than 1000.

Unless specified otherwise, capillary chromatographic columns of the same type with similar polarities can be used interchangeably. The number of theoretical plates shall not be less than 5000.

1. Nonpolar chromatographic columns: 100% dimethyl polysiloxane.
2. Polar chromatographic columns: polyethylene glycol PEG 20 M.
3. Moderate polar chromatographic columns: 6% cyanopropyl phenyl-94% dimethyl polysiloxane.
4. Weak polar chromatographic columns: 5% phenyl-95% methyl polysilicone.

The following conditions are generally used:

Chromatographic column: INNOWAX ( $60 \text{ m} \times 0.32 \text{ mm} \times 0.5 \mu\text{m}$ );

Detector: flame ionization detector (FID);

**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](mailto:Sales@ChineseStandard.net)

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

**----- The End -----**