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NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA

YBB 00342002-2015

**General Requirement for Multi-Layer
Co-Extrusion Film and Bag for Infusion**

多层共挤输液用膜、袋通则

General Requirement for Multi-Layer Co-Extrusion Film and Bag for Infusion

Multi-layer co-extrusion film refers to the film with two or more layers, formed by a co-extrusion process, without using a binder. Multi-layer co-extrusion bag for infusion refers to the bag made of multi-layer co-extrusion film by thermal sealing method.

This Standard is applicable to the 50mL and above multi-layer co-extrusion film and bag for infusion.

[Appearance] Take the appropriate amount of this product; visually examine it in the bright place of natural light. It shall be transparent, smooth, and free of visible foreign matters.

[Identification] Take the appropriate amount of this product; determine as per the fifth method of Test for Infrared Spectrum of Packaging Materials (YBB00262004-2015); each layer shall be basically consistent with the control atlas.

[Sterilization Adaptability Test] (Bag) Take several samples of this Product; add water for injection filtered through a 0.45 μ m pore size filter membrane to the marking capacity; and seal. After sterilization by damp heat sterilization (standard sterilization F_0 value ≥ 8 ; for instance, perform damp heat sterilization at 121°C for 15min), then carry out the following test.

Temperature adaptability Take a few of the above samples; stand for 24h at -25°C $\pm$ 2°C; then continuously stand for 24h at 50°C $\pm$ 2°C; finally stand for 24h at 23°C $\pm$ 2°C; place the sample between two plates; withstand an internal pressure of 67kPa; maintain for 10min; no liquid shall leak out.

Anti-drop Take a few of the above samples; stand for 24h at -25°C $\pm$ 2°C; then continuously stand for 24h at 50°C $\pm$ 2°C; finally stand for 24h at 23°C $\pm$ 2°C; according to the drop height in Table 1, separately drop the samples onto a rigid and smooth surface; there shall be no cracks or leaks.

Table 1 -- Drop Height

Marking capacity (mL)	Drop height (m)
50~749	1.00
750~1000	0.75

Transparency Take a few of the above samples; take another empty bag; add the Grade-4 turbidity of standard solution, which serves as control bag; under the black

to Test for Tensile Properties (YBB00112003-2015); the sample shall be Type-II; the test speed (no load) is at 100mm/min $\pm$ 10mm/min or 500mm/min $\pm$ 10mm/min; the average longitudinal and transverse tensile strength shall be no less than 20MPa.

Thermal Sealing Strength (Bag) Take appropriate amount of this product; determine according to Test for Welding Strength (YBB00122003-2015); it shall be no less than 20N/15mm.

[Light Transmittance] Take the flat part of this product; cut into 5 sections with size of 0.9cm $\times$ 4cm; separately place into the absorption cell in the vertical direction of the incident light; filled with water; take water as a blank; determine the light transmittance according to UV-Visible Spectrophotometry (*Chinese Pharmacopoeia* 2015 Edition, Volume 4, General Rules 0401) at the wavelength of 450nm; it shall be no less than 75%.

[Ignited Residue] Take 5.0g of this product; check according to (*Chinese Pharmacopoeia* 2015 Edition, Volume 4, General Rules 0841); the remained residue shall not exceed 0.05%.

[Metal Element] Take the residue under the ignited residue items; add 5mL of hydrochloric acid solution (1 $\rightarrow$ 2) and dissolve; then evaporate it; add 25mL of 5% nitric acid solution to residue to dissolve; determine according to Atomic Absorption Spectrophotometry (*Chinese Pharmacopoeia* 2015 Edition, Volume 4, General Rules 0406); it shall conform to the following provisions:

Copper Determine at the wavelength of 324.8nm, which shall not exceed three parts per million.

Cadmium Determine at the wavelength of 228.8nm, which shall not exceed three parts per million.

Chromium Determine at the wavelength of 357.9nm, which shall not exceed three parts per million.

Lead Determine at the wavelength of 217.0nm, which shall not exceed three parts per million.

Tin Determine at the wavelength of 286.3nm, which shall not exceed three parts per million.

Barium Determine at the wavelength of 553.6nm, which shall not exceed three parts per million.

[Test on Dissolved-Out Matter] Preparation of the test solution: Take the flat part of this product with inner surface area of 600cm²; cut into small pieces with size of 5cm $\times$ 0.5cm; place it into a conical flask; add appropriate amount of water to shake and

dissolve; and dilute to 1000mL), adding 46mL of blank solution and 2mL of alkaline potassium iodide test solution; it shall be no darker (0.00008%).

Barium Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Copper Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Cadmium Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Lead Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Tin Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Chromium Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine as per the provisions of corresponding metal element; it shall not exceed 1 part per million.

Aluminum Ions Take appropriate amount of test solution, which can be concentrated, if necessary; determine according to the atomic absorption spectrophotometry (Chinese Pharmacopoeia 2015 Edition, Volume 4, General Rules 0406) at the wavelength of 309.3nm; it shall not exceed 0.05 part per million.

[Bacterial Endotoxin] Preparation of test solution: Take an empty bag; add marking-capacity water for sterilization infusion, then seal the bag; extract at $121^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 30min; cool off for later-use; serve as test solution; check according to the law (Chinese Pharmacopoeia 2015 Edition, Volume 4, General Rules 1143); the content of endotoxin per 1mL of test solution shall not exceed 0.25EU.

[Biological Test] * * Cytotoxicity Take this product; determine according to the first method in Test for Cytotoxicity (YBB00012003-2015); take the serum-containing medium as the leaching medium; the ratio between surface area of sample and leaching medium is 6cm²/ml; which shall meet the requirements.

Skin Sensitization Take this product; determine according to Skin Sensitization Test (YBB00052003-2015); the sensitization reaction shall not exceed Degree-I.

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