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YBB 00132002-2015

General requirement for laminated films and products for pharmaceutical packaging

药用复合膜、袋通则

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General requirement for laminated films and products for pharmaceutical packaging

Composite film refers to the film formed by a variety of plastic and paper, metal or other plastic through adhesives, with the thickness of generally not greater than 0.25mm.

Composite bag refers to the bag made by heat sealing method of the composite film, which can be divided into three-sided sealed bag, middle sealed bag, organ bag, self-reliance bag, zipper bag, and so on.

This standard applies to the pharmaceutical composite film and bag for other uses than injection.

Pharmaceutical composite film is classified in accordance with the material combinations, as shown in Table 1.

Table 1 -- Composite film classification

Type	Material	Typical example
I	Paper, plastic	Paper or PT / adhesive layer / PE or EVA, CPP
II	Plastic	BOPET or BOPP, BOPA / adhesive layer / PE or EVA, CPP
III	Plastic, aluminized film	BOPET or BOPP / adhesive / aluminized CPP BOPET or BOPP / adhesive layer / aluminized BOPET / adhesive layer / PE or EVA, CPP, EMA, EAA, ionic polymer
IV	Paper, aluminium film, plastic	Paper or PT / adhesive layer / aluminium foil / adhesive layer / PE or EVA, CPP, EMA, EAA, ionic polymer Coating / aluminium foil / adhesive layer / PE or CPP, EVA, EMA, EAA, ionic polymer
V	Plastic (non-single layer), aluminium film	BOPET or BOPP, BOPA / adhesive layer / aluminium foil / adhesive layer / PE or CPP, EVA, EMA, EAA, ionic polymer

Note 1: The glass paper is shortly referred to as PT, the biaxially-oriented polypropylene is shortly referred to as BOPP, the biaxially-oriented polypropylene terephthalate is shortly referred to as BOPET, the biaxially-oriented polyamide nylon is shortly referred to as BOPA, The polyethylene is shortly referred to as PE, the casting polypropylene is shortly referred to as CPP, the copolymer of ethylene and ethylene vinyl acetate is shortly referred to as EVA, the copolymer of ethylene and acrylic acid is shortly referred to as EAA, AND the copolymer of ethylene and methacrylic acid is shortly referred to as EMA.

Note 2: The composite may be of dry composite method or solvent-free composite method, AND at this time the adhesive layer is general adhesive. It may also use extrusion composite method, AND at this time the adhesive layer is PE or EVA, EMA, EAA, and other resins.

1 mL of diluted sulfuric acid; MAKE it boil for 3 min; COOL it down quickly; ADD 0.1 g of potassium iodide; PLACE it in the dark for 5 min; USE the sodium thiosulfate titration solution (0.01 mol/L) to titrate it, until it approaches to the end point; ADD 5 drops of starch indicator solution; CONTINUE titration until it is colorless; TAKE water blank solution and REPEAT the operation; AND the difference of the sodium thiosulfate titration solution (0.01 mol/L) consumed between them shall be not more than 1.5 mL.

Non-volatile substance: respectively and precisely MEASURE 100 mL of water, 65% ethanol, n-hexane test solution, and blank solution into a evaporation dish which had been reached to constant weight; EVAPORATE it dry in water bath; DRY it at 105 °C for 2 hours; after cooling it down, WEIGH it precisely; AND the difference between the water non-volatile substance residues and the blank solution shall be not more than 30.0 mg; the difference between the 65% ethanol non-volatile substance residues and the blank solution residues shall be not more than 30.0 mg; AND the difference between the n-hexane non-volatile substance residues and the blank solution residues shall be not more than 30.0 mg.

Heavy metal: precisely MEASURE 20 mL of water test solution; ADD 2 mL of acetate buffer (pH 3.5); CHECK the method 1 of the four general rules 0821 of Chinese Pharmacopoeia 2015 version), AND the heavy metal content shall not exceed one millionth.

[Microbial limit]: TAKE this product; USE the sterilized metal template having an opening area of 20 cm² to press it onto the inner layer; USE sodium chloride injection to slightly wet the sterile cotton swab; WIPE within the plate hole range for 5 times; CHANGE another swab to wipe it for another 5 times, with each position wiped by 2 swabs for 10 times in total, AND totally 5 positions (100 cm²) are wiped. Each swab is cut (or burnt) off immediately after wiping operation, AND placed into a conical flask (or large tube) containing 30 mL of sodium chloride injection. After all swabs are placed into the flask, quickly SHAKE the flask for 1 min; LET it stand for 10 min, to obtain the test solution. MAKE the test solution be filtered by the film; CHECK the four general rules 1105 and 1106 of the Chinese Pharmacopoeia 2015 version; AND the results shall comply with the requirements of Table 6.

Table 6 -- Microbial limits

Item	Ordinary composite film and bag	Composite film and bag for drugs of external use	Composite film and bag for suppository
Number of bacteria (cfu / 100 cm ²)	≤ 1000	≤ 100	≤ 100
Number of mold and yeast (cfu / 100 cm ²)	≤ 100	≤ 100	≤ 10
Escherichia coli	Not detected	-	-
Staphylococcus aureus	-	Not detected	Not detected
Pseudomonas aeruginosa	-	Not detected	Not detected

Note: “-” means that not detected for every 100 cm².

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