



湖南新五洲医药包装有限责任公司

Hunan Xinwuzhou Pharmaceutical Packaging Co., Ltd.

Add.: No.10 Panpan Road, Xingsha District, Changsha City, Hunan Province, 410100 China.

Certificate of Analysis

Product name	PVC /PE FILM		Report Number	2018094030	
color	Transparent Brown Sheet		Production Lot	20180830	
specification	345 × 0.30mm		Sampling date	20180904	
Inspection department	Quality Supervision Department		Report Date	20180911	
Produce date	20180830		Validity time	2 years	
Test determined by: Hunan Xinwuzhou Pharmaceutical Packaging Co.,Ltd. standard in House					
Test items		Technical Requirements	test result	Individual judgment	
Exterior		Comply with requirements of the standard [Appearance]	Compliance	Compliance	
Standard sizes Physical properties	width	345±1mm	345	Compliance	
	thickness	0.30±0.025mm	0.30	Compliance	
Mechanical properties Standard sizes	Water vapor transmission	≤2.5g/(m ² ·24h)	0.9	Compliance	
	Oxygen transmission rate	≤20cm ³ /(m ² ·24h·0.1Mpa)	11	Compliance	
Physical properties	Tensile Strength	≥40Mpa	Longitudinally	52	
			Transversal	51	
	Impact resistance	Compliance	Compliance	Compliance	
	Heating expansion rate	≤±6%	1% -2	Compliance	
Residual solvents	Benzene	Benzene and benzene solvents shall not be detected	Not detected benzene	Compliance	
	Total	≤5mg/m ²	1. 87	Compliance	
The vinyl chloride monomer		Not more than a milionth	Less than a millionth	Compliance	
Dissolution test substance	Clarity	Compliance	Compliance	Compliance	
	Easy oxide	≤1.5ml	0.3	Compliance	
	UV absorbance	220~360 nm, A _{max} ≤0.50	0.03	Compliance	
	PH value change	≤1.0	0.3	Compliance	
	DOP migration	≤5.0mg/L	not detected	Compliance	
	Non-volatile matter	Water	≤30.0mg/100ml	1.6	Compliance
		65% ethanol	≤30.0 mg/100ml	11.3	Compliance
		Hexane	≤30.0 mg/100ml	13.4	Compliance
Heavy Metal	Not more than a millionth	Less than a millionth	Compliance		
Microbial limits	The number of bacteria	≤100 ↑/10cm ²	<1Compliance0	Compliance	
	The number of aerobe bacteria	≤190cfu/100 cm ²	<150	Compliance	
	The number of Mold and yeast	≤19 ↑/100cm ²	<10	Compliance	
	Plaguig bacteria (E.coli, Salmonella, Pseudomonas aeruginosan, S.aureus)	Not Detected	Not Detected		
	Escherichia coli	Not Detected	Not Detected	Compliance	
Storing condition	Cool and dry place, temperature ≤ 35° C, moisture ≤ 70%				
conclusion	This product is according Hunan Xinwuzhou Pharmaceutical Packaging Co.,Ltd. Standard in House verify the above items, the results of compliance.				

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