



武汉福鑫化工有限公司

Wuhan Fortuna Chemical Co.,Ltd

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CERTIFICATE OF ANALYSIS

Product	Ambroxol hydrochloride	Quantity	300KG
Date of Mfg.	2019-03-03	Batch NO.	190301
Date of Analysis	2019-03-05	Date of Expiry	2022-03-01

Testing Items	Specifications	Result
Description	White or yellowish crystalline powder	Conforms
Appearance of solution	Not more intensely colored than the reference solution Y6	<Y6
Solubility		
Water	Sparingly soluble	Conforms
Methanol	Soluble	Conforms
Methylene chloride	Practically insoluble	Conforms
Identifications		
1) UV Absorption	Ratio 3.2 to 3.4	Conforms
2) IR Spectrum	Meet the requirement	Conforms
3) Thin layer chromatography	Meet the requirement	Conforms
4) Chloride test	Meet the requirement	Conforms
pH	4.5 to 6.0	4.8
Related substances	Any impurity Not more than 0.1% Total impurity Not more than 0.3%	0.05% 0.06%
Heavy metals(Pb)	Not more than 20ppm	<20ppm
Loss on drying	Not more than 0.5%	0.10%
Sulphated ash	Not more than 0.1%	0.05%
Residual solvents	Acetone NMT 5000ppm Methanol NMT 3000ppm	105ppm 85ppm
Hygienic control	Bacterial: NMT 100CFU/G Yeast & Mould: NMT 10CFU/G Pathogens: Free	25CFU/G 6CFU/G Free
Assay	99.0% to 101.0% (dried substances)	99.7%
Conclusion	Conform with the requirement of EP8.0	
Storage	Protected from light.	

Director: Luo Xiaofeng

Re-tester: AT03

Tester: AT02