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分析报告单

CERTIFICATE OF ANALYSIS

产品名称 Product Name	氨甲环酸 Tranexamic acid	批号 Batch No.	F0022322072
标准规格 Standard	25 kg/drum	数量 Quantity	500KG
生产日期 MFG Date	2022-12-27	有效日期 Exp. Date	2025-12-26

Items	Specification	Results
Appearance	White to White Crystalline Powder	White Crystalline Powder
solubility	Soluble in water and glacial acetic acid, barely soluble in acetone and ethyl alcohol(96%)	conform
Identity	Infrared absorption spectrum complies with that of tranexamic acid	conform
PH	7.0-8.0	7.5
Related substances		
Impurity A	Not more than 0.1%	0.038%
Impurity B	Not more than 0.2%	0.63%
Unspecified impurities	Not more than 0.1%	0.042%
Sum of unspecified impurities	Not more than 0.2%	0.042%
Loss on Drying	Maximum 0.5%	0.2%
Halides expressed as chlorides	Maximum 140 ppm	<140 ppm
Heavy metal	Maximum 10 ppm	<10 ppm
Sulfate ash	Maximum 0.1%	0.05%
Assay	99.0%~101.0%	99.6%
Conclusion	Conform to BP 2012	

Approved by: Tawm Zhy/2018,05.03

Qualified Person/Date