

CERTIFICATE OF ANALYSIS

品名 Product Name	盐酸溴己新 Bromohexine HCL	生产日期 Manufacturing Date	2019-12-24
CAS No:	611-75-6	包装 Packing	25kg/桶
批号 Batch No.	20191221	数量 Quantity	100kg
检测日期 Test Date	2019-12-24	报告日期 Report Date	2019-12-24
有效期 Expiry Date	2021-12-23	检验依据 Specification	BP2015

检测项目 Items	标准规定 Standard	检验结果 Results
外观 Appearance	白色或类白色结晶性粉末 White or almost white crystalline powder	类白色结晶性粉末 Almost white crystalline powder
鉴别 Identification	IR	Complies
	TLC	Complies
	Brownish-yellow color develops in the lower layer	Complies
	The reaction of primary aromatic amines	Complies
	Reaction of chlorides	Complies
溶解度 Solubility	Very slightly soluble in water, slightly soluble in alcohol and in methylene chloride	Complies
溶液外观 Appearance solution	The solution is clear and not more intensely coloured than reference solution Y6	Complies
有关物质 Related substances	Any impurity $\leq 0.02\%$	0.07%
	Total impurity $\leq 0.3\%$	0.19%
	Impurity(>0.1%) ≤ 1	Complies
干燥失重 Loss on drying	$\leq 1.0\%$	0.12%

硫酸盐灰分 Sulphated ash	≤1.0%	0.06%
含量 Assay	98.5%-101.5%	99.8%
结论 Conclusion	本品符合英国药典2015的标准要求 This product complies with prescribed standard of B2015	

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Analyst: LiLin

