



HANGZHOU SARTORT BIOPHARMA CO., LTD

CERTIFICATE OF ANALYSIS

Product Name: Bromhexine hydrochloride		
Molecular Formula: C ₁₄ H ₂₁ Br ₂ ClN ₂	CAS No.: 611-75-6	
Molecular Weight: 412.59	Quantity: 500kgs	
Batch No.: ST-20191224	Manufacturing date: 2019.12.24	
Item	Specification	Results
Appearance	White or almost white, crystalline powder	Conforms
Solubility	Very slightly soluble in water, slightly soluble in alcohol and in methylene chloride	Conforms
Identification First identification: A E Second identification: B C D E	A: IR	Conforms
	B: TLC	Conforms
	C: Brownish-yellow color develops in the lower layer	Conforms
	D: Reaction of primary aromatic amines	Conforms
	E: Reaction of chlorides	Conforms
Appearance of solution	The solution is clear and not more intensely colored than reference solution Y6	Conforms
Loss on drying	≤1.0%	0.12%
Heavy metals	≤20ppm	Conforms
Sulphated Ash	≤0.1%	0.06%
Related substance	Impurity A ≤0.1%	Conforms
	Impurity B ≤0.1%	Conforms
	Impurity C ≤0.1%	Conforms
	Impurity D ≤0.1%	Conforms
	Impurity E ≤0.1%	Conforms
	Single impurity ≤0.2%	0.07%
	Total impurities ≤0.3%	0.19%
Assay (on dried bases)	98.5%-101.5%	99.8%
Storage	Protected from light	
Conclusion	The batch is in compliance with BP2015 Standard.	

QC:

QA:

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