Certificate of Analysis

Ambroxol Hcl

CAS No	23828-92-4	Code	BIOJAMB001
Batch No	AMLH-260602	Manufacture Date	Jun.22, 2026
Retest date	Jun.21, 2031	Quantity	1.5Kgs

Testing Items	**Specifications**	**Results**
Appearance	White or yellowish crystalline powder	Conforms
Identification First identification: B D Second identification: A C D	A) Ultraviolet and visible absorption spectrophotometry	Conforms
	B) Infrared absorption spectrophotometry	Conforms
	C) Thin-layer chromatography	Conforms
	D) Reaction of chlorides	Conforms
Solubility	Sparingly soluble in water, soluble in methanol, practically insoluble in methylene chloride	Conforms
Appearance of solution	Clear and not more intensely coloured than reference solution Y_6	Conforms
pH	4.5~6.0	5.00
Loss on drying	≤0.5%	0.20%
Sulfated ash	≤0.1%	0.06%
Heavy metals	≤20ppm	<20ppm
Related substances	Impurity A≤0.1% Impurity B≤0.1% Impurity C≤0.1% Impurity D≤0.1% Impurity E≤0.1% Unspecified impurity≤0.1% Total impurities≤0.3%	Conforms Conforms Conforms Conforms Conforms 0.02% 0.03%
Assay	99.0%~101.0% (Calculated on the dried basis)	99.9%
Conclusion	This product conforms to EP10 standard	

***Storage condition: Store below 25℃, Protect from moisture and light.**