

Certificate of Analysis

Ambroxol Hcl

CAS No	23828-92-4	Code	BIOJAMB001
Batch No	AMLH-240802	Manufacture Date	Aug.22, 2024
Retest date	Aug.21, 2029	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	4.99
Loss on drying	≤0.5%	0.10%
Sulfated ash	≤0.1%	0.06%
Heavy metals	≤20ppm	<20ppm
Related substances	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
	Unspecified impurity ≤0.1%	0.02%
	Total impurities ≤0.3%	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°C, Protect from moisture and light.**