

Certificate of analysis

Mexiletine Hcl

CAS No	5370-01-4	Code	BIOJMLT001
Batch No	Y240301	Manufacture Date	Mar.15, 2024
Retest Date	Mar.14, 2026	Quantity	5Kgs

Testing Items	Specifications	Results
Appearance	White or almost white, crystalline powder	White, crystalline powder
Solubility	Freely soluble in water and in methanol, sparingly soluble in methylene chloride	Complies
Identification	IR: Mexiletine hydrochloride RS	Complies
	Reaction of chloride	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Melting point	200~204°C	201~202°C
PH	4.0~5.5	5.2
Residue solvent	Ethyl acetate ≤0.5%	0.03%
Impurity D	≤0.1%	Not detected
Related substances	Impurity A: ≤0.1%	Not detected
	Impurity C: ≤0.1%	Not detected
	Any single impurity: ≤0.1%	0.05%
	Total impurities: ≤0.5%	0.07%
Sulfated ash	≤0.1%	<0.1%
Water	≤0.5%	0.4%
Microbial limits	Aerobic bacteria ≤10 ³ cfu/g	<10cfu/g
	Fungi and yeast ≤10 ² cfu/g	<10cfu/g
	Escherichia coli: Not detected in 1g	Not detected
Assay(Titration)	99.0%~101.0%	100.5%
Conclusion	This product conforms to EP10.3 standard	

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