

## Certificate of Analysis

### Mexiletine Hcl

CAS No	5370-01-4	Code	BIOJMLT001
Batch No	Y240701	Manufacture Date	Jul.31, 2024
Retest Date	Jul.30, 2026	Quantity	4.8Kgs

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	202~203°C
PH	4.0~5.5	4.7
Residue solvent	Ethyl acetate ≤0.5%	Complies
Impurity D	≤0.1%	0.04%
Related substances	Impurity A: ≤0.1%	0.07%
	Impurity C: ≤0.1%	0.03%
	Any single impurity: ≤0.1%	0.03%
	Total impurities: ≤0.5%	0.20%
Sulfated ash	≤0.1%	0.08%
Water	≤0.5%	0.4%
Microbial limits	Aerobic bacteria ≤10 <sup>3</sup> cfu/g	<10cfu/g
	Fungi and yeast ≤10 <sup>2</sup> cfu/g	<10cfu/g
	Escherichia coli: Not detected in 1g	Not detected
Assay(Titration)	99.0%~101.0%	100.7%
Conclusion	This product conforms to EP11 standard	

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