



山东八方化工科技有限公司

SHANDONG OCTAGON CHEMICALS LIMITED



CERTIFICATE OF ANALYSIS

Product name	<u>Mexiletine Hydrochloride (Cas 5370-01-4)</u>		
Batch No.	230601	Mfg. Date	2023.06.15
Rep. Date	2024.06.25	Retest Date	2026.06.14
Packaging	25KG/Bag/TIn/Drum	Batch Quantity	330KG
Test Items	Standards: EP10.3		Results
Appearance	A white or almost white crystalline powder		A white crystalline powder
Solubility	Freely soluble in water and methanol, sparingly soluble in methylene chloride		Conform
Identification	IR Reaction of chloride		Conforms
Appearance of solution	Clear and colorless		conforms
Melting range	202°C~204°C		201°C~203°C
PH	4.0~5.5		5.1
Residual solvents	Ethyl acetate: NMT5000ppm		200ppm
Impurity D	NMT0.10%		ND
Related substances	Impurity A: NMT0.10% Impurity C: NMT0.10% Any other single impurity: NMT0.10% Total impurities: NMT0.5%		ND 0.03% 0.03% 0.06%
Sulfated ash	NMT0.1%		<0.1%
Water	NMT0.5%		0.12%
Microbial test	TAMC: NMT1000cfu/g TYMC: NMT100cfu/g E. coli: Negative		<10cfu/g <10cfu/g Negative
Assay	99.0%~101.0% (on the dried basis by titration)		99.8%
Conclusion	It meets the requirements of EP10.3 Standards		
Storage	Store in an air-tight container at ambient temperatures		
Reporter: LI	Reviewed By: WEI		

山东八方化工科技有限公司
SHANDONG OCTAGON CHEMICALS LIMITED