

Certificate of Analysis

Code Number / Product
44A029 MEXILETINE HYDROCHLORIDE

Batch No.: 24015
Analysis No.: 77417
Date of Manufacture: 17.May.2024
Weight: 290,6 kg
Test Spec. No.: PSC-E-000025 26.0

Test	Specification	Result
Appearance	- White to off white crystalline powder	Conforms
Identification IR spectrum	- Corresponding to reference spectrum	Conforms
Identification Test for chloride	- White curdy precipitate form, which is soluble in an excess of 6N ammonium hydroxide	Conforms
Solubility	In methanol Freely soluble	Conforms
	In water Freely soluble	Conforms
	In dichloromethane Sparingly soluble	Conforms
Colour of solution	- Not more intensely coloured than reference sol. B9	Conforms
Clarity of solution	- Clear as water or not more opalescent than reference susp. I	Conforms
pH	- 4.0 - 5.5	4.8
Chromatographic purity	Impurity A <= 0.10%	<0.05 %
	Impurity B <= 0.10%	<0.05 %
	Impurity C <= 0.10%	<0.05 %
	Any other Individual Impurity <= 0.10%	<0.05 %
	Total Impurities <= 0.50%	<0.05 %
Chromatographic purity	Impurity D <= 0.10%	<0.05 %
Residual Solvents	Methanol <= 3000 ppm	<300 ppm
	Acetone <= 5000 ppm	<100 ppm
	Toluene <= 890 ppm	<10 ppm
Loss on drying	- <= 0.5 %	0.1 %
Water	- <= 0.5 %	0.5 %
Sulphated ash	- <= 0.10 %	0.02 %
Assay	Titration with perchloric acid 99.0% - 101.0% (calculated with reference to the dried substance)	99.6 %

Remarks:

Retesting Date: May.2029

Batch Comment:

Results: Manufacture of batch in compliance with GMPs
Batch specifications in conformance with market
authorisation

Bernat Turon
Quality Control

Approval

This is an electronic signature

Date of Issue : 12.February.2025 13:20:51