

Certificate of Analysis

Code Number / Product

44A029 MEXILETINE HYDROCHLORIDE

Batch No.:

21018

Analysis No.:

62410

Date of Manufacture:

14.July.2021

Weight:

322,9 kg

Test Spec. No.:

PSC-E-000025 23.0

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

Remarks:

Retesting Date: July.2026

Batch Comment:

Results:

Manufacture of batch in compliance with GMPs
Batch specifications in conformance with market
authorisationBernat Turon
Quality Control

Approval

This is an electronic signature

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