

AGC PHARMA CHEMICALS EUROPE, S.L.U.

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METAPHARMACEUTICAL

N DE LOTE:

0090522

10/05/2022

AGC

Certificate of Analysis

Code Number / Product

44A029 MEXILETINE HYDROCHLORIDE

Batch No.:

21014

Analysis No.:

60866

Date of Manufacture:

26.March.2021

Weight:

308.2 kg

Test Spec. No.:

PSC-E-000025 23.0

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
	In water	Freely soluble
	In dichloromethane	Sparingly soluble
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	4.7
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 %	0.1 %
Water	<= 0.5 %	0.1 %
Sulfated ash	<= 0.10 %	0.03 %
Assay	Titration with perchloric acid	99.0% - 101.0%
	(calculated with reference to the dried substance)	99.6 %

Remarks:

Retesting Date: March.2026

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

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