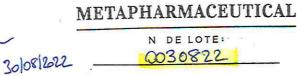
AGC PHARMA CHEMICALS EUROPE, S.L.U.

Cami de la Pomereda, 13 08380 - Malgrat de Mar (SPAIN) Phone (+34) 93 766 97 00



N DE LOTE: 0030822



Certificate of Analysis

Code Number / Product

44A029 MEXILETINE HYDROCHLORIDE Batch No.:

21018

Analysis No.:

62410

Date of Manufacture: Weight:

14.July.2021 322,9 kg

Test Spec. No.:

PSC-E-000025 23,0

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Test		Specification	Result
Appearance	20	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	≅″ V	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	5.0
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	12 ppm
Loss on drying		<= 0.5 %	<0.1 %
Water	# /	<= 0.5 %	0.3 %
Sulfated ash	-	<= 0.10 %	0.04 %
Assay	Titration with perchloric acid	99.0% - 101.0% (calculated with reference to the dried substance)	99.8 %

Remarks:

Retesting Date:

July.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 14.July.2022 15:17:02 Date of Issue: