



## TECHNICAL DATA SHEET

002872-TDS-ENG-2021

MEXILETINA HCL - USP/EP		
DESCRIPTION DCI: MEXILETINE HYDROCHLORIDE		DESCRIPTION DOE: MEXILETINA HIDROCLORURO
CAS N°: 5370-01-4	EC N°: 226-362-1	AEMPS CODE: 1081CH
MOL. WEIGHT: 215.72	MOL. FORMULA: C <sub>11</sub> H <sub>18</sub> CINO	ARTICLE CODE: 002872

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in methanol, sparingly soluble in methylene chloride
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	4.0 - 5.5
Impurity D	= < 0.10 %
Related substances	
Impurity A	= < 0.10 %
Impurity C	= < 0.10 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Water	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %
Residual solvents	
2,6-Dimethylphenol	= < 0.1 %

### COMPLIES WITH

European Pharmacopoeia 10.3

### STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

### REMARKS

It shows polymorphism (5.9).

Mexiletine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.