



## MEXILETINA HCL (EUR. PH.)

PRODUCT CODE: 2563	CAS Nº: 5370-01-4	ANALYSIS Nº: 250/24
MANUFACTURER BATCH: 24012	CERTIFICATE ID: 43.670	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 09/05/2024	
METAPH BATCH: 0021024	RETEST DATE: 30/05/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Solubility	Freely soluble in water and in methanol, sparingly soluble in methylene chloride	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Complies (*)
pH	4.0 - 5.5	4.9 (*)
Impurity D	=< 0.10 %	< 0.05 % (*)
Related substances		(*)
Impurity A	=< 0.10 %	< 0.05 %
Impurity C	=< 0.10 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Water	=< 0.5 %	0.4 %
Sulfated ash	=< 0.1 %	0.05 %
Assay	99.0 - 101.0 %	100.7 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

It shows polymorphism.

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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

(\*) Data adapted from the manufacturer's certificate of analysis.

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.

### STORAGE

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

Analysis date: 18/10/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40001159