

MEXILETINA HCL (EUR. PH.)

PRODUCT CODE: 2563	CAS Nº: 5370-01-4	ANALYSIS Nº: 189/22
MANUFACTURER BATCH: 21018	CERTIFICATE ID: 35.784	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 14/07/2021	
METAPH BATCH: 0030822	RETEST DATE: 14/07/2026	

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	Freely soluble in water and in methanol, sparingly soluble in methylene chloride
Identification A	Complies	Complies (*)
Identification B	Complies	Complies (*)
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.0 - 5.5	5.0
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 %	0.48 % (*)
Sulfated ash	=< 0.1 %	< 0.1 % (*)
Assay	99.0 - 101.0 %	99.8 % (*)
Residual solvents [In-house]		(**)
Methanol	=< 3000 ppm	< 300 ppm
Acetone	=< 5000 ppm	< 100 ppm
Toluene	=< 890 ppm	12 ppm

COMPLIES WITH

European Pharmacopoeia 10.3

REMARKS

Mexiletine Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

(*) Data controlled by Metapharmaceutical Industrial SL.

(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 05/09/2022
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001159
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