

**MEXILETINA HCL (EUR. PH.)**

PRODUCT CODE: 2563	CAS Nº: 5370-01-4	ANALYSIS Nº: 008/23
MANUFACTURER BATCH: 21021	CERTIFICATE ID: 36.944	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 21/07/2021	
METAPH BATCH: 0060123	RETEST DATE: 21/07/2026	

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	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Complies
pH	4.0 - 5.5	4.5
Impurity D	=< 0.10 %	0.04 %
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 %	0.21 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	99.0 - 101.0 %	100.4 %
Residual solvents [In-house]		(*) (**)
Methanol	=< 3000 ppm	< 300 ppm
Acetone	=< 5000 ppm	< 100 ppm
Toluene	=< 890 ppm	13 ppm

COMPLIES WITH

European Pharmacopoeia 11.0

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.

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

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

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: 25/01/2023

Signature: Ferran Gonzalez de Rivera Rier

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40001159

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