



## DILTIAZEM HCL (EUR. PH.)

PRODUCT CODE: 0510	CAS Nº: 33286-22-5	ANALYSIS Nº: 047/24
MANUFACTURER BATCH: 202311034084	CERTIFICATE ID: 41.313	
SUPPLIER BATCH: 0125447	MANUFACTURING DATE: 14/11/2023	
METAPH BATCH: 0010324	EXPIRY DATE: 12/11/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder (*)
Solubility	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol	Complies
Identification A	Complies	Complies (*)
Identification D	Complies	Complies (*)
Appearance of solution	Clear and colourless	Clear and colourless
pH	4.3 - 5.3	5.0
Specific optical rotation	+115 / +120	+118
Related substances		
Impurity F	=< 0.3 %	0.1 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.3 %	0.1 %
Loss on drying	=< 0.5 %	0.04 % (*)
Sulfated ash	=< 0.1 %	0.04 % (*)
Assay	98.5 - 101.0 %	100.3 % (*)

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

Product fully analysed inside the EU.

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

(\*) Data controlled by Metapharmaceutical Industrial SL.

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 the container in a fresh, dry and well-ventilated place.

Analysis date: 08/03/2024  
Signature: Albert Sánchez López (QP)  
Conclusion: Complies  
Original certificate available upon request

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