



TECHNICAL DATA SHEET

0510-TDS-ENG-2024

DILTIAZEM HCL (EUR. PH.)		
DESCRIPTION DCI: DILTIAZEM HYDROCHLORIDE		DESCRIPTION DOE: DILTIAZEM HIDROCLORURO
CAS N°: 33286-22-5	EC N°: 251-443-3	AEMPS CODE: 3735CH
MOL. WEIGHT: 451,00	MOL. FORMULA: C22H27CIN2O4S	ARTICLE CODE: 0510

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Diltiazem 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.