

Certificate of Analysis

Productname: Diltiazemi hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-179376B
Batchnumber: 18H09-B03-364807
Reference code / No.: 4112 / AZ-0560718
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chloride
Appearance of solution	Clear and colourless	Conform		5% <i>m/V</i>
pH	4,3 - 5,3	4,9		1% <i>m/V</i>
Specific optical rotation	+115 - +120	+115		1% <i>m/V</i> ; dried
Related substances	Conform	Conform		HPLC
Impurity F	<=0,3	< 0,05	%	
Unspecified impurities	<=0,10	< 0,05	%	
Total impurities	<=0,3	< 0,3	%	
Loss on drying	<=0,5	0,3	%	2 h 105 °C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Diltiazem hydrochloride	98,5 - 101,0	100,0	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

01/08/20

Expiration: 06-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.