

Certificate of Analysis

Productname: Diltiazemi hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-186451B
Batchnumber: 20C12-F03-373391
Reference code / No.: 4112 / AZ-0150120
Analysed according to: PH.EUR10.2

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	+118		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	<0,05	%	
Loss on drying	<=0,5	0,2	%	2 h 105 °C
Sulphated ash	<=0,1	<0,1	%	
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	99,9	% <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:
Paul Hofman
Pharmacist - Qualified Person

10/20/20

Expiration: 12-2024

Conclusion: APPROVED

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