

## Certificate of Analysis

**Productname:** Diltiazemi hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-187056B  
**Batchnumber:** 20J01-F11-374758  
**Reference code / No.:** 4112 / AZ-0810520  
**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	5,0		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	0,0	%	
Loss on drying	<=0,5	0,2	%	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	99,8	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

11/16/20

Expiration: 04-2025

Conclusion: APPROVED

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