

Certificate of Analysis

Product name: **Diltiazemi hydrochloridum**
Batch number / Weight: **21F11-B03-218831 / 5 G**
Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	4,3 - 5,3	5,1		
Specific optical rotation	+115 - +120	+117	°	
Related substances	Conform	Conform		
Impurity F	<=0,3	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	<0,05	%	
Loss on drying	<=0,5	0,16	%	
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
		601	ppm	
2-propanol	nie więcej niż 5000 ppm	241	ppm	
Toluen	nie więcej niż 890 ppm	<LOD	ppm	
Assay Diltiazem hydrochloride	98,5 - 101,0	99,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
TotalAerobicMicrob.Count(TAMC)	<=10 ³ CFU/g	<1	CFU/g	
Total yeasts and moulds (TYMC)		<1	CFU / g	

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

26-04-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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