

Certificate of Analysis

Product name: **Diltiazemi hydrochloridum**

Batch number / Weight: **22I13-B07-223057 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22I13-B07 / INS-22-8336**

Reference Code / No.: **V01390 / AZ-0350522**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Melting point	about 213°C	213,6	°C	
pH	4,3 - 5,3	4,66		
Specific optical rotation	+115 - +120	+117,5	°	
Related substances	Conform	Conform		
Impurity F	<=0,3	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,3	0,00	%	
Loss on drying	<=0,5	0,17	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Methanol	<=3000	<3000	ppm	
2-propanol	<= 5000	<5000	ppm	
Toluen	<= 890	<890	ppm	
Assay	98,5 - 101,0	99,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

21-11-2022

Expiration: 30-04-2027

Conclusion: APPROVED

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