

Certificate of Analysis

Product name: Diltiazemi hydrochloridum
Batch number / Weight: 25D02-B12-011127 / 5 g
Producer / Producer Batch Number: Divi's Laboratories Ltd - Unit I / AZ-0301224
Analyzed according to: Ph. Eur.11.7
Number of Analysis / Certificate no.: 25D02-B12 / QO0016573

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A, D	Conform		
Appearance of solution	Clear and colourless	Conform		
Melting point	about 213	211 - 213	°C	
pH	4,3 - 5,3	4,9		
Specific optical rotation	(+115) - (+120)	+119		
Related substances	Conform	Conform		
Impurity F	<= 0,3	0,0	%	
Unspecified impurities	<= 0,10	0,04	%	
Total impurities	<= 0,3	<0,05	%	
Loss on drying	<=0,5	0,2	%	
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,5 - 101,0	99,7	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP

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 FSNE lab

Release:

3-6-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 31-12-2026

Conclusion: APPROVED

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