Certificate of Analysis

Product name: Enalaprili maleas
Batch number / Weight: 24D10-B09-002184 / 5 g
Producer / Producer Batch Number: Zhejiang Changming Pharmaceutical Co., Ltd / 3012-2312-038
Analyzed according to: Ph.Eur. 11.5
Number of Analysis / Certificate no.: 24D10-B09 / QO0004779

	Requirement	Result	Unit	Standard remark
Appearance	(Almost)white, crystalline powder	Conform		
IR-spectrum	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
pH	2,4-2,9	2,60		
Specific optical rotation	(-51)-(-48)	-49,8		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,00	%	
Impurity C	<=0,2	0,07	%	
Impurity G	<=0,2	0,13	%	
impurity H	<=0,3	0,11	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,31	%	
Loss on drying	<=1,0	0,07	%	
Sulfated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,5 - 101,5	100,07	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	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:

3-10-2024
Ewelina Gadzinowska
Qualified Person

Expiration: 3-12-2026
Conclusion: APPROVED

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

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