

Certificate of Analysis

Product name: **Enalapril maleas**
Batch number / Weight: **23H22-B08-232432 / 5 G**
Producer / Producer Batch Number: Zhejiang Changming Pharmaceutical Co., Ltd / 3012-2305-021
Analysed according to: **Ph.Eur.11**
Number of analysis / Inspection Code **23H22-B08 / INS-23-6756**
Reference Code / No.: **V01774 / 3012-2305-021**

Tests	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	2,56		
Specific optical rotation	-51 - -48	-50,2		
Related substances	Conform	Konform		
Impurity A	<=0,5	0,00	%	
Impurity C	<=0,2	0,10	%	
Impurity G	<=0,2	0,15	%	
Impurity H	<=0,3	0,09	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,34	%	
Loss on drying	<=1,0	0,14	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Enalapril maleate	98,5 - 101,5	100,35	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Correction factor		1,001		

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
 ul. Armii Krajowej 3
 32-540 Trzebinia, Poland
 e-mail: fsne@fagron.pl

fagron.pl

Fagron sp. z o.o.
 ul. Pasternik 26, 31-354 Kraków, Poland
 tel.: +48 12 3343 512
 e-mail: biuro@fagron.pl

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:

Agnieszka Pszczółka

Qualified Person

16-10-2023

Expiration: 17-05-2026

Conclusion: APPROVED

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

fagron.pl

Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:fsne@fagron.pl