



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 240289

Product:	CAPTOPRIL
Lot:	240289
Expiry date:	16/11/2026
Reference:	Cumple PhEur11.3
Synonyms:	
Formula:	C ₉ H ₁₅ NO ₃ S
Molecular weight:	217.28 g/mol

Assay	Result	Specification	
Identification	Conform (A ,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform	Test PhEur	
pH	2,1	2,0 - 2,6	
Related substances (HPLC)	Conform		
Specific rotation	-130	(-127) - (-132)	
Loss on drying	0,06 %	<= 1,0 %	
Sulphated ashes	0,12 %	<= 0,2 %	
Assay	99,2 %	98,0-101,5%	
Impurity F	0,04%	<= 0,2 %	
Impurity A	0,36 %	<= 1,0 %	
Impurity B	ND	<= 0,15 %	
Impurity C	ND	<= 0,15 %	
Impurity D	0,01 %	<= 0,15 %	
Impurity E	< 0,05 %	<= 0,15 %	
Impurity J	0,02 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	0,39 %	<= 1,2 %	
Organic solvents residues	Conform		#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics: White or almost white, crystalline powder. Soluble in water, freely soluble in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 26/02/2024

Responsible: M. Mesa

Technical director: Montserrat Enrique

Judgement:
APPROVED

Manufacturer: F00390 ZHONGFU PHARMACEUTICAL Co. Ltd.

Manufacturer batch: 1012023110068

Product	Name	Capacity	Batch
1118102	CAPTOPRIL	1 g	240289-D-2
1200107	CAPTOPRIL	5 g	240289-E-1
1200107	CAPTOPRIL	5 g	240289-E-2
1200107	CAPTOPRIL	5 g	240289-E-3
1200108	CAPTOPRIL	10 g	240289-F-2
1200108	CAPTOPRIL	10 g	240289-F-3
1200108	CAPTOPRIL	10 g	240289-F-4
1200109	CAPTOPRIL	25 g	240289-G-1
1200109	CAPTOPRIL	25 g	240289-G-2
1200109	CAPTOPRIL	25 g	240289-G-3
1370102	CAPTOPRIL (FLB)	10 g	240289-F-1
1370114	CAPTOPRIL (FLB)	1 g	240289-D-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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