

## CAPTOPRIL (EUR. PH.)

PRODUCT CODE: 002153	CAS Nº: 62571-86-2	ANALYSIS Nº: 256/24
MANUFACTURER BATCH: 5102-24-004	CERTIFICATE ID: 43.707	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 10/03/2024	
METAPH BATCH: 0091024	RETEST DATE: 09/03/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
pH	2.0 - 2.6	2.55
Specific optical rotation	-132 / -127	-130
Impurity F	=< 0.2 %	0.07 %
Related substances		
Impurity A	=< 1.0 %	0.08 %
Impurity J	=< 0.2 %	0.07 %
Impurity B	=< 0.15 %	Not Detected
Impurity C	=< 0.15 %	Not Detected
Impurity D	=< 0.15 %	Not Detected
Impurity E	=< 0.15 %	No Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 1.2 %	0.15 %
Loss on drying	=< 1.0 %	0.1 %
Sulfated ash	=< 0.2 %	0.1 %
Assay	98.0 - 101.5 %	100.1 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Captopril is subjected to the requirements of the ICH Q3D "Elemental Impurities" and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

### STORAGE

Store in tightly closed containers. Store in a cool, dry place.

Analysis date: 24/01/2025  
 Signature: Albert Sanchez Lopez (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000772  
 ZHEJIANG HUAHAI PHARMACEUTICAL CO. LTD  
 Xunqiao, Linhai  
 317000 ZHEJIANG  
 (Xina)

