METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

CAPTOPRIL (EUR. PH.)

PRODUCT CODE: 002153	CAS Nº: 62571-86-2	ANALYSIS Nº: 071/24	
MANUFACTURER BATCH:	5102-23-009	CERTIFICATE ID:	41.514
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/04/2023
METAPH BATCH:	0240324	RETEST DATE:	31/03/2027

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	2.3
Specific optical rotation	-132 / -127	-130
Impurity F	=< 0.2 %	0.1 %
Related substances		
Impurity A	=< 1.0 %	< 0.05 %
Impurity J	=< 0.2 %	< 0.05 %
Impurity B	=< 0.15 %	0.05 %
Impurity C	=< 0.15 %	Not Detected
Impurity D	=< 0.15 %	Not Detected
Impurity E	=< 0.15 %	Not Detected
Unspecified impurities	=< 0.10 %	Not Detected
Total impurities	=< 1.2 %	0.05 %
Loss on drying	=< 1.0 %	0.1 %
Sulfated ash	=< 0.2 %	< 0.2 %
Assay	98.0 - 101.5 %	100.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

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: 29/05/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000772