



## TECHNICAL DATA SHEET

002153-TDS-ENG-2023

CAPTOPRIL (PH.EUR)		
DESCRIPTION DCI: CAPTOPRIL		DESCRIPTION DOE: CAPTOPRIL
CAS N°: 62571-86-2	EC N°: 263-607-1	AEMPS CODE: 3871A
MOL. WEIGHT: 217.28	MOL. FORMULA: C <sub>9</sub> H <sub>15</sub> NO <sub>3</sub> S	ARTICLE CODE: 002153

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Soluble in water, freely soluble in methanol and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	2.0 - 2.6
Specific optical rotation	-132 / -127
Impurity F	=< 0.2 %
Related substances	
Impurity A	=< 1.0 %
Impurity J	=< 0.2 %
Impurity B	=< 0.15 %
Impurity C	=< 0.15 %
Impurity D	=< 0.15 %
Impurity E	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.2 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.2 %
Assay	98.0 - 101.5 %
Zinc	=< 20 ppm

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

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

### REMARKS

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

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.