



## TECHNICAL DATA SHEET

8355113-TDS-ENG-2024

LOSARTAN POTASSIUM (EUR. PH.)		
DESCRIPTION DCI: LOSARTAN POTASICO		DESCRIPTION DOE: LOSARTAN POTASSIUM
CAS Nº: 124750-99-8	EC Nº: 627-032-3	AEMPS CODE: 7157PK
MOL. WEIGHT: 461,0	MOL. FORMULA: C22H22ClKN6	ARTICLE CODE: 8355113

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Freely soluble in water and in methanol, slightly soluble in acetonitrile
Identification A	Complies
Identification B	Complies
Related substances	
Impurity D	<= 0,15 %
Impurity J	<= 0,15 %
Impurity K	<= 0,15 %
Impurity L	<= 0,15 %
Impurity M	<= 0,15 %
Unspecified impurities	<= 0,10 %
Total impurities	<= 0,3 %
Loss on drying	<= 0,5 %
Assay	98,5 - 101,5 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container tightly closed, in a cool, dry place.

### REMARKS

Losartan Potassium is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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, among others, 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.