

TECHNICAL DATA SHEET

009462-TDS-ENG-2026

AMLODIPINO BESILATO (EUR. PH.)		
DESCRIPTION DCI: AMLODIPINE BESILATE		DESCRIPTION DOE: AMLODIPINO BESILATO
CAS Nº: 111470-99-6	EC Nº: 601-097-8	AEMPS CODE: 2503KB
MOL. WEIGHT: 567,1	MOL. FORMULA: C ₂₀ H ₂₅ N ₂ O ₅ Cl·C ₆ H ₆ O ₃	ARTICLE CODE: 009462

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	White or almost white powder
Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol
Identification	Complies
Optical rotation	-0.10° / +0.10°
Impurity I	=< 0.10 %
Related substances	
Impurity D	=< 0.3 %
Impurity A	=< 0.15 %
Impurity E	=< 0.15 %
Impurity F	=< 0.15 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.8 %
Water	=< 0.5 %
Sulfated ash	=< 0.2 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.1

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Amlodipine Besilate 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.