METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

009462-TDS-ENG-2025

AMLODIPINA 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: C20H25N2O5Cl·C6H6O3S	ARTICLE CODE: 009462

ATTRIBUTES	SHOULD BE
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	-0.10º / +0.10º
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 11.0

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.