METAPHARMACEUTICAL IND SL
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AMLODIPINA BESILATO (EUR. PH.)

PRODUCT CODE: 009462	CAS Nº: 111470-99-6	ANALYSIS Nº: 119/25	
MANUFACTURER BATCH:	AL24050063	CERTIFICATE ID:	46.372
SUPPLIER BATCH:	----	MANUFACTURING DATE:	01/05/2024
METAPH BATCH:	0050525	RETEST DATE:	30/04/2029

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol, slightly soluble in 2-propanol	Complies (*)
Identification	Complies	Complies
Optical rotation	-0.10º / +0.10º	0.00 º
Related substances		
Impurity D	=< 0.3 %	< 0.05 %
Impurity A	=< 0.15 %	Not Detected
Impurity E	=< 0.15 %	Not Detected
Impurity F	=< 0.15 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.8 %	< 0.05 %
Water	=< 0.5 %	0.01 %
Sulfated ash	=< 0.2 %	0.12 %
Assay	97.0 - 102.0 %	101.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

All data controlled by Metapharmaceutical Industrial SL.
(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 27/06/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000272
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