



AMINOFILINA ANHIDRA (EUR. PH.)

PRODUCT CODE: 46433147	CAS Nº: 317-34-0	ANALYSIS Nº: 151/25
MANUFACTURER BATCH: 032406050	CERTIFICATE ID: 46.693	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 28/06/2024	
METAPH BATCH: 0380525	RETEST DATE: 27/06/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly yellowish powder, sometimes granular, hygroscopic	White powder, sometimes granular, hygroscopic
Identification A	Complies	Complies
Identification C	Complies	Complies
Identification E	Complies	Complies
Appearance of solution	Complies	Complies
Related substances		
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.10 %	< 0.05 %
Water	=< 1.5 %	0.8 %
Sulfated ash	=< 0.1 %	0.09 %
Assay		
Theophylline	84.0 - 87.4 %	84.5 %
Ethylenediamine	13.5 - 15 %	13.6 %

COMPLIES WITH

European Pharmacopoeia 11.1

REMARKS

Aminophylline 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.

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

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

Analysis date: 03/07/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001553
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