



## TECHNICAL DATA SHEET

46433147-TDS-ENG-2025

AMINOFILINA ANHIDRA (EUR. PH.)		
DESCRIPTION DCI: AMINOPHYLLINE		DESCRIPTION DOE: AMINOFILINA
CAS Nº: 317-34-0	EC Nº: 206-264-5	AEMPS CODE: 384A
MOL. WEIGHT: 420,4	MOL. FORMULA: C <sub>16</sub> H <sub>24</sub> N <sub>10</sub> O <sub>4</sub>	ARTICLE CODE: 46433147

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish powder, sometimes granular, hygroscopic
Solubility	Freely soluble in water (the solution becomes cloudy through absorption of carbon dioxide), practically insoluble in anhydrous ethanol
Identification A	Complies
Identification C	Complies
Identification E	Complies
Appearance of solution	Complies
Related substances	
Unspecified impurities	=< 0,10 %
Total impurities	=< 0,10 %
Water	=< 1,5 %
Sulfated ash	=< 0,1 %
Assay	
Theophylline	84,0 - 87,4 %
Ethylenediamine	13,5 - 15 %

### COMPLIES WITH

European Pharmacopoeia 11.1

### STORAGE

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

### 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".

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.