

TECHNICAL DATA SHEET

01694-TDS-ENG-2025

TEOFILINA PURA ANHIDRA (EUR. PH.)		
DESCRIPTION DCI: ANHYDROUS THEOPHYLLINE		DESCRIPTION DOE: TEOFILINA ANHIDRA
CAS Nº: 58-55-9	EC Nº: 200-385-7	AEMPS CODE: 365ZU
MOL. WEIGHT: 180,16	MOL. FORMULA: C ₇ H ₈ N ₄ O ₂	ARTICLE CODE: 01694

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, sparingly soluble in ethanol (96 %). It dissolves in solutions of alkali hydroxides, in ammonia and in mineral acids
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and colourless
Acidity	=< 1.0 mL 0.01 M NaOH
Related substances	
Impurity A	=< 0.1 %
Impurity B	=< 0.1 %
Impurity C	=< 0.1 %
Impurity D	=< 0.1 %
Any other impurity	=< 0.1 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

Preserve in well-closed containers. Store in a cool and well-ventilated place.

REMARKS

Theophylline is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

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.