

**TEOFILINA PURA ANHIDRA (EUR. PH.)**

PRODUCT CODE: 01694	CAS Nº: 58-55-9	ANALYSIS Nº: 162/23
MANUFACTURER BATCH: 21018	CERTIFICATE ID: 38.620	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 06/01/2021	
METAPH BATCH: 0050623	RETEST DATE: 01/01/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, crystalline powder	White crystalline powder
Identification B	Complies	Complies
Identification D	Complies	Complies
Appearance of solution	Clear and colourless	Clear and colourless
Acidity	=< 1.0 mL 0.01 M NaOH	0.08 mL 0.01 M NaOH
Related substances		
Impurity A	=< 0.1 %	Not Detected
Impurity B	=< 0.1 %	< 0.05 %
Impurity C	=< 0.1 %	Not Detected
Impurity D	=< 0.1 %	No Detected
Any other impurity	=< 0.1 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.05 %
Sulfated ash	=< 0.1 %	0.07 %
Assay	99.0 - 101.0 %	100.9 %

**COMPLIES WITH**

European Pharmacopeia 11.0

**REMARKS**

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

(\*) 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**

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

Analysis date: 21/07/2023  
Signature: Cristina Borrell Olea (QA/QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000462  
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