METAPHARMACEUTICAL IND SL
Josep Plà, 163, 2n 5a / Tel. 933 089 976 / info@metapharmaceutical.com

TEOFILINA PURA ANHIDRA (EUR. PH.)

PRODUCT CODE: 01694	CAS Nº: 58-55-9	ANALYSIS Nº: 249/25	
MANUFACTURER BATCH:	23019	CERTIFICATE ID:	47.738
SUPPLIER BATCH:	----	MANUFACTURING DATE:	09/01/2023
METAPH BATCH:	0470725	RETEST DATE:	30/01/2028

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	0.025 mL 0.01 M NaOH
Related substances		
Impurity A	=< 0.1 %	Not Detected
Impurity B	=< 0.1 %	Not Detected
Impurity C	=< 0.1 %	< 0.05 %
Impurity D	=< 0.1 %	Not Detected
Any other impurity	=< 0.1 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.04 %
Sulfated ash	=< 0.1 %	0.02 %
Assay	99.0 - 101.0 %	100.6 %

COMPLIES WITH

European Pharmacopeia 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.

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

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

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

Analysis date: 08/10/2025
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000462
SHANDONG XINHUA PHARMACEUTICAL Co., Ltd.
14 Dongyi Road
3703 Zhangdian, Zibo City
Shandong Province(Xina)