

CERTIFIED REFERENCE MATERIAL Organic substance

Ref No: CM 51753
Barcode: 41588536

Lot No: 1140947

Certification Date: 31.07.2025
Expiry date: 31.08.2027

Description: Amoxicillin trihydrate

CAS No: 61336-70-7

Empirical formula: $C_{16}H_{19}N_3O_5S_3H_2O$

MW: 419.45

Certified Purity / Uncertainty: 0.9924 +/- 0.0018 g/g (99.24 +/- 0.18 %)

Purity=100% - Assay organic impurities

Storage Conditions: Store in a refrigerator at temperatures between 2°C to 8°C

Method of certification:	Concept of Certification and traceability statement:	Intended use:	Instructions for the correct use of this reference material:	Stability and storage:	Level of homogeneity:
CRM's calibration procedure (WQP 5.15.1/22).The following methods of analysis are used to determine purity (acc. to ISO 33407:2024): Characterization using indirect methods	The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k = 2$, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EA 4/02. Metrological traceability is established through in-house validated method. The measurement results are traceable to SI .	For Laboratory Use Only. This CRM is intended for: Calibration of TLC, GC/FID, GC/TCD, GC/ECD, GC/MS, GC/MS/MS, LC/UV, LC/MS and LC/MS/MS. Validation of analytical methods. Preparation of "working reference samples". Detection limit and linearity studies. This statement is not intended to restrict the use for other purposes.	This CRM can be used directly or can be diluted in an appropriate solvent. Only a clean glassware should be used. Hazardous situation: The normal laboratory safety precautions should be observed when working with this CRM. Further details for the handling of this chemical are available as safety data sheet.	This CRM is with a guaranteed purity +/- 2% deviation prior to the expiration date. Stability is guaranteed, provided that the material is kept in its original packaging, tightly closed stored, as written in the section: Storage Conditions.	The material was tested for homogeneity by analyzing randomly selected samples according to an in-house procedure. The level of homogeneity proved satisfactory for a sample volume of min. 2 mg. The uncertainty incorporates the sample standard deviation combined with the uncertainty calculated from homogeneity and stability studies.

This certificate relates solely to the lot number given above.

All processes (including generating of this certificate) are completely controlled by the specialized Computer-Aided-Manufacturing (CAM) software.

This Certified Reference Material was produced under a quality management system that is:

- Registered to ISO 9001 Quality Management System (Lloyd's Register Quality Assurance Ltd Cert No 0039638)
- Accredited according to ISO/IEC 17025
- Accredited according to ISO 17034

This document is designed and the certified value and uncertainty are determined in accordance with ISO 33401, ISO 33405, and Eurachem / CITAC Guides

Signed by:



Manufacturing Manager

Analytical Data:

ESI Conditions		Time	Gradient Elution	
			A%	B%
Capillary Voltage:	4000 V	0	80	20
Drying Gas Flow:	10 l/min	3	50	50
Drying gas temperature:	350°C	5	50	50
Nebulizer Pressure:	40 psig	8	80	20
Quad temp:	100°C	10	80	20
LC Conditions				
Column:	Agilent Poroshell 120 EC-C18 3x50 mm, 2.7µm			
Column temp.:	30°C			
Flow rate:	0.5 ml/min			
Injection volume:	1µl			
Mobile phase:	A: 0.1 % Formic acid B: Acetonitrile			

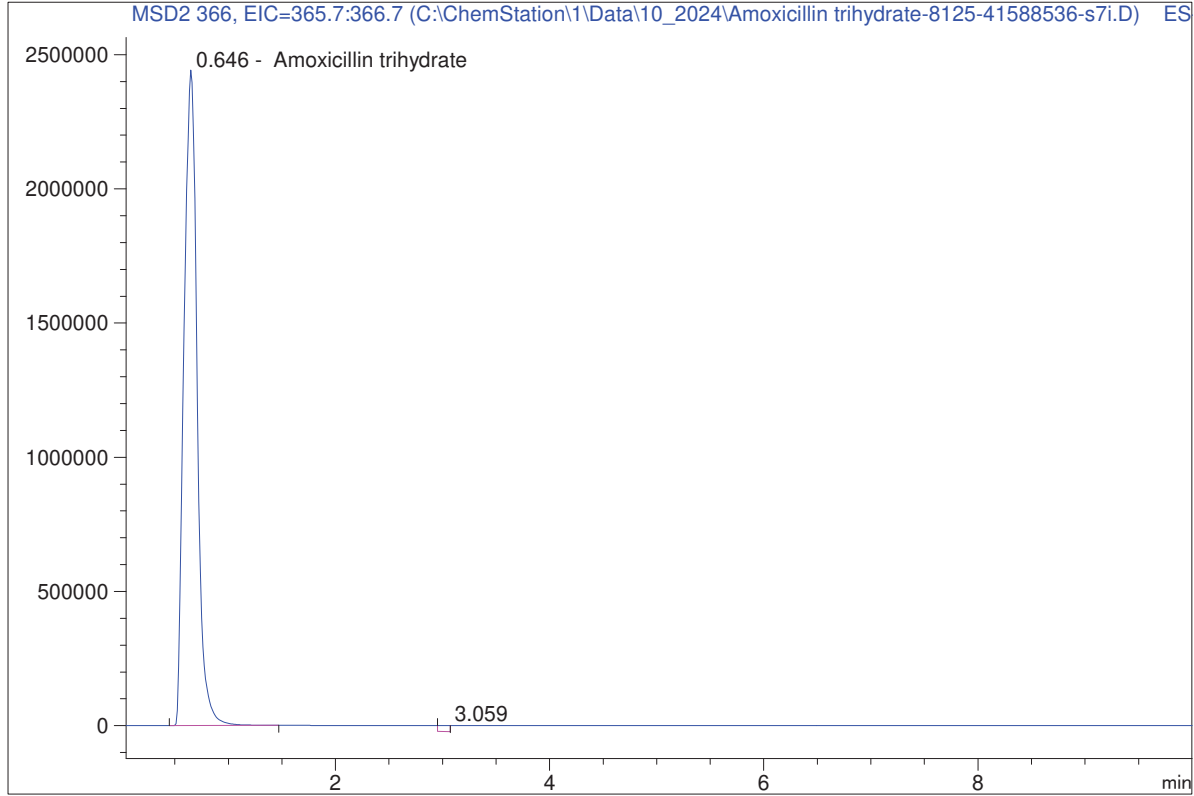
Sample Name: Amoxicillin trihydrate-812->

Location:P1-F4

Inj. Vol.:1 µl

Acq. Method:C:\ChemStation\1\Methods\CAPORGAN.M

Analysis Method: C:\CHEMSTATION\1\METHODS\CAPORGAN_CALC.M



Signal 1: MSD2 366, EIC=365.7:366.7

Name	Height	Area	Area %
Amoxicillin trihydrate	2.436e6	2.088e7	99.230
	2.303e4	1.620e5	0.770