

Certificate of Analysis

CERTIFIED REFERENCE MATERIAL Organic substance

Ref No: SB46334.250MG **Lot No:** XXXXXX

Certification Date: XXXXXXXXXXXX

Barcode: XXXXXXXXX

Description of the Reference Material (CRM): Cloxacillin Sodium Salt Monohydrate

CAS No: 7081-44-9

Empirical formula: C₁₉H₁₇ClN₃NaO₅S·H₂O

MW: 475.88

Certified Purity/ Uncertainty: 97.7 +/- 0.1 %

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

Expiry date: XXXXXXXXXXXX

Method of certification: CRM's calibration procedure (WQP 5.15.1/22)

The following methods of analysis are used to determine purity: HPLC

Analytical Data:

Parameter	Value	Gradient elution (time):	A%	B%
Column:	Allure C18, 4.6x250 mm, 5µm particle size			
Mobile phase:	A: 0.14 % H ₃ PO ₄ in water B: Acetonitrile	0 30	90 10	10 90
Flow rate:	1.0 ml/min	33	10	90
Column temperature:	30 °C	35	90	10
Injection volume:	10µl	37	90	10
Detector	DAD			

Concept of Certification and traceability statement:

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.

Intended use:

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.

Instructions for the correct use of this reference material:

This CRM can be used directly or can be diluted in an appropriate solvent. Only a clean glassware should be used.

Stability and storage:

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. Product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to ampoules stored after opening.

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.

Level of homogeneity

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 Guide 31, ISO Guide 35, and Eurachem / CITAC Guides

Names of certifying officers:

Laboratory:  Margarita Dimitrova

Manager:  Krassimira Taralova

End

Peak Integration Report

Sample Name:	Cloxacillin Sodium Salt Monohydrate-7459-41456132	Inj. Vol.:	10.00
Injection Type:	Unknown	Dilution Factor:	1.0000
Instrument Method:	Allure_C18_10% B_new	Operator:	org_spec2
Inj. Date / Time:	14-Mar-2022 / 18:10	Run Time:	35.00

No.	Time min	Peak Name	Peak Type	Area mAU*min	Height mAU	Rel.Area %
7	15.97	Cloxacillin Sodium Salt Mor	BMB*	58.388	559.877	97.71
TOTAL:				58.39	559.88	97.71

