

CERTIFIED REFERENCE MATERIAL Organic substance

Ref No: SB34960.100MG

Lot No: XXXXXX

Certification Date: XXXXXX

Barcode: XXXXXXXXX

Description of the Reference Material (CRM): Roxithromycin

CAS No: 80214-83-1

Emperical formula: C₄₁H₇₆N₂O₁₅

MW: 837.03

Certified Purity/ Uncertainty: 98.9 +/- 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/MS (Purity=100% - Assay impurities)

Analytical Data:

LC Conditions:

		Gradient elution		
		Time	A%	B%
Column	Agilent Poroshell 120 EC-C18 3x50 mm, 2.7 µm			
Mobile phase	A: 0.1 % Formic acid B: Acetonitrile			
Flow rate	0.5 ml/min	0	80	20
Injection volume	1 µl	3	50	50
Column temp.	30°C	5	50	50
		8	80	20
		10	80	20

ESI Conditions:

Drying Gas Flow	10 l/min	Nebulizer Pressure	40 psig
Capillary Voltage	4000 V	Drying gas temperature	350°C
Quad temp	100°C		

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



CPAchem Ltd. is ISO 17034 (Cert No AR-1835)
and ISO/IEC 17025 (Cert No AT-1836) accredited by ANAB



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.

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

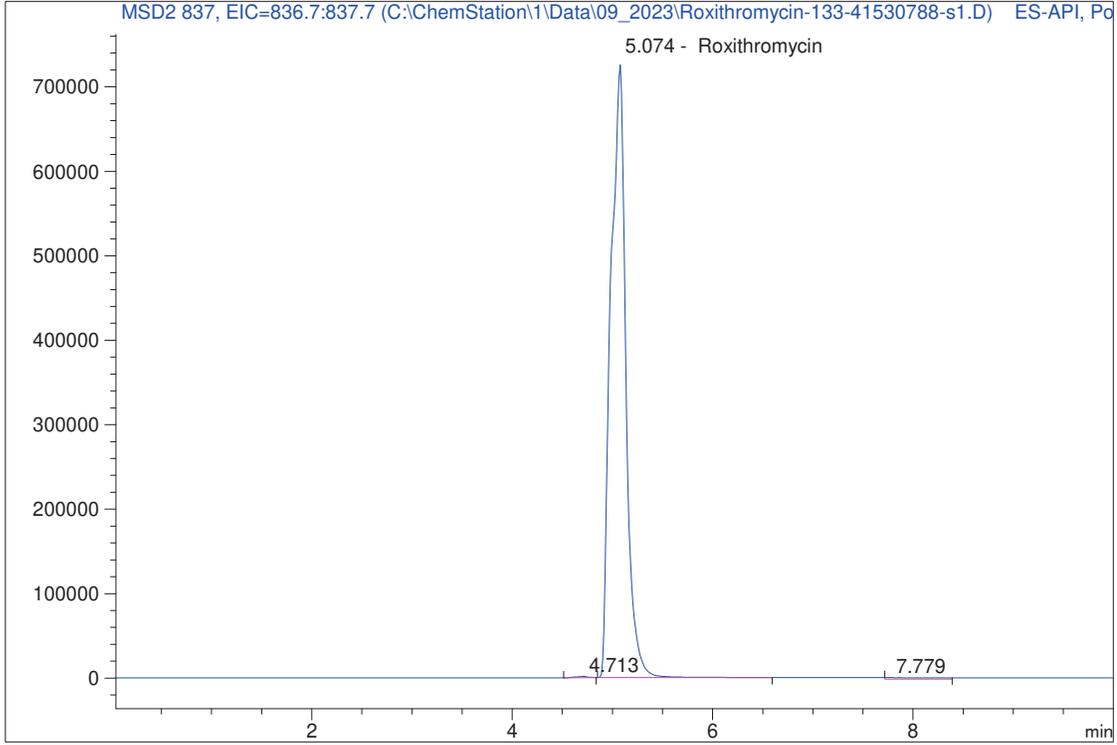
End

Sample Name: Roxithromycin-133-41530788-> Location:P1-B1

Inj. Vol.:1 µl

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

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



Signal 1: MSD2 837, EIC=836.7:837.7

Name	Height	Area	Area %
	1.496e3	1.229e4	0.159
Roxithromycin	7.345e5	7.657e6	99.000
	1.630e3	6.501e4	0.841