

CERTIFIED REFERENCE MATERIAL

1 component: Dexmedetomidine Hydrochloride as Dexmedetomidine [CAS:145108-58-3] 1g/l in Methanol

Lot N: 0819290
Barcode: 93511087

Ref N: 38806

Certification Date: 23 Mar 2026

Component	Certified Value* and uncertainty [µg/ml]	CAS	Chemical Formula
Dexmedetomidine Hydrochloride as Dexmedetomidine	1001.4 ± 9.5	145108-58-3	C ₁₃ H ₁₇ ClN ₂

* WQP 5.15.1.24 The certified value was obtained by a weighted mean of the results of two independent testing methods among: Primary Gravimetric and Instrumental (GC/MS or HPLC)

Density 0.7872 g/cm³ at 20°C

Starting Material	Purity, Batch
Dexmedetomidine Hydrochloride	99.59% (41655719)

Storage Conditions: Store in a freezer at -18°C or below

Expiry Date: 23 Apr 2028

Concept of Certification and traceability statement:

This certified reference material is produced by gravimetric measurement and directly dissolving the individual substances in the corresponding solvent, when such is needed. In case direct dissolution is not possible, the individual substances are pre-dissolved in a suitable solvent and then gravimetrically added into the solution.

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 and incorporates the uncertainties of the raw-material purity, the mass and the volume.

The metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".

The metrological traceability is ensured through gravimetric measurement and dissolving of certified reference material/s (traceable to SI) from laboratories/producers, accredited according to ISO 17034.

The measurement results are traceable to SI. All analytical balances used for the preparation of the solution are calibrated yearly under an in-house procedure with class E1 and class E2 analytical weights, traceable to SI (DKD), and are checked daily.

Class A laboratory glassware is used.

The results from temperature measurement are traceable to SI. The thermometers used for solution's calibration are calibrated from an ISO 17025 accredited laboratory. The ambient conditions are controlled with a hygrometer calibrated from an ISO 17025 accredited laboratory.

Both, purity of the starting materials and solvent, were checked using appropriate analytical instrument.

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 certified reference material:

The CRM should be used shortly after opening to avoid concentration changes due to evaporation.

It is recommended to use 1 ml as the minimum sample size.

This CRM can be used directly or can be diluted in an appropriate solvent. Only a clean class A glassware should be used. Obtained concentration (in mg/l) after dilution is a result from the multiplication of certified value of CRM concentration and the CRM's volume used for dilution and divided into the flask's volume used for dilution. For quantitative analysis, we recommend analyzing this mixture separately, without mixing it with other solutions, to ensure accurate results for every compound.

Stability and storage:

This CRM is with a guaranteed stability until $\pm 5\%$ of the certified concentration for a period of 24 months. Stability is guaranteed of an unopened original packaging stored, as written in the section: Storage Conditions. Even if the product is stable at normal laboratory conditions, in order to increase its stability, we highly recommend it to be stored in a refrigerator. The product should be used shortly after opening to avoid concentration changes due to evaporation. Warranty does not apply to a product stored after opening.

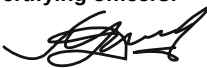
Hazardous situation:

The normal laboratory safety precautions should be observed when working with this RM. Further details for the handling of this RM are available in a safety data sheet.

Level of homogeneity

This solution was mixed according to an in-house procedure (MQP 5.13.1) and is guaranteed to be homogeneous. To ensure sufficient homogeneity of the sample prior to use thoroughly mix by inversion or sonicate.

Names of certifying officers:

Laboratory:  Margarita Dimitrova

Manager:  Krassimira Taralova

This document QF 5.17.1/1 version 1 is designed and the certified value(s) and uncertainty(ies) are determined in accordance with ISO 33401, ISO 33405, and Eurachem / CITAC Guides

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

Additional Information

Analytical Data:

LC Conditions:

Column	Thermo Synchronis C18 (100 x 2.1 mm, 3 μ m)	Gradient elution		
Mobile phase	A: Water (add 0.1 % HCOOH) B: Acetonitrile (add 0.1 % HCOOH)	Time (min)	A%	B%
Flow rate	0.4 ml/min	0	95	5
Injection volume	1 μ l	11	0	100
Column temp.	30°C	12	0	100
		13	95	5
		16	95	5

MS Parameters:

Sheath Gas (Arb)	35	Ion Transfer Tube temp	300°C
Aux Gas (Arb)	10	Vaporizer temp	370°C

Gravimetric Data

Component	Purity %	Source Lot No	Weighed quantity, g	Final quantity, g	Bulk/Standard Solution lot No	Concentration mg/kg	Chemist ID
Dexmedetomidine Hydrochloride	99.59	41655719	0.11881	78.718	93511087	1503.13	EB

1213688-01_3202026_028

Sample Name: 93511087

Dexmedetomidine Hydrochloride

Q 201.0100>94.9000 (+)

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