

CERTIFIED REFERENCE MATERIAL

1 component: Duloxetine Hydrochloride as Duloxetine [CAS:136434-34-9] 1g/l in Methanol

Lot N: 0809627
Barcode: 93381369

Ref N: 40160

Certification Date: 11.07.2025

Component	Certified Value* and uncertainty [µg/ml]	CAS	Chemical Formula
Duloxetine Hydrochloride as Duloxetine	1001.7 ± 9.4	136434-34-9	C ₁₈ H ₂₀ ClNO ₂

* WQP 5.15.1/2 The certified value was obtained gravimetrically and confirmed experimentally by GC/MS or HPLC

Density 0.7859 g/cm³ at 20°C

Starting Material	Purity, Batch
Duloxetine Hydrochloride	97.5% (41540299)

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

Expiry Date: 11.08.2027

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/TCO, 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:

This CRM can be used directly or can be diluted in an appropriate solvent. Only a clean class A glassware should be used. Do not pipet from container.

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 ±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.



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

Produced by:
CPAchem Ltd
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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 µm)	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 µl	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
Duloxetine Hydrochloride	97.5	41540299	0.11533	78.593	93381369	1430.75	DG

Results File: C:\LabSolutions\Data\2025\07_2025\1135739-02\1135739-02.iproc - 1135739-02.lcm

1135739-02_7102025_001**Duloxetine Hydrochloride-2**

Conc. 122.4616

Area 793680

Q 298.10>44.00 (+)

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