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CERTIFIED REFERENCE MATERIAL

Certificate of Analysis
chromatographic plus



FOR LABORATORY USE ONLY-READ SDS PRIOR TO USE.

This Reference Material is intended for Laboratory Use Only as a standard for the qualitative and/or quantitative determination of the analyte(s) listed.

Catalog No. : 34081 **Lot No.:** A0212973
Description : Dextromethorphan HBr Monohydrate Standard
Dextromethorphan HBr Monohydrate 1mg/mL, Methanol, 1mL/ampul
Container Size : 2 mL **Pkg Amt:** > 1 mL
Expiration Date : June 30, 2027 **Storage:** 10°C or colder
Handling: This product is photosensitive. **Ship:** Ambient

CERTIFIED VALUES

Elution Order	Compound	CAS #	Lot #	Purity	Grav. Conc. (weight/volume)	Expanded Uncertainty * (95% C.L.; K=2)
1	Dextromethorphan HBr Monohydrate	6700-34-1	3-EOD-175-1	76%	1.0 mg/mL	+/- 0.0126

* Expanded Uncertainty displayed in same units as Grav. Conc.

Solvent: Methanol
CAS # 67-56-1
Purity 99%

Quality Confirmation Test

Column:
150mm x 4.6mm
Allure C18 Cat. (#9164565)

Flow Rate:
1.0 ml/min.

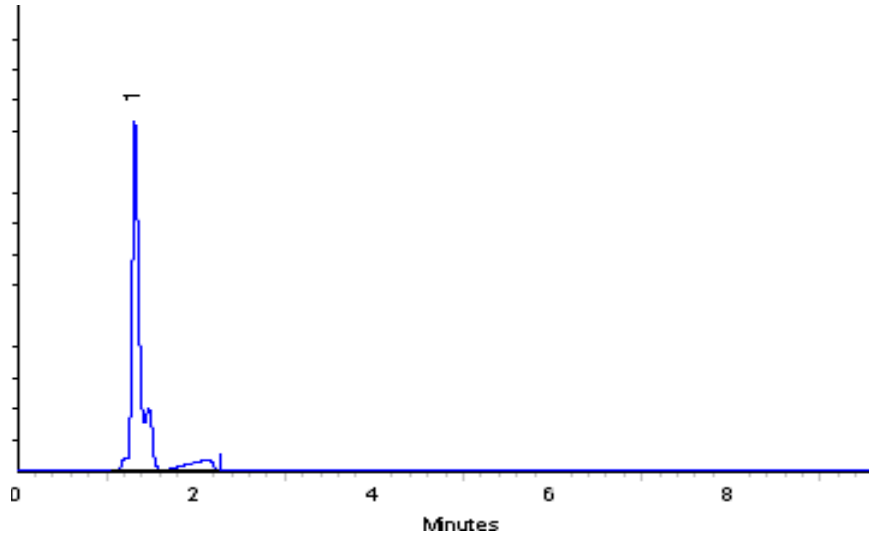
Mobile Phase A:
0.14% H3PO4 in water

Mobile Phase B:
acetonitrile

Mobile Phase Composition:
90%B Isocratic

Det. Type:
Wavelength: 220 & 254 nm

Inj. Vol
5µl



This chromatogram represents a general set of testing conditions chosen for product acceptance. For optimal results in your lab, conditions should be adjusted for your specific instrument, method, and application.


Rebecca Gingerich - Operations Tech II

Date Mixed: 19-Jun-2024

Balance Serial # 1127510105


Jennifer Pollino - Operations Tech III - ARM QC

Date Passed: 25-Jun-2024

Manufactured under Restek's ISO 9001:2015
Registered Quality System
Certificate #FM 80397

General Certified Reference Material Notes

Expiration Notes:

- Expiration date valid for unopened ampul stored in compliance with the recommended conditions.
- Uncertainty, concentration, and expiration of the CRM are based on the unopened product being stored according to the recommended condition found in the storage field.

Purity Notes:

- Purity and/or chemical identity are determined by one or more of the following techniques: GC/FID, HPLC, GC/μECD, GC/MS, LC/MS, RI, and/or melting point.
- Compounds with a listed purity of less than 99% have been weight corrected to compensate for impurities and/or salts. A correction factor is used to calculate the amount of compound necessary to achieve the desired concentration of the parent compound in solution.
- Purity of isomeric compounds is reported as the sum of the isomers.
- Purity values are rounded to the nearest whole number.

Certified Uncertainty Value Notes:

- The uncertainties are determined in accordance with ISO 17034 and Guide 35. The certified expanded uncertainty value includes gravimetric uncertainty, homogeneity between-ampul uncertainty, storage stability uncertainty and shipping stability uncertainty and were combined using the following formula:

$$U_{combined\ uncertainty} = k \sqrt{u_{gravimetric}^2 + u_{homogeneity}^2 + u_{storage\ stability}^2 + u_{shipping\ stability}^2}$$

k is a coverage factor of 2, which gives a level of confidence of approximately 95%.

- The packaged amount is the minimum sample size for which uncertainty is valid. The ampuls are over-filled to ensure that the minimum packaged amount can be sufficiently transferred.

Manufacturing Notes:

- Concentration is based upon gravimetric preparation using either a balance whose calibration has been verified daily using NIST traceable weights, and/or dilutions with Class A glassware.

Handling Notes:

- Stability of the unopened product, when stored in compliance with the recommended conditions, is guaranteed through the expiration displayed on the product label and certificate. Contact Restek for additional opened product stability information, with the knowledge/understanding that open product stability is subject to the specific handling and environmental conditions to which the product is exposed. For your convenience Restek supplies deactivated vials with most standards packed in 2mL ampuls. Larger volume deactivated vials are available through Restek as a custom ordered item. Additionally, Restek sells DMDCS for the purpose of glassware deactivation as catalog number 31861, which includes complete instructions.
- If any undissolved material is visible inside the ampul, sonicate the unopened ampul until the material is completely dissolved.