

CERTIFIED REFERENCE MATERIAL











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www.restek.com

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. :	34002	Lot No.: <u>A0211883</u>					
Description :	Hydrocodone Standard						
	Hydrocodone 1000μg/mL, P&T Methanol, 1mL/ampul						
Container Size :	2 mL	Pkg Amt:	> 1 mL				
Expiration Date :	May 31, 2026	Storage:	10°C or colder				
		Ship:	Ambient				

CERTIFIED VALUES

Elution Order	Compound	CAS#	Lot #	Purity	Grav. Conc. (weight/volume)	Expanded Uncertainty * (95% C.L.; K=2)
1	Hydrocodone bitartrate hemi-pentahydrate	34195-34-1	1DE0512	60%	1,008.0 μg/mL	+/- 12.7812

^{*} Expanded Uncertainty displayed in same units as Grav. Conc.

Solvent: P&T Methanol CAS# 67-56-1

Purity 99%

Quality Confirmation Test

Column:

 $30m\,x\,0.25mm\,x\,0.25\mu m$ Rtx-5 (cat.#10223)

Carrier Gas:

hydrogen-constant pressure 10 psi.

Temp. Program:

75°C (hold 1 min.) to 330°C @ 20°C/min. (hold 10 min.)

Inj. Temp:

250°C

Det. Temp:

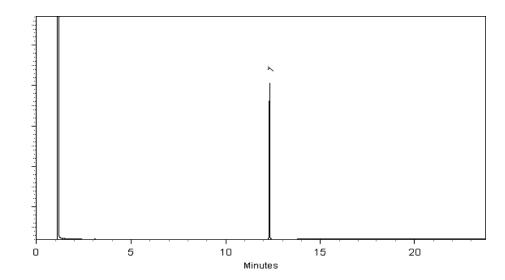
Det. Type:

Split Vent:

10 ml/min.

Inj. Vol

1μΙ



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.



Date Mixed:

22-May-2024

Balance Serial #

B251644995

Jennifer Pollino - Operations Tech III - ARM QC

Date Passed: 24-May-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.