

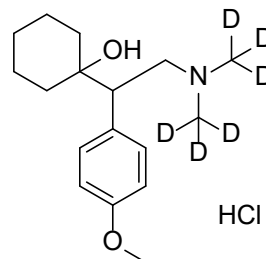
CERTIFICATE OF ANALYSIS



Venlafaxine-d₆ (hydrochloride) CRM
1-[2-[di(methyl-d₃)amino]-1-(4-methoxyphenyl)ethyl]-cyclohexanol,
monohydrochloride

Item #: 25525
Batch #: 0534197
CAS Registry Number: 1062606-12-5

Expiry: 21JUN2022 (valid from date of certification)
Provided as: 1 mg/mL (nominal, as free base) solution in methanol
Volume per ampule: not less than 1 mL
*Ampules are overfilled. It is advised that labs use measured volumes.
Storage and Handling: Store unopened at -20°C. Warm to RT prior to opening.
Safety: Flammable, Poison



ISO/IEC 17025
#AT-1773
ISO Guide 34
#AR-1774



Compound Information

Chemical Formula	C ₁₇ H ₂₁ D ₆ NO ₂ •HCl
Formula Weight	319.90 amu

Certified Concentration

Certified Concentration (as free base)	1.000 mg/mL ± 0.028 mg/mL
Concentration is calculated based on product mass (as free base), solution mass corrected purity and density at 20°C and is traceable to SI units through an unbroken chain of measurements.	
Uncertainty of concentration is expressed as and expanded uncertainty in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of k=2 and incorporates uncertainties from the corrected purity, solution preparation, homogeneity, long and short term stability.	
Concentration was verified by comparison to an independently prepared calibration standard.	

Neat Material Quality Information (Item: 15863 Batch: 0529830)

Qualifier	Method	Limit	Result	Meets Specification
Chromatographic Purity, HPLC	Cayman Method TST SD152	≥98.00%	99.34% ± 0.18%	Y
Identity, LCMS	Cayman Method TST SD13, +ESI	284.2 ± 0.5 amu	284.4 amu	Y
Identity, GCMS	Cayman Method TST SD12	Conforms	Conforms	Y
FTIR	USP<851> (diamond ATR)	Conforms	Conforms	Y
% LOD	Cayman Method TST SD24	≤5.00%	0.19% ± 0.50%	Y
% ROI	Cayman Method TST SD06	≤3.00%	0.27% ± 0.22%	Y
Isotopic Purity, LCMS (SIM)	Cayman Method TST SD154	<1.00%	<0.10% D ₀ vs. D ₆	Y
*Identity, NMR	¹ H NMR	Conforms	Conforms	Y
**Corrected Purity			98.88% ± 0.57%	

*NMR is provided as supplemental info but is not within scope of ISO accreditation

**Corrected purity is determined as follows: Corrected Purity = [(100 - % LOD - % ROI)*Chromatographic Purity/100]

Measurement Uncertainty

All measurement uncertainties are expressed as expanded uncertainties in accordance with ISO 17025 and Guide 34 at the approximate 95% confidence interval using a coverage factor of k=2.

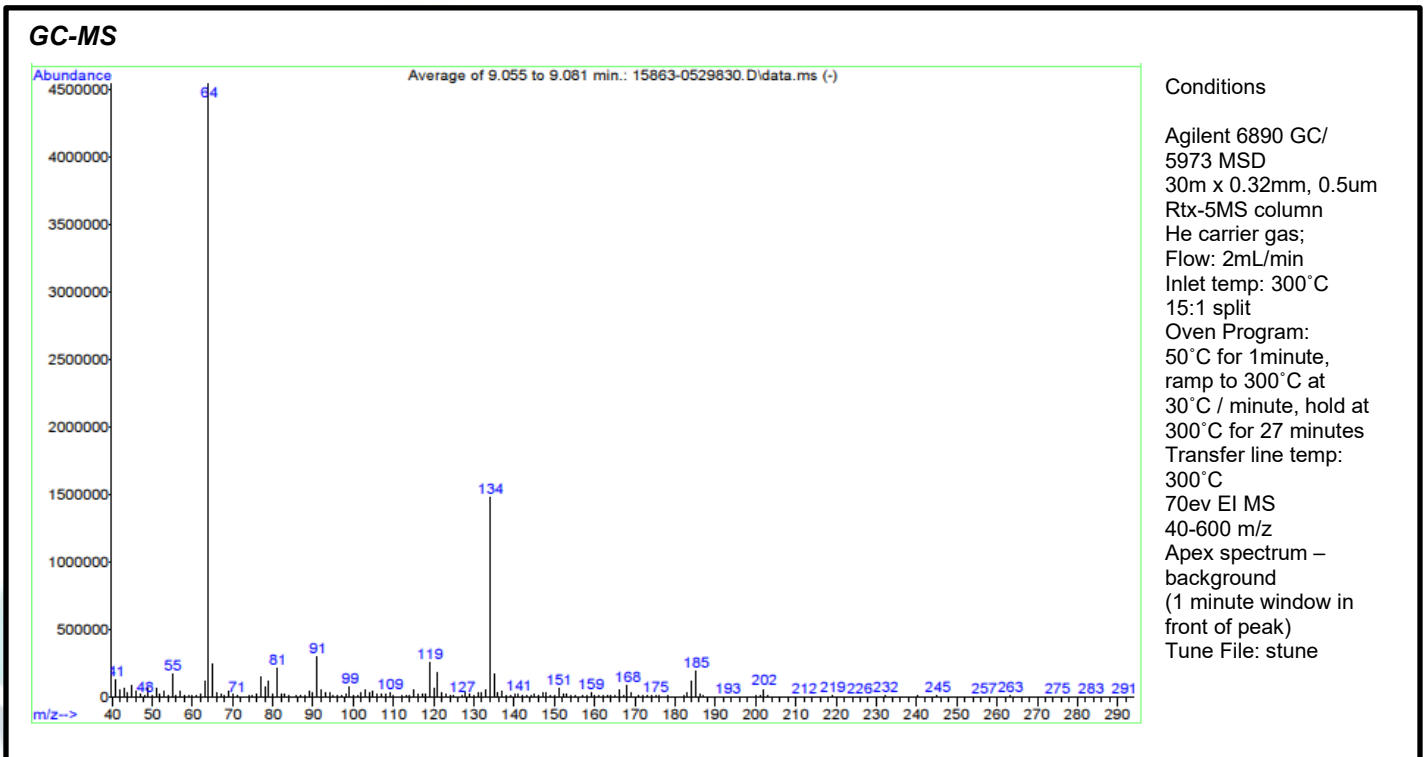
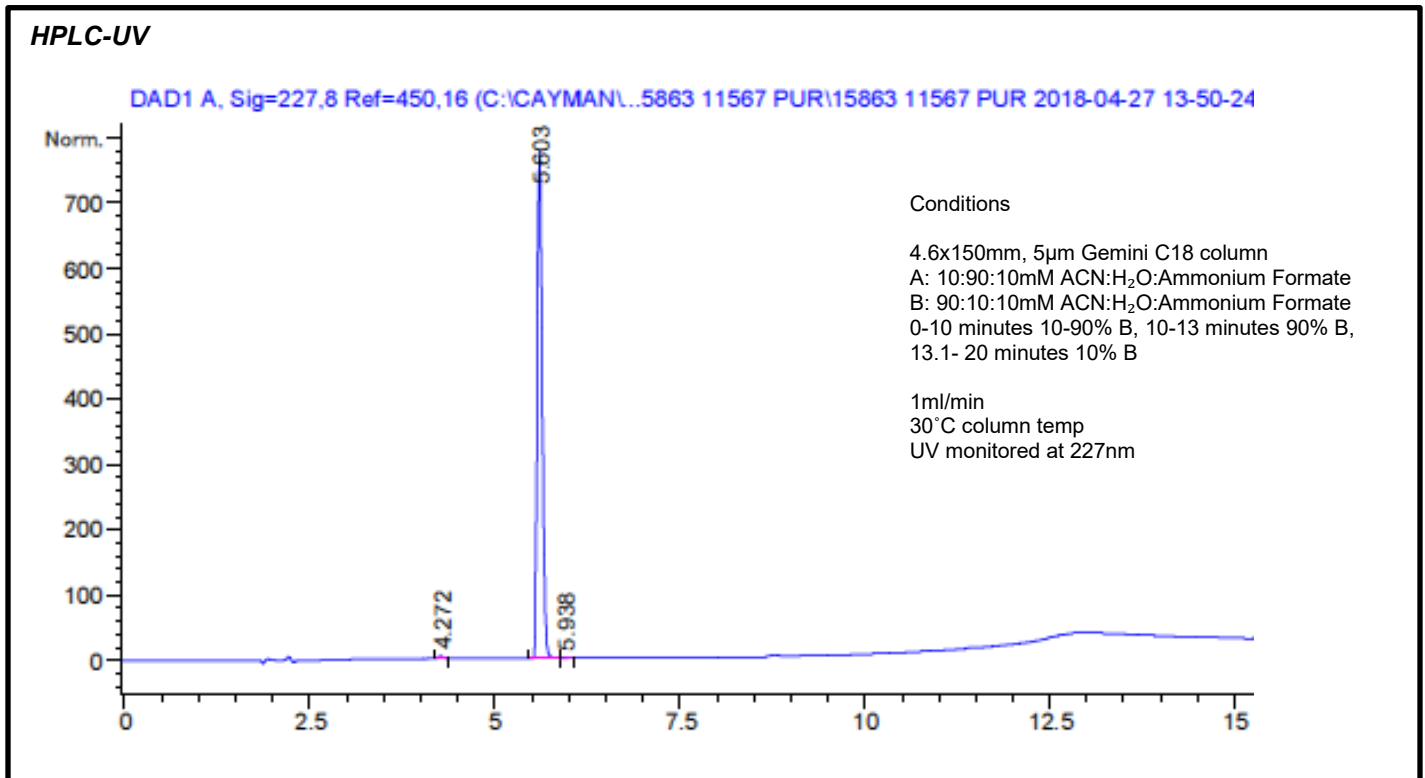
Cayman Chemical certifies that this standard meets the specifications stated in this certificate and warrants this product to meet the stated acceptance criteria through the expiration date when stored unopened as recommended.

Approval:

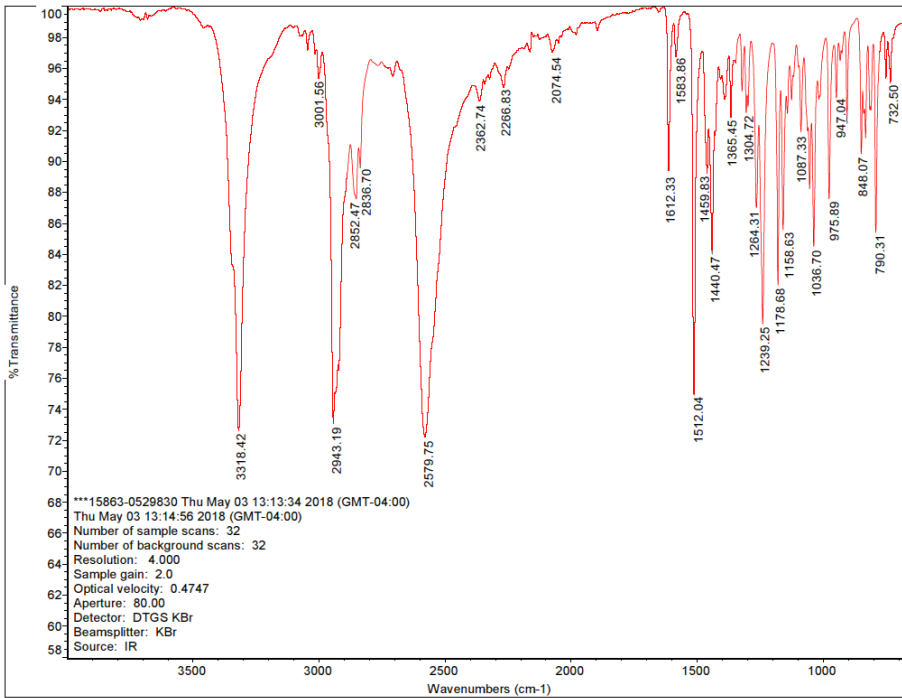
Title: Cayman Chemical ISO Quality Manager

Certification Date: 21JUN2018

Supplemental Data (Neat Material)



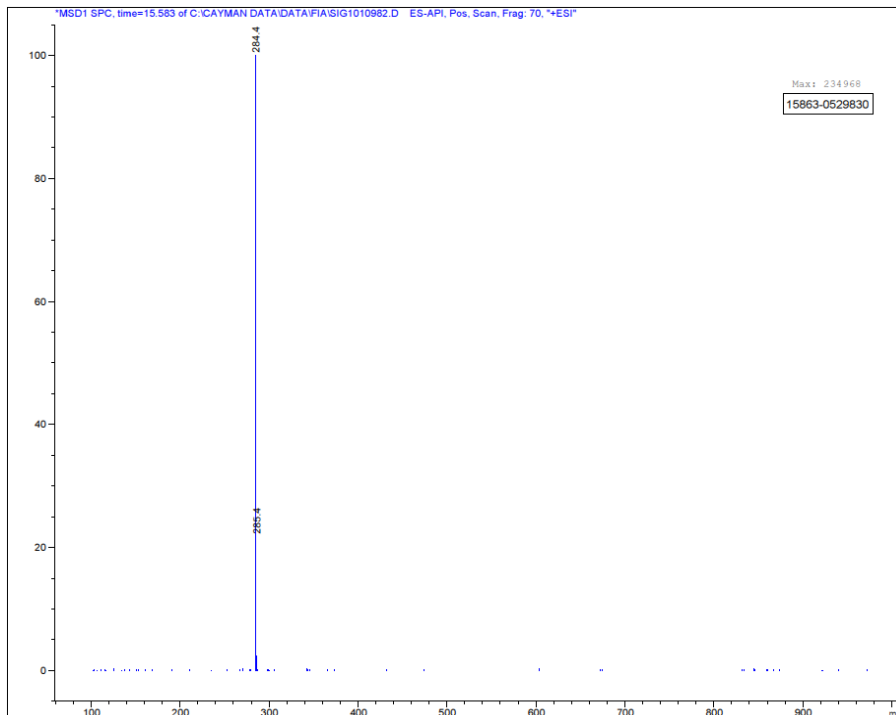
FTIR



Conditions

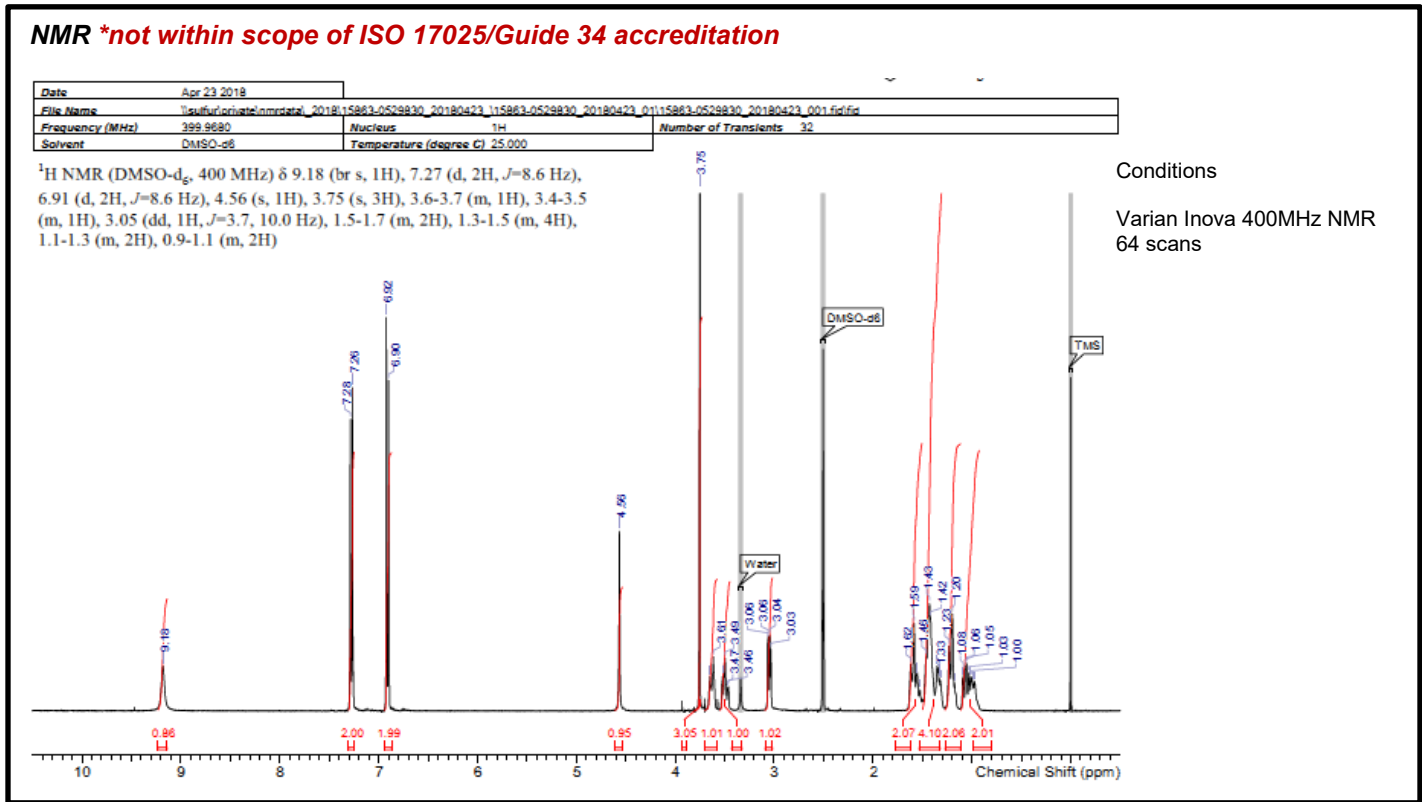
Thermo Nicolet iS10 FTIR /
Diamond SmartATR (single bounce)
32 scans / 32 background scans
Range: 650-4000cm⁻¹
Resolution: 4.000
ATR and background corrected

ESI-MS



Conditions

Agilent 1100 HPLC / G1956MSD
FIA-MS (no column)
Mobile phase: 50:50:0.1
MeOH/H₂O/acetic acid
Flow: 0.5mL/min
+ESI 100-1000m/z range
Nebulizer: 60psi
Desolvation Gas: 13L/min
Desolvation Temp: 350°C
Electrospray Voltage: 4kV
MS collected across peak width
at half height



Homogeneity

A minimum injection of 2.0 µg was used to determine homogeneity. Homogeneity was determined by HPLC from 12 randomly selected bottles from early, middle and late fill positions.

	Result	Acceptance Criteria
%RSD	2.04%	≤3%

The recommended minimum quantity for use is 2.0 µg. Quantities below this have not been evaluated.

Stability

The effect of the components of stability on the combined standard uncertainty of the CRM property value are considered negligible unless indicated in stability studies.

Short Term Stability

No decrease in the property value was observed at 60°C after 2 weeks. This data supports shipping of this product at ambient temperature. Uncertainty of short term stability has been deemed insignificant to the overall uncertainty.

Long Term Stability

Long term stability data predicts 4 years stability at the -20°C storage temperature. Long term stability studies are ongoing and the Certificate of Analysis will be updated upon study completion.

Cayman Chemical Co.

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For R&D purposes only. Not intended for human or animal use.

Revision History

Revision #	Date	Reason for Revision
01	21JUN2018	Initial Version
02	09DEC2020	Expiry extension

Disclaimers**Material Safety Data**

This material should be considered hazardous until information to the contrary becomes available. Do not ingest, swallow, or inhale. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling. This information contains some but not all of the information required for the safe and proper use of this material. Before use, review the complete Material Safety Data Sheet, which has been sent via email to your institution.

Warranty and Limitation of Remedy

Cayman Chemical Company makes no warranty or guarantee of any kind, whether written or oral, expressed or implied, including without limitation, any warranty of fitness for a particular purpose, suitability and merchantability, which extends beyond the description of the chemicals hereof. Cayman warrants only to the original customer that the material will meet our specifications at the time of delivery.

Cayman will carry out its delivery obligations with due care and skill. Thus, in no event will Cayman have any obligation or liability, whether in tort (including negligence) or in contract, for any direct, indirect, incidental or consequential damages, even if Cayman is informed about their possible existence.

This limitation of liability does not apply in the case of intentional acts or negligence of Cayman, its directors or its employees.

Buyer's exclusive remedy and Cayman's sole liability hereunder shall be limited to a refund of the purchase price, or at Cayman's option, the replacement, at no cost to Buyer, of all material that does not meet our specification.

Said refund or replacement is conditioned on Buyer giving written notice to Cayman within thirty (30) days after arrival of the material at its destination. Failure of Buyer to give said notice within thirty (30) days shall constitute a waiver of Buyer of all claims hereunder with respect to said material.

For further details, please refer to our Warranty and Limitations of Remedy located on our website and in our catalog.

This Certificate shall not be reproduced except in full, without written approval from the Cayman Chemical ISO Quality Manager

ISO CRT SD02 v 1.0

