BDG SYNTHESIS

Certificate of Analysis

This material is a research-grade material prepared by custom synthesis. The quantity available is limited, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of research-grade materials. Research materials often contain higher levels of residual solvents and/or water, and we urge you to use the corrected purity where needed rather than the raw HPLC purity.

BDG Synthesis certifies that this reference material meets or exceeds the specifications stated in this data sheet.

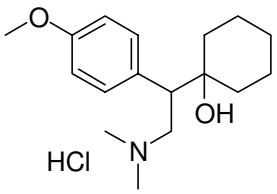
Barry Dent

Barry R. Dent, PhD, Director
26 April 2006

Name: Venlafaxine HCl

CAS Number: 99300-78-4

Structure:



Molecular Weight: $C_{17}H_{27}NO_2 \bullet HCl = 313.87$

Lot Number: BDG 5422

Appearance: White, crystalline solid

Purity by HPLC: 100 %

Expiry Date: 26 April 2007
Because of the small amount of material available it is not possible to perform formal storage stability studies. This expiry date is assigned from experience gained with the material in the laboratory and/or on storage.

Storage and Handling:
Temperature: ambient laboratory temperature; may be refrigerated.
Humidity: not believed to be hygroscopic; may be handled in normal laboratory atmosphere.
Light: protect from strong sunlight.
Caution: Only experienced laboratory personnel should handle the material.

• Custom synthesis of analytical reference standards, metabolites, stable isotope labelled compounds • Contract research • BDG Synthesis is a division of B Dent Global Limited

Mailing:
BDG Synthesis
PO Box 38 627, Wellington Mail Centre,
Wellington, New Zealand.

Shipping:
BDG Synthesis
Gracefield Research Centre, Building F,
Gracefield Road, Lower Hutt, New Zealand.

Phone: + 64 4 569 0520
Fax: + 64 4 569 0521

info@bdg.co.nz
www.bdg.co.nz

Identity and Purity:

Source of Material
The material was made by an unambiguous synthetic route, using literature procedures where possible; starting materials were purchased from reputable sources and all intermediates were checked for identity by NMR.

Proton NMR Spectrum
Identity: the signals are consistent with the proposed structure and in accord with literature where available.
Residual solvents: no residual solvents are observed.
Impurities: no significant impurities are evident in the spectrum.

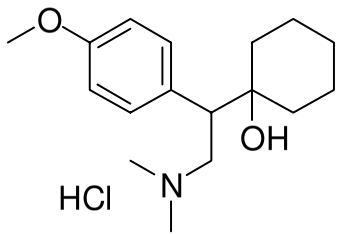
Carbon-13 NMR Spectrum
Identity: the signals are consistent with the proposed structure and in accord with literature where available.

High-resolution mass spectrum (ESI+): found *m/z* 278.2093. $C_{17}H_{28}NO_2$ $[M+H]^+$ requires *m/z* 278.2115. The deviation of 7.6 ppm is somewhat outside normally accepted limits for the establishment of identity by HRMS, and the mass spectral data should be considered in conjunction with other identity criteria.

HPLC: A broad, tailing peak is observed (100.0 area %). Note: in the absence of reference materials for preparing calibration curves, it is assumed that all peaks have the same detector response. Where possible, the conditions of analysis follow a pharmacopeial or literature method, or have been adapted from same.

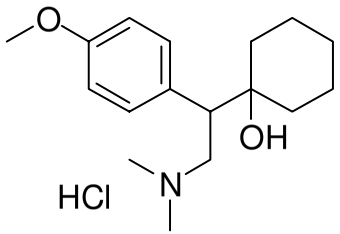
Elemental Analysis: Found: C 65.25, H 8.48, N 4.45 %
$C_{17}H_{27}NO_2 \bullet HCl$ requires: C 65.05, H 8.99, N 4.46 %
The elemental analyses fall within generally accepted limits (+/- 0.4 %) for establishing the molecular formula given, except the result for hydrogen. The results may also be taken to imply the absence of significant quantities of water or inorganic salts (which have not been elsewhere tested for because of sample size limitations).

BDG SYNTHESIS



Proton NMR spectrum of Venlafaxine HCl
(BDG 5422) in D_2O

BDG SYNTHESIS

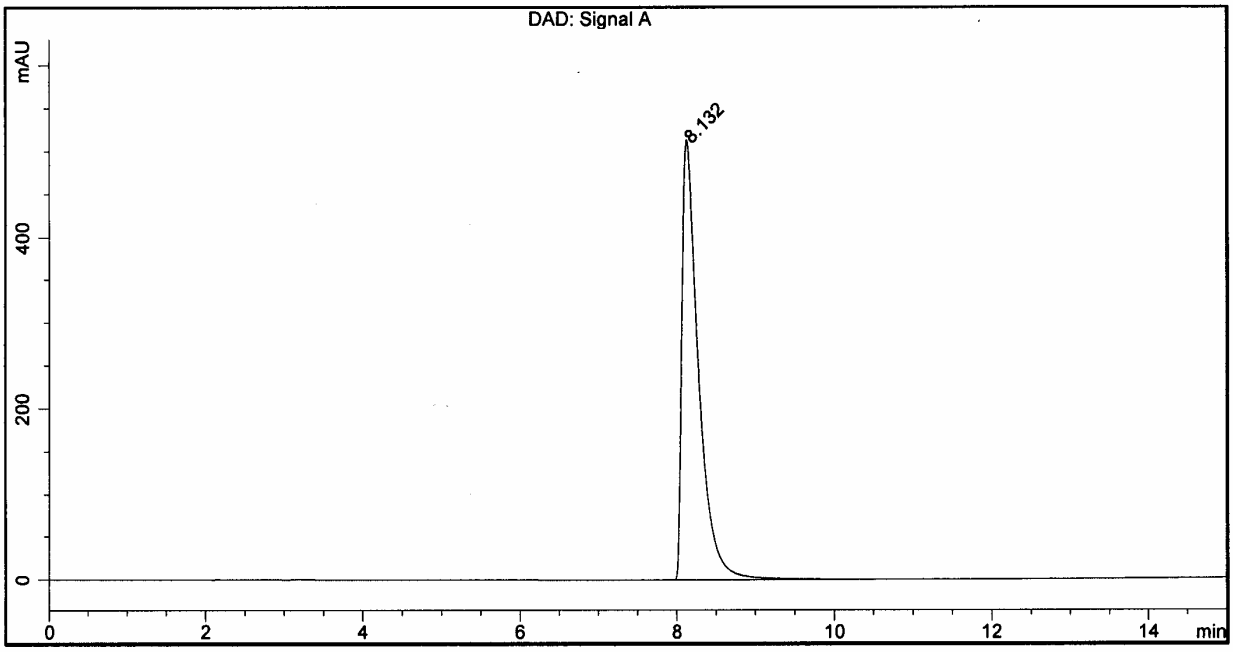


Carbon NMR spectrum of Venlafaxine HCl
(BDG 5422) in D_2O

BDG - Analysis of Venlafaxine

Column : Phenomenex Luna C18, 5um 250 x 4.6mm.
Guard : Phenomenex Security Guard C18 4 x 3
Mobile Phase A: Aqueous 20 mM KH2PO4, 20 mM Na2HPO4, pH 6.8
Mobile Phase B: Acetonitrile
Gradient (A:B) : T0=70:30, T15=25:75
Flow Rate : 1 mL/min
Sample : 1 mg/mL 1:1 Mobile Phase
Column Temp : 20C
Injection Volume : 10 ul
Detection : UV at 230 nm

Sample Name	BDG 5422	Instrument	Analytical LC 01
Acquisition	10-Apr-06, 21:49:53	Method (rev.)	LC10030 (14)
Sequence	BDG_10Apr2006d - Reprocessed	Vial Position	2
Operator	solvation010\cerityadmin	Injection	2 of 2



Area Percent Report

Peak #	RT	Height	Area	Width	Area %
1	8.13	514.0751	7578.3339	0.2180	100.000