BDG SYNTHESIS

Certificate of Analysis

BDG Synthesis certifies that this reference material meets or exceeds the specifications stated herein.

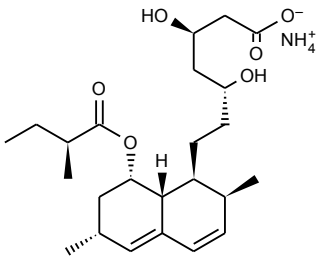
Barry Dent

Barry R. Dent, PhD, Director
5 September 2009

Name: **Lovastatin Acid Ammonium Salt**

CAS Number: 77550-67-5

Structure:



Molecular Weight: $C_{24}H_{37}O_6 \cdot NH_4 = 439.59$

Lot Number: BDG 5748

Appearance: White, crystalline powder

Purity By HPLC: 98.2 %

Re-test Date: 5 September 2010

Storage and Handling:

Temperature:	ambient laboratory temperature; may be refrigerated.
Humidity:	not believed to be hygroscopic; may be handled in normal laboratory atmosphere.
Light:	store in an amber vial and protect from bright light.
Caution:	only experienced laboratory personnel should handle the material. Avoid warming solutions- the material may revert to the lactone form.

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Identity and Purity

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* 421.2590. $C_{24}H_{37}O_6$ $[M-^{+}NH_4]^-$ requires *m/z* 421.2596. The deviation of 1.2 ppm is within normally accepted limits for the establishment of identity by HRMS.

HPLC

A sharp, symmetrical peak is observed (98.2 %). 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 65.52, H 9.44, N 3.17 %
$C_{24}H_{37}O_6 \cdot NH_4$	Requires:	C 65.57, H 9.40, N 3.19 %

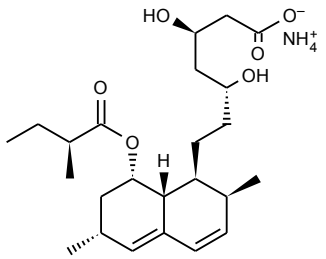
The elemental analyses fall within generally accepted limits for establishing the molecular formula given. The results may also be taken to imply the absence of significant quantities of water or inorganic salts (which have not been elsewhere tested for because of sample size limitations).

The available quantity of custom-synthesised material is always small, 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 custom-synthesised materials. Custom 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. This compound is intended for use as an analytical reference material and it is not for human administration. Structures are shown with relative stereochemistry unless otherwise specified.

The re-test date is assigned from experience gained with the material in the laboratory and/or on storage. It is not possible to perform formal storage studies because of the small amount of material available.

BDG SYNTHESIS

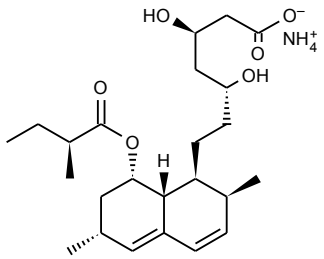
Proton NMR Spectrum of Lovastatin Acid Ammonium Salt in DMSO-d_6



Lot Number: BDG 5748

BDG SYNTHESIS

Carbon-13 NMR Spectrum of Lovastatin Acid Ammonium Salt in DMSO-d_6

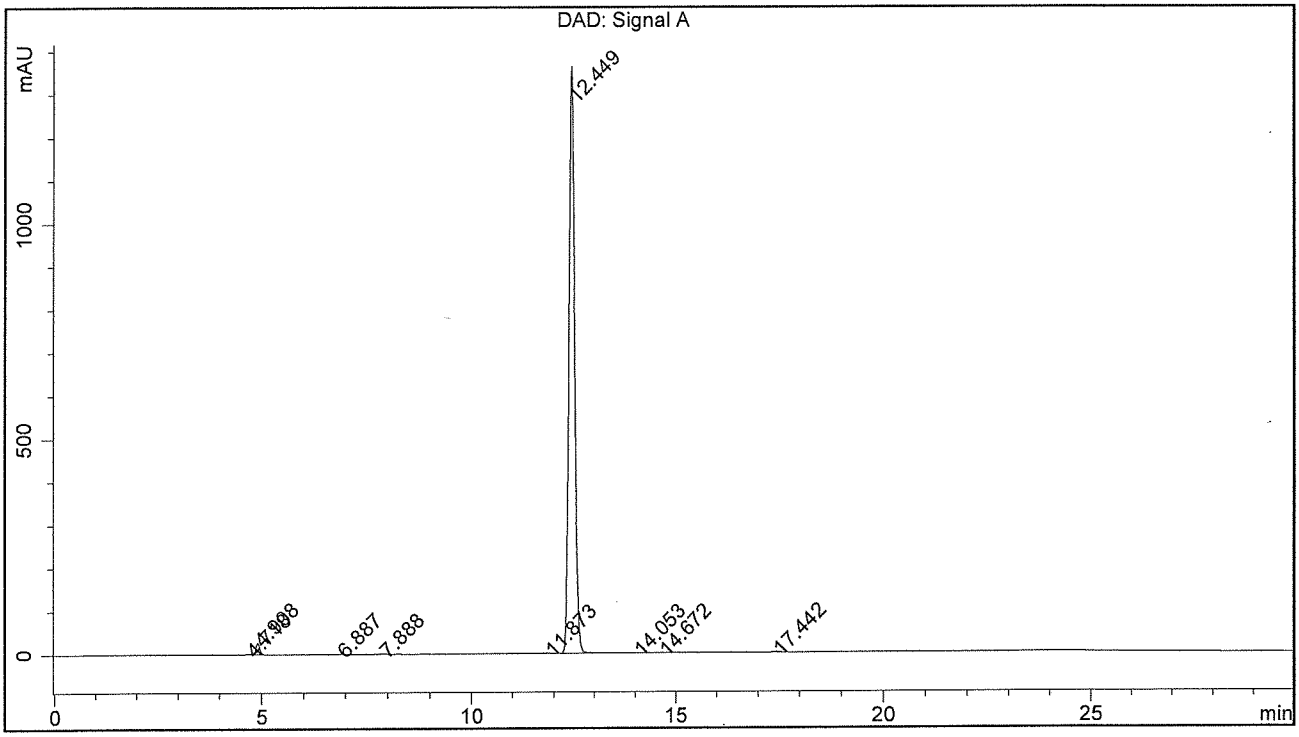


Lot Number: BDG 5748

BDG - Analysis of Lovastatin acid ammonium salt

Column : Phenomenex Luna C18 5um 250 x 4.6 mm
Guard : Phenomenex Security Guard C18 RP 4 x 3 mm
Mobile Phase A : 1:1 Water + 0.1% Phosphoric Acid : Acetonitrile
Mobile Phase B : Acetonitrile + 0.1% Phosphoric Acid
Gradient : T0=100:0, T15=50:50, T20=50:50, T25=100:0, T30=100:0
Flow Rate : 1.0 mL/min .... Column Temperature : 20C
Sample Solvent : 40:60 10 mM KH2PO4 pH=4.0 : Acetonitrile
Detection UV 238nm

Sample Name	BDG 5748	Instrument	AnalyticalLC01
Acquisition	05/09/2009, 12:54:51	Method (rev.)	LC10120a (18)
Sequence	BDG_05Sep2009c - Reprocessed	Vial Position	1
Operator	solvation010\cerityadmin	Injection	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	4.72 min	1.9794	13.4962	0.1035 min	0.098 %
2	4.91 min	26.5131	170.9433	0.0992 min	1.243 %
3	6.89 min	1.1158	8.5654	0.1176 min	0.062 %
4	7.89 min	1.1638	15.6810	0.1832 min	0.114 %
5	11.87 min	0.6128	5.8900	0.1481 min	0.043 %
6	12.45 min	1360.3118	13510.5114	0.1539 min	98.220 %
7	14.05 min	0.6817	6.7120	0.1529 min	0.049 %
8	14.67 min	0.3873	6.3817	0.2482 min	0.046 %
9	17.44 min	1.4067	17.1688	0.1824 min	0.125 %