



BDG SYNTHESIS

Certificate of Analysis

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

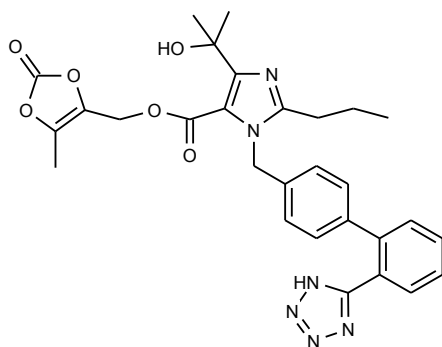
Barry Dent

Barry R. Dent, PhD, Director
10 August 2012

Name: Olmesartan Medoxomil

CAS Number: 144689-63-4

Structure:



Molecular Weight: $C_{29}H_{30}N_6O_6 = 558.59$

Lot Number: BDG 3627.2

Appearance: White, crystalline solid

Corrected Purity: 99.1 % (HPLC) - 1.3 % (2-propanol) - 2.4 % (water) = 95.4 %

Re-test Date: 10 August 2017

Storage and Handling:

Temperature:	refrigerate for prolonged storage; may be handled and shipped at ambient temperature.
Humidity:	may be hygroscopic; store desiccated; recommended to determine water content periodically.
Light:	store in an amber vial and protect from bright light.
Caution:	only experienced laboratory personnel should handle the material.

Identity and Purity

Proton NMR Spectrum

Identity: the signals are consistent with the proposed structure and in accord with literature where available.

Residual Solvents: a small amount of 2-propanol (1.3 % w/w) is 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 559.2321. $C_{29}H_{31}N_6O_6$ $[M+H]^+$ requires m/z 559.2300. The deviation of 3.4 ppm is within normally accepted limits for the establishment of identity by HRMS.

HPLC

A sharp, slightly tailing peak is observed (99.1 %). 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 61.29, H 5.62, N 14.81 %
$C_{29}H_{30}N_6O_6 \cdot 0.7H_2O$	Requires:	C 60.98, H 5.54, N 14.71 %
$C_{29}H_{30}N_6O_6$	Requires:	C 62.36, H 5.41, N 15.05 %

The elemental analyses fall somewhat outside those expected for anhydrous material; the presence of water is reasonably expected from the method of purification and/or the type of material, and the "best-fit" hydrated molecular formula is given.

Karl-Fischer Analysis

	Found:	H ₂ O 2.4 %
$C_{29}H_{30}N_6O_6 \cdot 0.7H_2O$	Requires:	H ₂ O 2.2 %

Of necessity, only a small sample could be used and only a single or duplicate analysis performed. We are unable to state what the errors in the reported water content are, but recommend that the result be used, as the best available, when determining corrected purity.

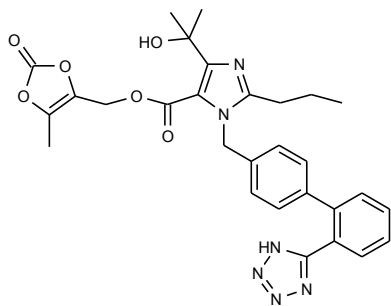
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials 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.

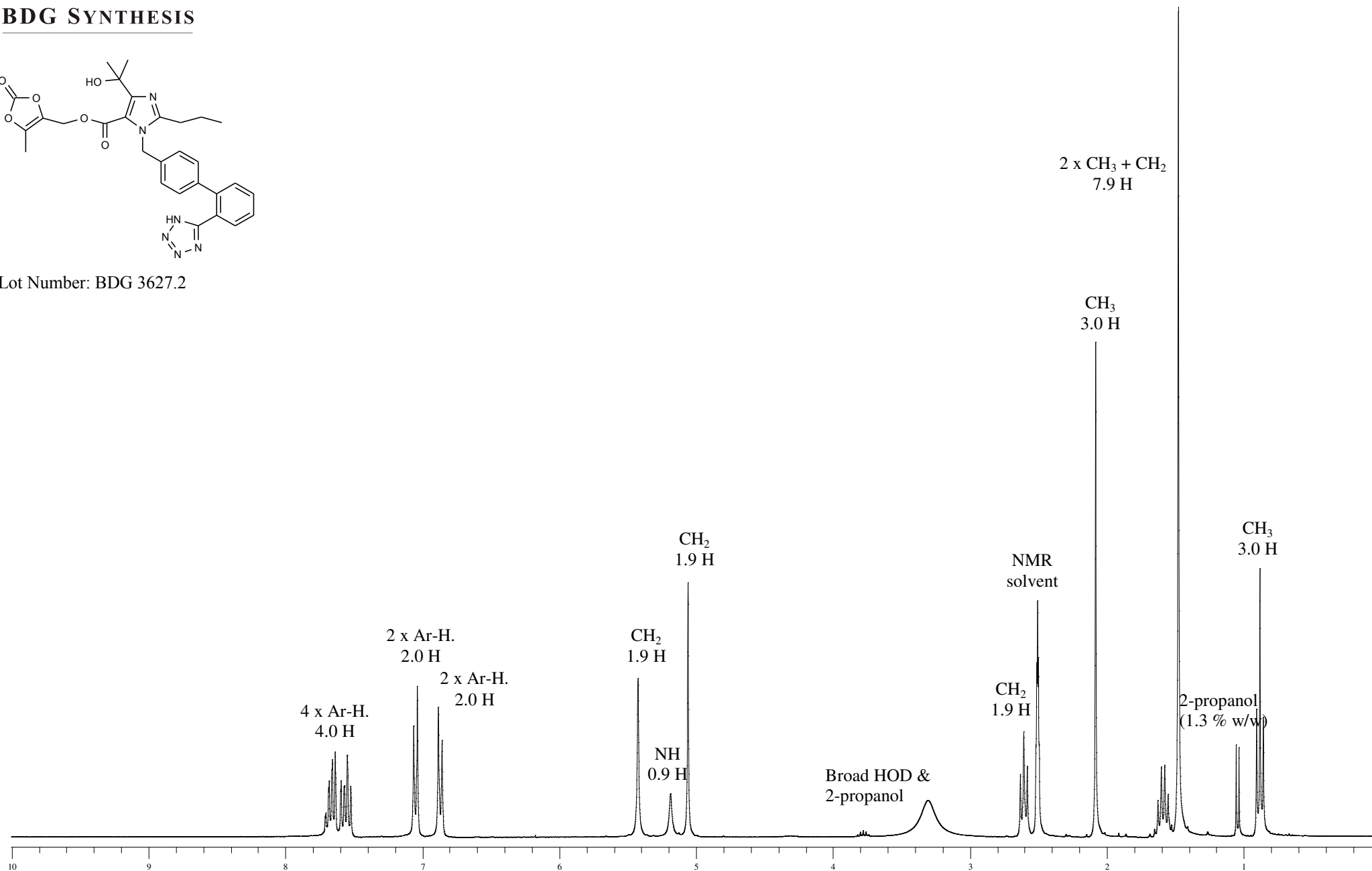


Proton NMR Spectrum of Olmesartan Medoxomil in DMSO-d₆

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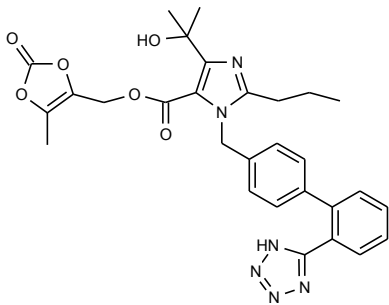
Lot Number: BDG 3627.2



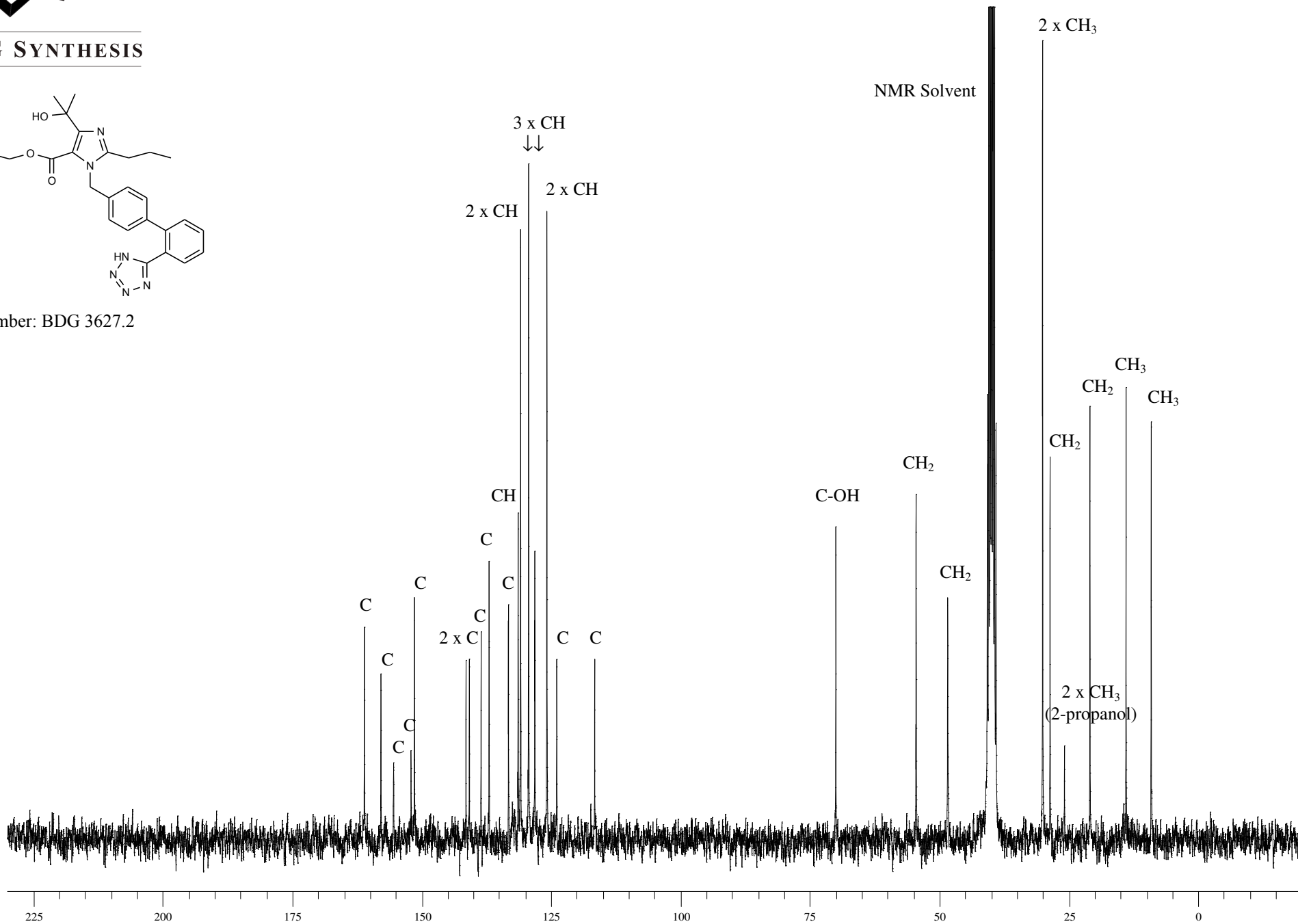


Carbon-13 NMR Spectrum of Olmesartan Medoxomil in DMSO-d₆

BDG SYNTHESIS



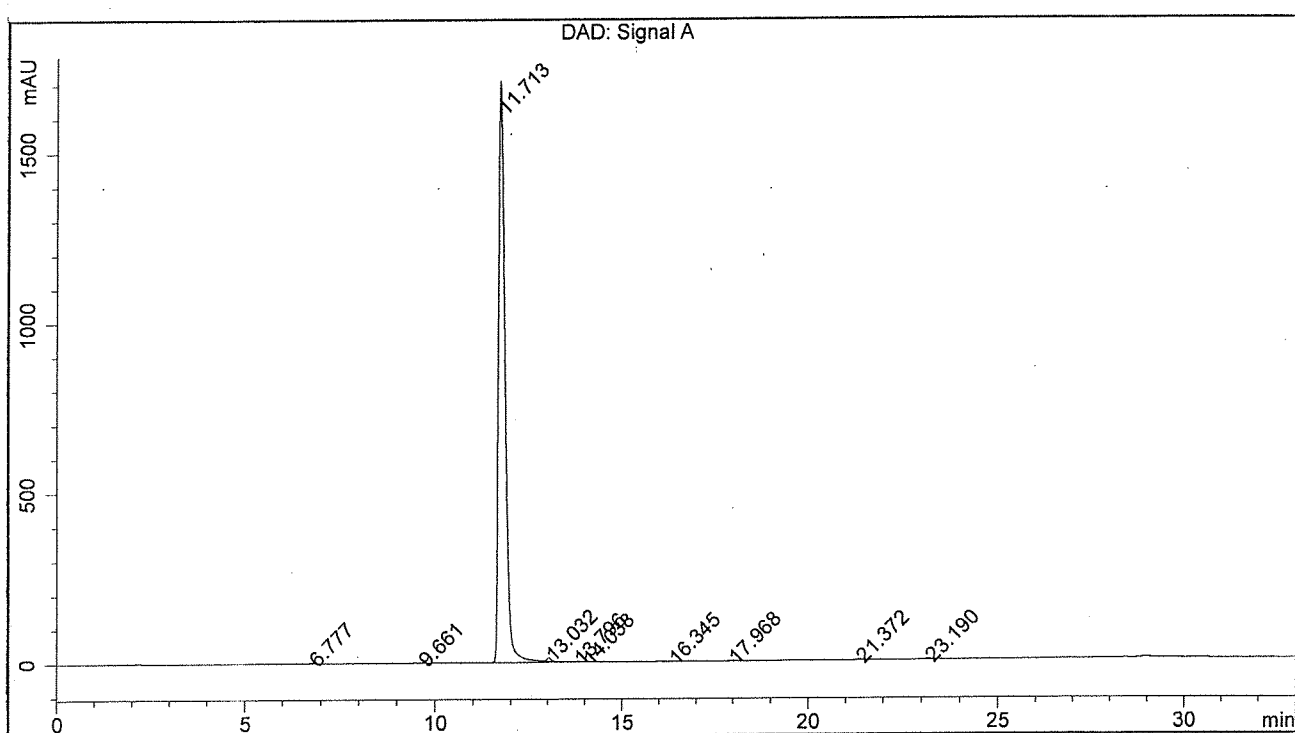
Lot Number: BDG 3627.2



BDG - Analysis of Olmesartan

Column : Phenomenex Luna Phenyl Hexyl 5um 250 x 4.6 mm
 Guard : Phenomenex Security Guard Phenyl 4 x 3 mm
 Mobile Phase A : 70:30:0.1 Water : Acetonitrile : Trifluoroacetic Acid
 Mobile Phase B : 30:70:0.1 Water : Acetonitrile : Trifluoroacetic Acid
 Gradient (A:B) : T0 = 100:0, T25 = 0:100, T30 = 0:100, T32 = 100:0, T35 = 100:0
 Flow Rate : 1.0 mL/min
 Sample Solvent : Mobile Phase
 Column Temperature : 20C
 Injection Volume : 10 uL
 Detection : UV at 250 nm

Sample Name	BDG 3627.2	Instrument	AnalyticalLC01
Acquisition	10/08/2012, 11:01:32	Method (rev.)	LC10210d (7)
Sequence	BDG_10Aug2012a - Reprocessed	Vial Position	1
Operator	solvation010\cerityadmin	Injection	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	6.78 min	2.5892	21.1291	0.1252 min	0.101 %
2	9.66 min	0.5637	3.7977	0.1046 min	0.018 %
3	11.71 min	1710.5426	20650.9562	0.1828 min	99.051 %
4	13.03 min	10.0668	90.7847	0.1332 min	0.435 %
5	13.80 min	1.0809	10.4033	0.1403 min	0.050 %
6	14.04 min	0.8888	8.3161	0.1372 min	0.040 %
7	16.34 min	0.6507	6.4433	0.1435 min	0.031 %
8	17.97 min	1.8136	17.2861	0.1412 min	0.083 %
9	21.37 min	2.1028	18.3351	0.1337 min	0.088 %
10	23.19 min	2.1431	21.4476	0.1508 min	0.103 %