



## BDG SYNTHESIS

### Certificate of Analysis

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

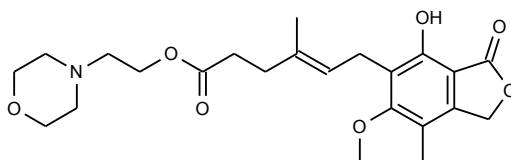
*Barry Dent*

Barry R. Dent, PhD, Director  
24 April 2010

**Name:** Mycophenolate Mofetil

**CAS Number:** 128794-94-5

**Structure:**



**Molecular Weight:**  $C_{23}H_{31}NO_7 = 433.49$

**Lot Number:** BDG 6991.1

**Appearance:** White, crystalline solid

**Purity By HPLC:** 100.0 %

**Re-test Date:** 24 April 2011

**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.

## 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  $m/z$  434.2175.  $C_{23}H_{32}NO_7$   $[M+H]^+$  requires  $m/z$  434.2173. The deviation of 0.4 ppm is within normally accepted limits for the establishment of identity by HRMS.

### HPLC

A somewhat broadened, symmetrical peak is observed (100.0 %). 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 63.81, H 7.43, N 3.18 %
$C_{23}H_{31}NO_7$	Requires:	C 63.73, H 7.21, N 3.23 %

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).

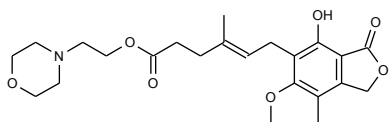
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

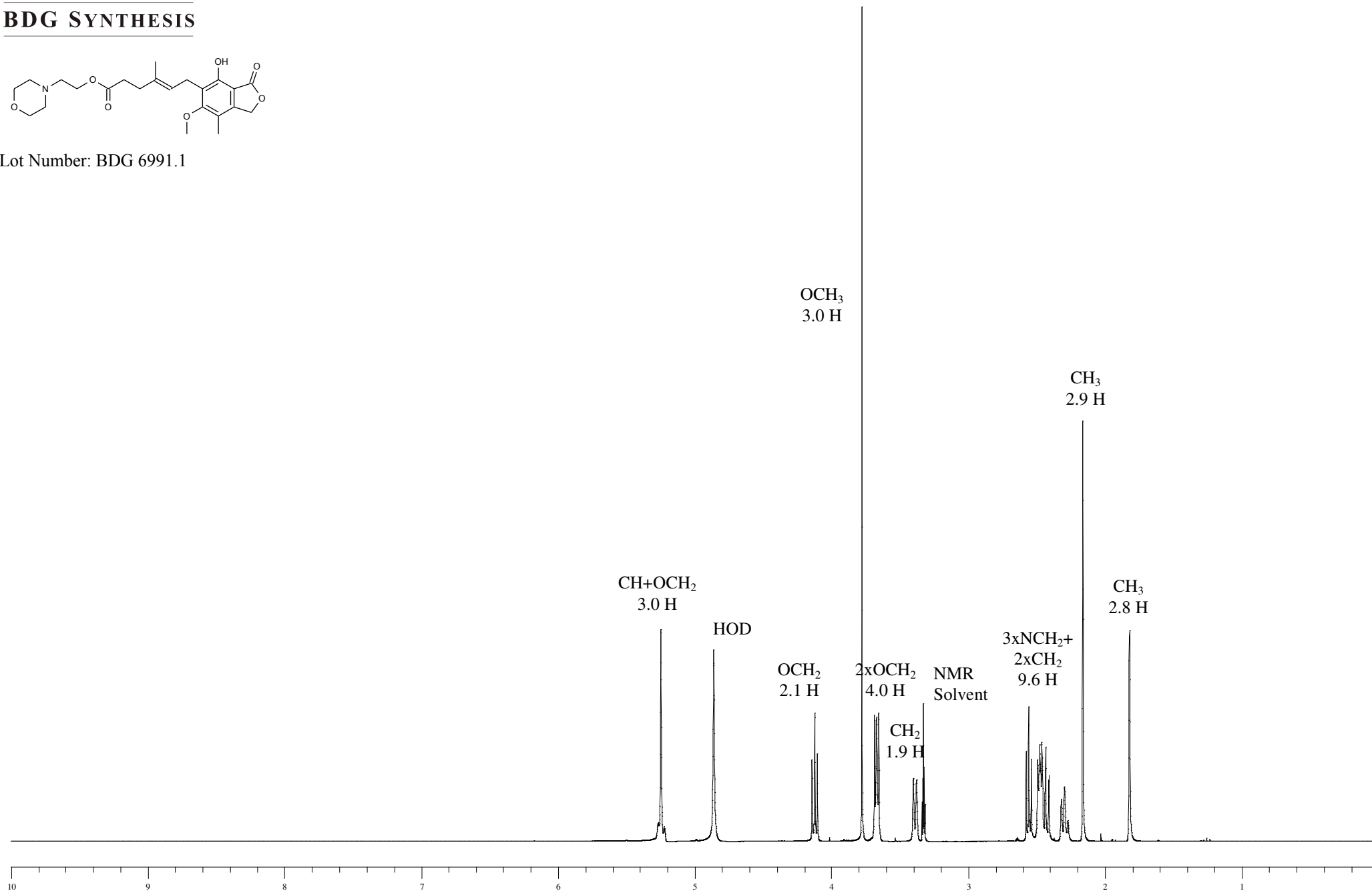


# Proton NMR Spectrum of Mycophenolate Mofetil in Methanol-d<sub>4</sub> and DMSO-d<sub>6</sub>

## BDG SYNTHESIS



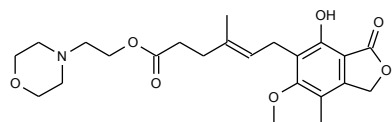
Lot Number: BDG 6991.1



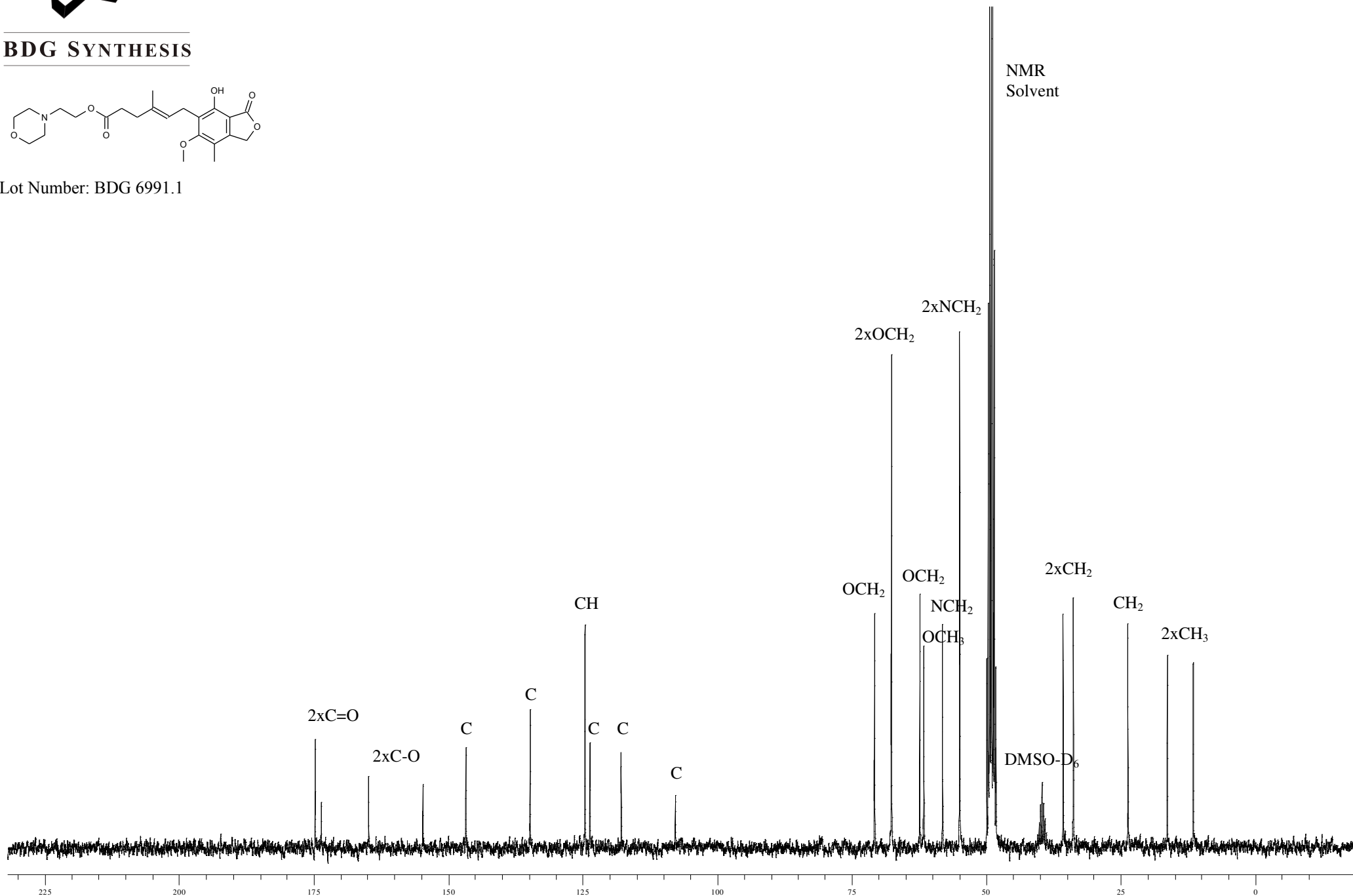


# Carbon-13 NMR Spectrum of Mycophenolate Mofetil in Methanol-d<sub>4</sub> and DMSO-d<sub>6</sub>

## BDG SYNTHESIS



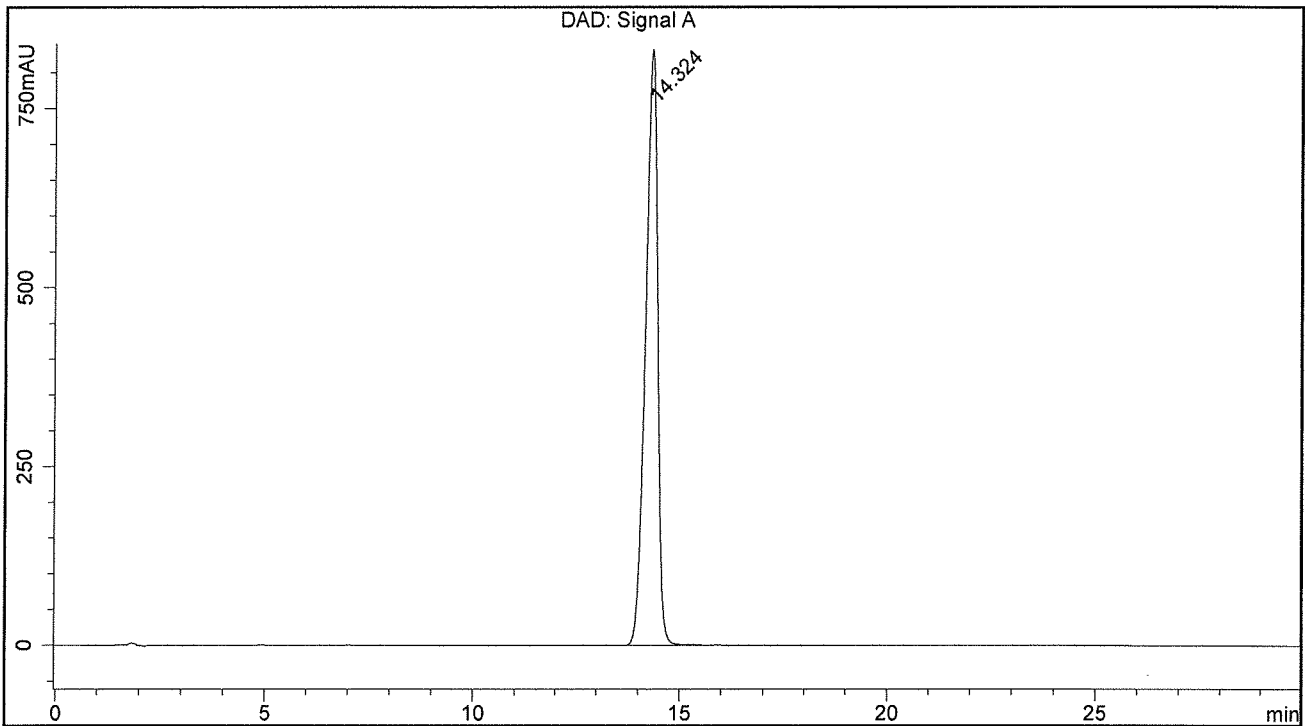
Lot Number: BDG 6991.1



BDG - Analysis of Mycophenolate Mofetil

Column : Phenomenex Luna C8(2) 5 um 250 x 4.6 mm  
Guard : Phenomenex Security Guard C8 4 x 3 mm  
Mobile Phase : 65:35 0.2% Triethylamine pH=5.3 : Acetonitrile  
Flow Rate : 1.5 mL/min  
Sample Solvent : Acetonitrile  
Column Temperature : 45C  
Injection Volume : 10 uL  
Detection : UV at 250 nm

<b>Sample Name</b>	BDG 6991.1	<b>Instrument</b>	AnalyticalLC01
<b>Acquisition</b>	24/04/2010, 13:44:07	<b>Method (rev.)</b>	LC10208c ( 3)
<b>Sequence</b>	BDG_24Apr2010a	<b>Vial Position</b>	1
<b>Operator</b>	solvation010\cerityadmin	<b>Injection</b>	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	14.32 min	823.5802	17025.9597	0.3372 min	100.000 %