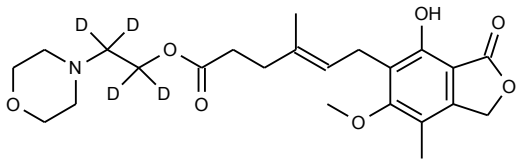
BDG SYNTHESIS

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-d_4**
CAS Number:	128794-94-5 (unlabelled)
Structure:	
Molecular Weight:	$C_{23}H_{27}D_4NO_7$ = 437.52
Lot Number:	BDG 6024.1
Appearance:	White, crystalline solid
Purity By HPLC:	98.5 %
Isotopic Purity:	Under 0.5 % d_0
Re-test Date:	24 April 2015

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.

Mailing:
BDG Synthesis Limited
PO Box 38627, Wellington Mail Centre,
Wellington 5045, New Zealand.

Shipping:
BDG Synthesis Limited
Gracefield Research Centre, Building F,
69 Gracefield Rd, Lower Hutt 5010, New Zealand.

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

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

Identity and Purity

Proton NMR Spectrum

Identity: the signals are consistent with the proposed structure and in accord with literature where available.
Isotopic Labelling: signals at the sites of deuteration are absent, compared with the spectrum of unlabelled material, indicating clean deuteration.
Residual Solvents: no residual solvents are observed.
Impurities: traces of unidentified impurities are seen in the baseline.

Carbon-13 NMR Spectrum

Identity: the signals are consistent with the proposed structure and in accord with literature where available.
Isotopic Labelling: signals at the sites of deuteration have collapsed to small multiplets compared with the spectrum of unlabelled material, indicating clean deuteration.

High-resolution Mass Spectrum (ESI+)

Found *m/z* 438.2450. $C_{23}H_{28}D_4NO_7$ $[M+H]^+$ requires *m/z* 438.2425. The deviation of 5.7 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. No signal for d_0 material was seen (detection limit about 0.5 %).

HPLC

A somewhat broadened, slightly tailing peak is observed (98.5 %). 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 63.29, H 6.17, D 1.82, N 3.10 %
$C_{23}H_{27}D_4NO_7$	Requires:	C 63.14, H 6.22, D 1.84, N 3.20 %

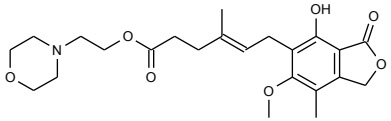
The elemental analyses fall within generally accepted limits for establishing the molecular formula given. The results may also be taken to imply the absence of significant quantities of water or inorganic salts (which have not been elsewhere tested for because of sample size limitations).

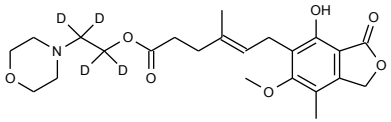
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials 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 Mycophenolate Mofetil (top) and Mycophenolate Mofetil-d_4 (bottom) in Methanol-d_4

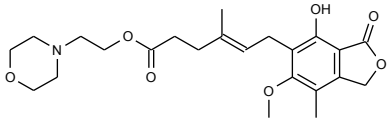


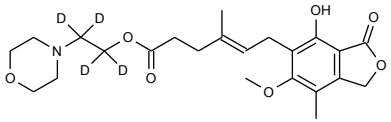


Lot Number: BDG 6024.1

BDG SYNTHESIS

Carbon-13 NMR Spectrum of Mycophenolate Mofetil (top) and Mycophenolate Mofetil-d_4 (bottom) in Methanol-d_4



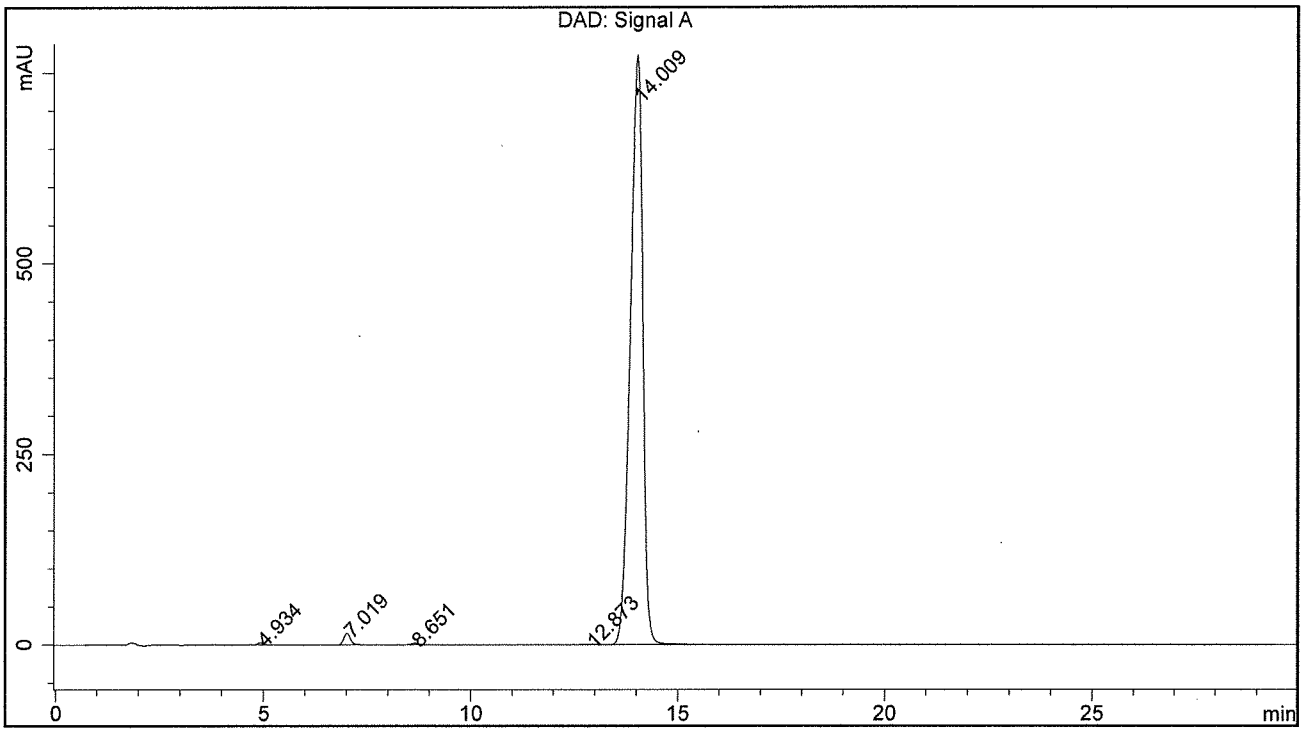


Lot Number: BDG 6024.1

BDG - Analysis of Mycophenolate Mofetil-d4

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

Sample Name	BDG 6024.1	**Instrument**	AnalyticalLC01
Acquisition	24/04/2010, 16:58:00	**Method (rev.)**	LC10208d (2)
Sequence	BDG_24Apr2010b	**Vial Position**	2
Operator	solvation010\cerityadmin	**Injection**	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	4.93 min	2.5481	29.7589	0.2163 min	0.182 %
2	7.02 min	14.6215	172.0283	0.2173 min	1.050 %
3	8.65 min	2.0565	29.6678	0.2323 min	0.181 %
4	12.87 min	0.9646	21.0213	0.3502 min	0.128 %
5	14.01 min	758.2676	16129.2470	0.3602 min	98.459 %