

BDG SYNTHESIS

Certificate of Analysis

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

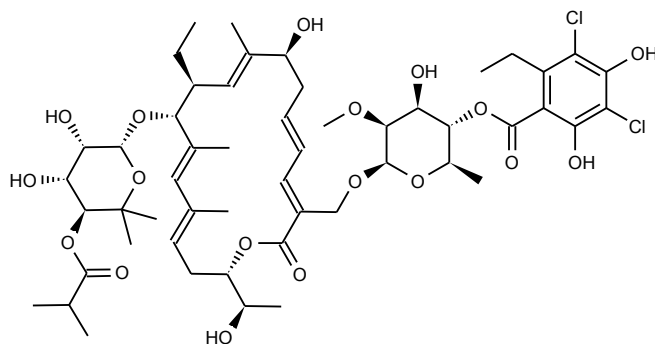
Barry Dent

Barry R. Dent, PhD, Director
6 May 2012

Name: Fidaxomicin

CAS Number: 873857-62-6

Structure:



Molecular Weight: $C_{52}H_{74}Cl_2O_{18} = 1058.04$

Lot Number: BDG 13435.2

Appearance: White, crystalline solid

Corrected Purity: 97.6 % (HPLC) - 7.0 % (water) = 90.6 %

Re-test Date: 6 May 2013

Storage and Handling: Temperature: refrigerate for prolonged storage; may be handled and shipped at ambient temperature.

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 1079.4160. $C_{52}H_{74}Cl_2NaO_{18}$ $[M+Na]^+$ requires m/z 1079.4150. The deviation of 0.9 ppm is within normally accepted limits for the establishment of identity by HRMS.

HPLC

A sharp, symmetrical peak is observed (97.6 %). 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 55.96, H 7.38 %
$C_{52}H_{74}Cl_2O_{18} \cdot 3.5H_2O$	Requires:	C 55.71, H 7.28 %
$C_{52}H_{74}Cl_2O_{18}$	Requires:	C 59.03, H 7.05 %

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 7.0 %
$C_{52}H_{74}Cl_2O_{18} \cdot 3.5H_2O$	Requires:	H ₂ O 5.6 %

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.

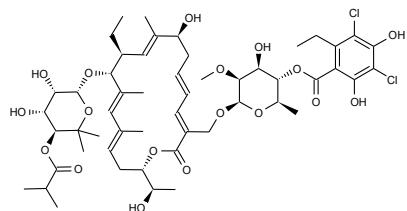
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

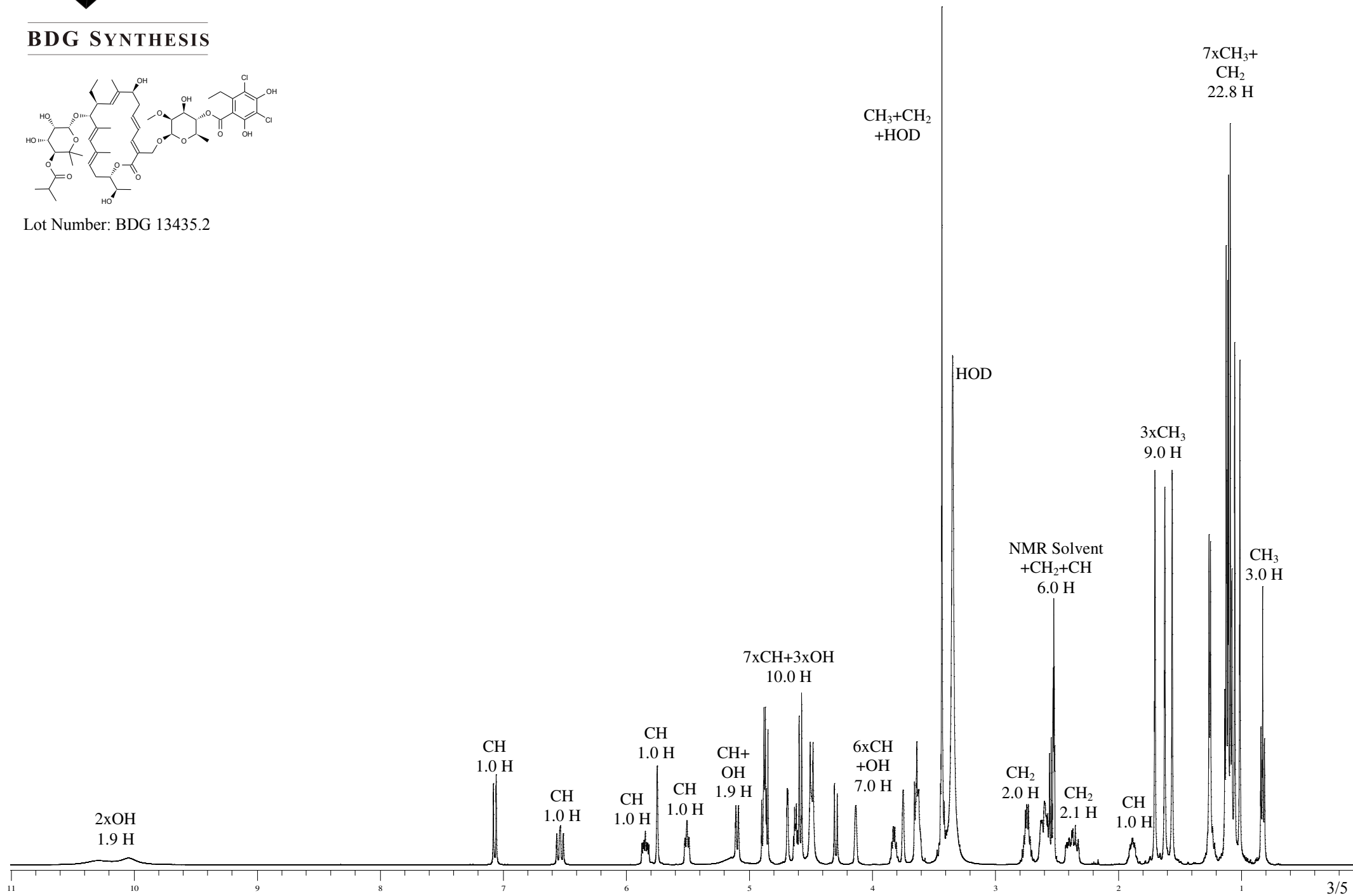


Proton NMR Spectrum of Fidaxomicin in DMSO-d₆

BDG SYNTHESIS



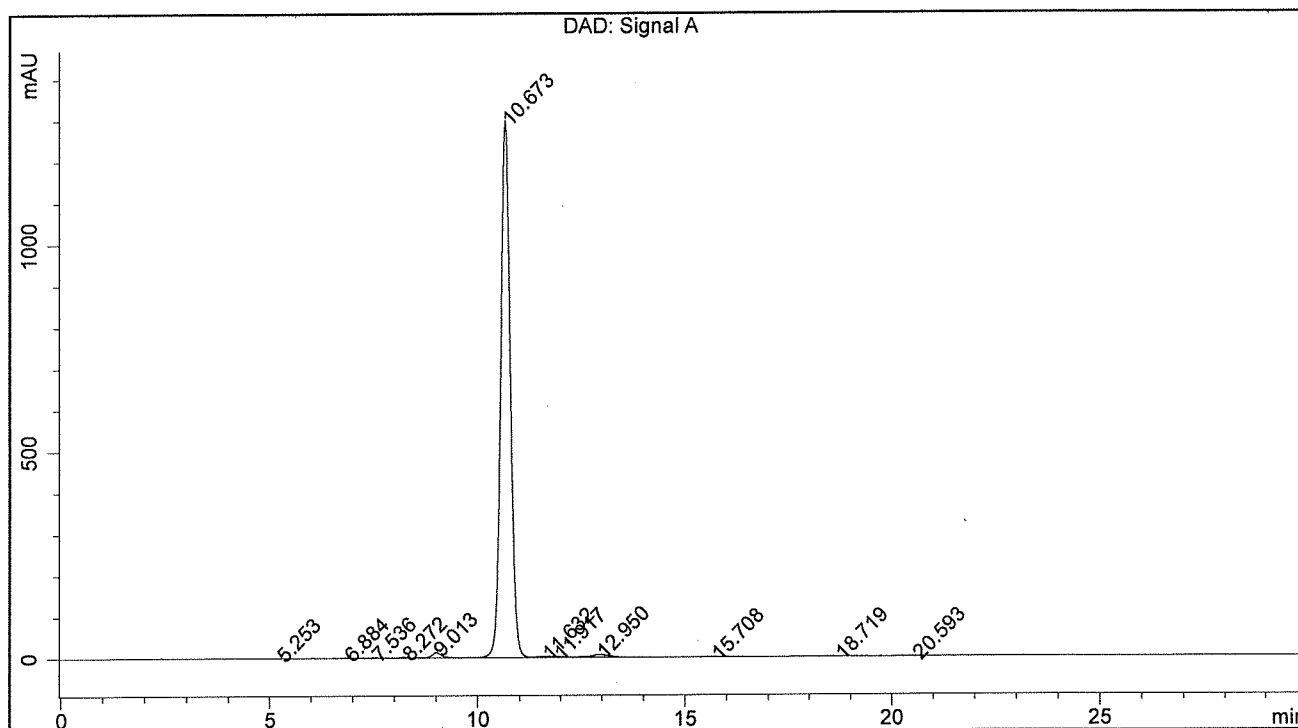
Lot Number: BDG 13435.2



BDG - Analysis of Fidaxomicin

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm
 Guard : Phenomenex SecurityGuard C18 4 x 3mm
 Mobile Phase : 40:60 20 mM Potassium diHydrogen Phosphate pH=3.0 : Acetonitrile
 Flow Rate : 1.0 mL/min Sample Solvent : Mobile Phase
 Column Temperature : 20C Injection Volume : 10 uL Detection : UV at 230 nm

Sample Name	BDG 13435.2	Instrument	AnalyticalLC01
Acquisition	06/05/2012, 13:22:44	Method (rev.)	LC10508a (8)
Sequence	BDG_06May2012c - Reprocessed	Vial Position	55
Operator	solvation010\cerityadmin	Injection	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	5.25 min	0.2371	3.1264	0.2099 min	0.015 %
2	6.88 min	0.5317	9.4804	0.2640 min	0.045 %
3	7.54 min	1.2533	24.9159	0.2799 min	0.117 %
4	8.27 min	2.1676	28.6787	0.2104 min	0.135 %
5	9.01 min	12.5148	208.6482	0.2505 min	0.980 %
6	10.67 min	1295.1468	20774.6430	0.2511 min	97.559 %
7	11.63 min	1.4648	37.3600	0.3536 min	0.175 %
8	11.92 min	0.6120	6.8854	0.1792 min	0.032 %
9	12.95 min	6.1824	176.4872	0.4450 min	0.829 %
10	15.71 min	0.2708	8.9395	0.4652 min	0.042 %
11	18.72 min	0.1175	4.4279	0.4878 min	0.021 %
12	20.59 min	0.3356	10.8829	0.5064 min	0.051 %