



## BDG SYNTHESIS

### Certificate of Analysis

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

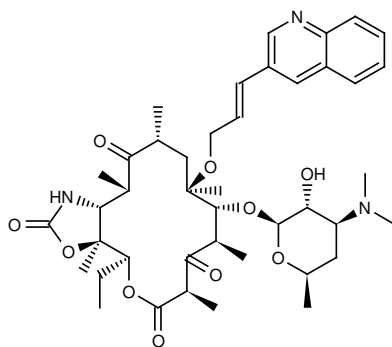
*Neil Beare*

Neil Beare, PhD, Director  
8 February 2017

**Name:** Cethromycin

**CAS Number:** 205110-48-1

**Structure:**



**Molecular Weight:**  $C_{42}H_{59}N_3O_{10} = 765.93$

**Lot Number:** BDG 16822

**Appearance:** White, crystalline solid

**Corrected Purity:** 97.1 % (HPLC) - 8.9 % (heptane) - 0.3 % (diethyl ether) - 0.5 % (ethyl acetate) = 87.4 %

**Re-test Date:** 8 February 2018

**Storage and Handling:** Temperature: Freeze (-20°C) 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. Solutions of this material in Acetonitrile and Methanol are light sensitive. The material is also very susceptible to static.

## Identity and Purity

### Proton NMR Spectrum

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

Residual Solvents: heptane (8.9 % w/w) and small amounts of diethyl ether (0.3 % w/w) and ethyl acetate (0.5 % w/w) 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.

### High-resolution Mass Spectrum (TOF MS ES+)

Found  $m/z$  766.4276.  $C_{42}H_{60}N_3O_{10}$   $[M+H]^+$  requires  $m/z$  766.4279. The deviation of 0.4 ppm is within normally accepted limits for the establishment of identity by HRMS.

### HPLC

A sharp, symmetrical peak is observed (97.1 %). 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 65.64, H 8.06, N 5.32 %
$C_{42}H_{59}N_3O_{10}$	Requires:	C 65.86, H 7.76, N 5.49 %

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).

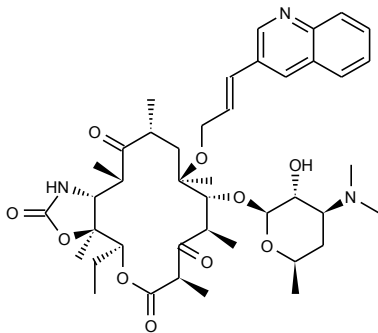
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

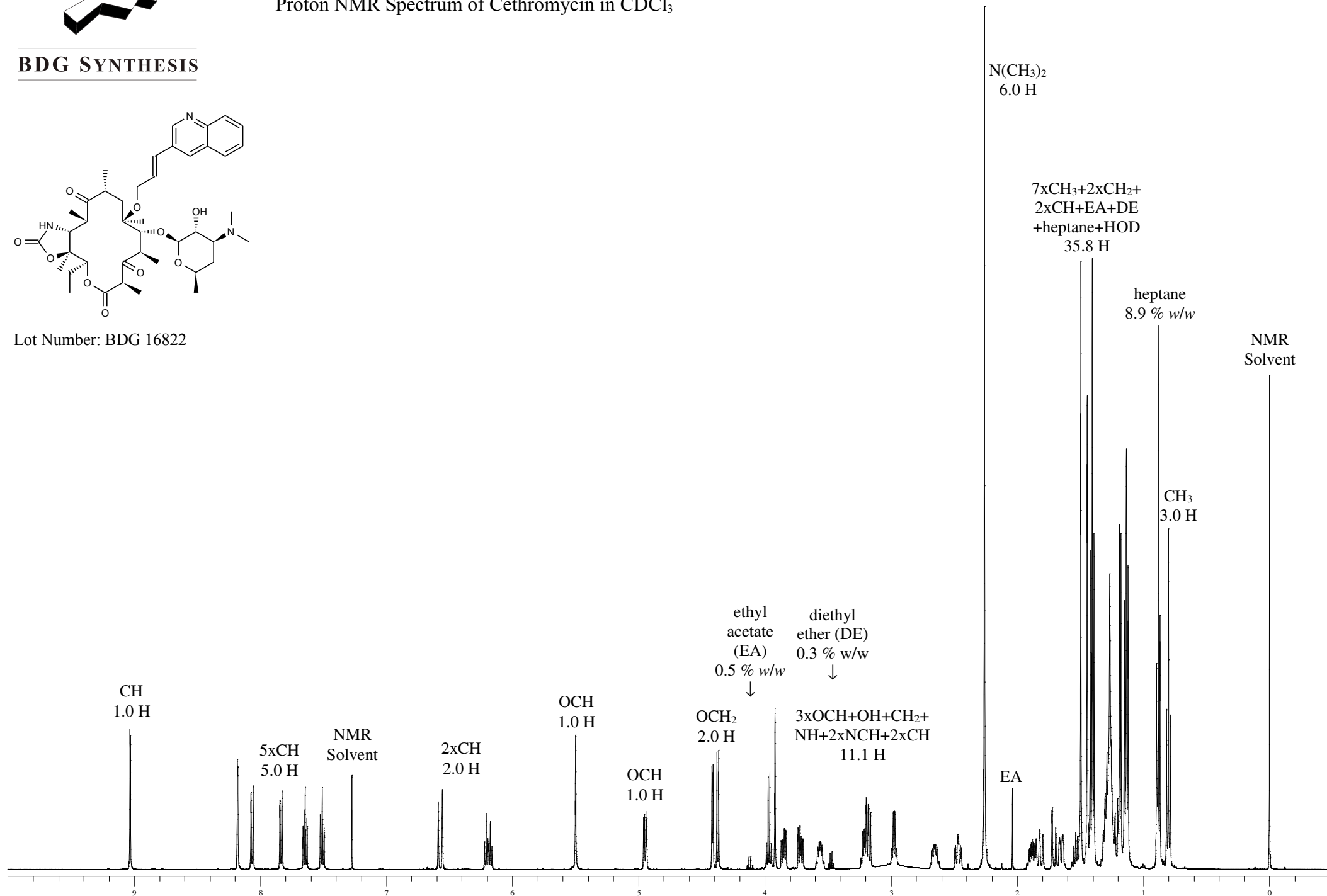


Proton NMR Spectrum of Cethromycin in CDCl<sub>3</sub>

**BDG SYNTHESIS**



Lot Number: BDG 16822

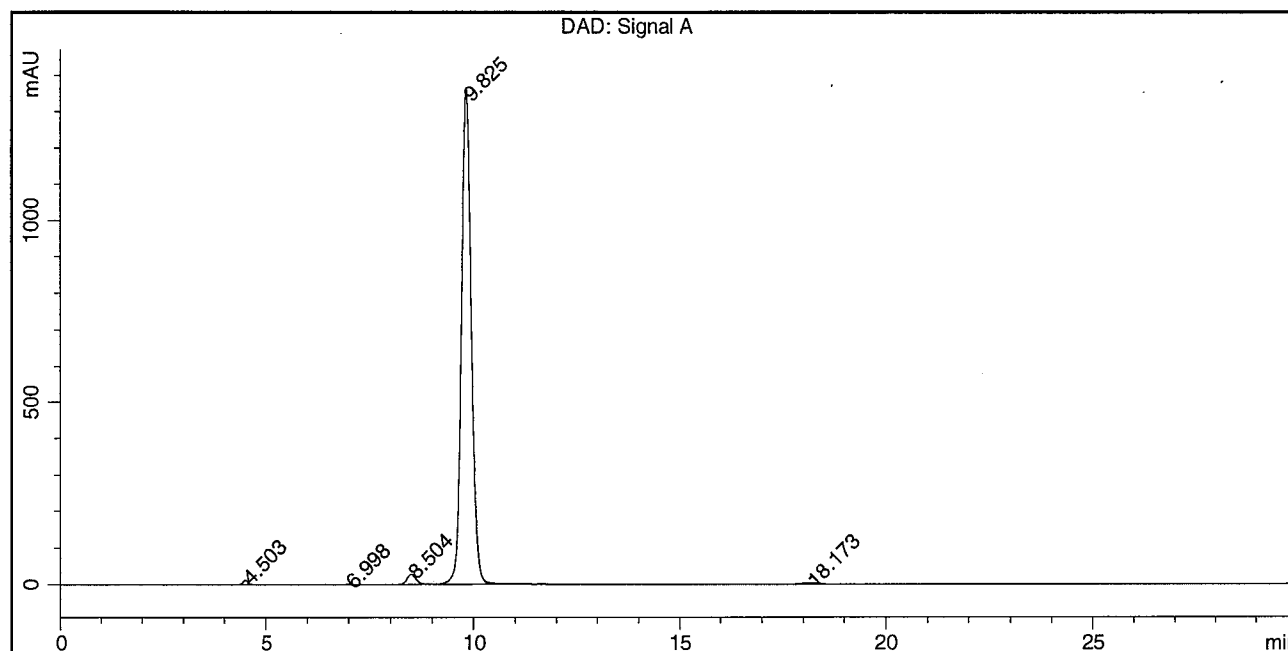




BDG - Analysis of Cethromycin

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm  
 Guard : Phenomenex Security Guard C18 4 x 3 mm  
 Mobile Phase : 20:80 10 mM diPotassium Hydrogen Phosphate pH=7.0 : Methanol  
 Flow Rate : 1.0 mL/min  
 Sample Solvent : 25:75 Water : Methanol  
 Column Temperature : 40 C  
 Injection Volume : 10 uL  
 Detection : UV at 250 nm

<b>Sample Name</b>	BDG 16822	<b>Instrument</b>	AnalyticalLC01
<b>Acquisition</b>	08/02/2017, 14:11:25	<b>Method (rev.)</b>	LC104001 ( 8 )
<b>Sequence</b>	BDG_08Feb2017a - Reprocessed	<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	4.50 min	11.9146	96.7289	0.1267 min	0.418 %
2	7.00 min	0.8232	11.8611	0.2041 min	0.051 %
3	8.50 min	27.8275	440.5703	0.2407 min	1.905 %
4	9.83 min	1365.1393	22454.2853	0.2559 min	97.112 %
5	18.17 min	4.0690	118.6710	0.4363 min	0.513 %