



## BDG SYNTHESIS

### Certificate of Analysis

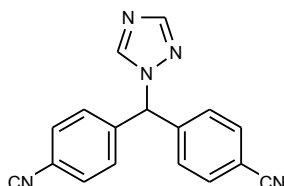
BDG Synthesis certifies that this reference material meets or exceeds the specifications stated herein.

*Barry Dent*

Barry R. Dent, PhD, Director  
10 October 2008

**Name:** Letrozole  
**CAS Number:** 112809-51-5

**Structure:**



**Molecular Weight:**  $C_{17}H_{11}N_5 = 285.30$

**Lot Number:** BDG 6116.1

**Appearance:** White, crystalline solid

**Purity By HPLC:** 99.4 %

**Re-test Date:** 10 October 2009

**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: 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 (ESI+)

Found  $m/z$  286.1091.  $C_{17}H_{12}N_5$   $[M+H]^+$  requires  $m/z$  286.1087. The deviation of 1.3 ppm is within normally accepted limits for the establishment of identity by HRMS.

### HPLC

A sharp, symmetrical peak is observed (99.4 %). 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 71.78, H 4.05, N 24.85 %
$C_{17}H_{11}N_5$	Requires:	C 71.57, H 3.89, N 24.55 %

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).

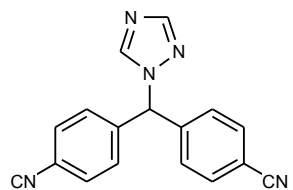
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

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.

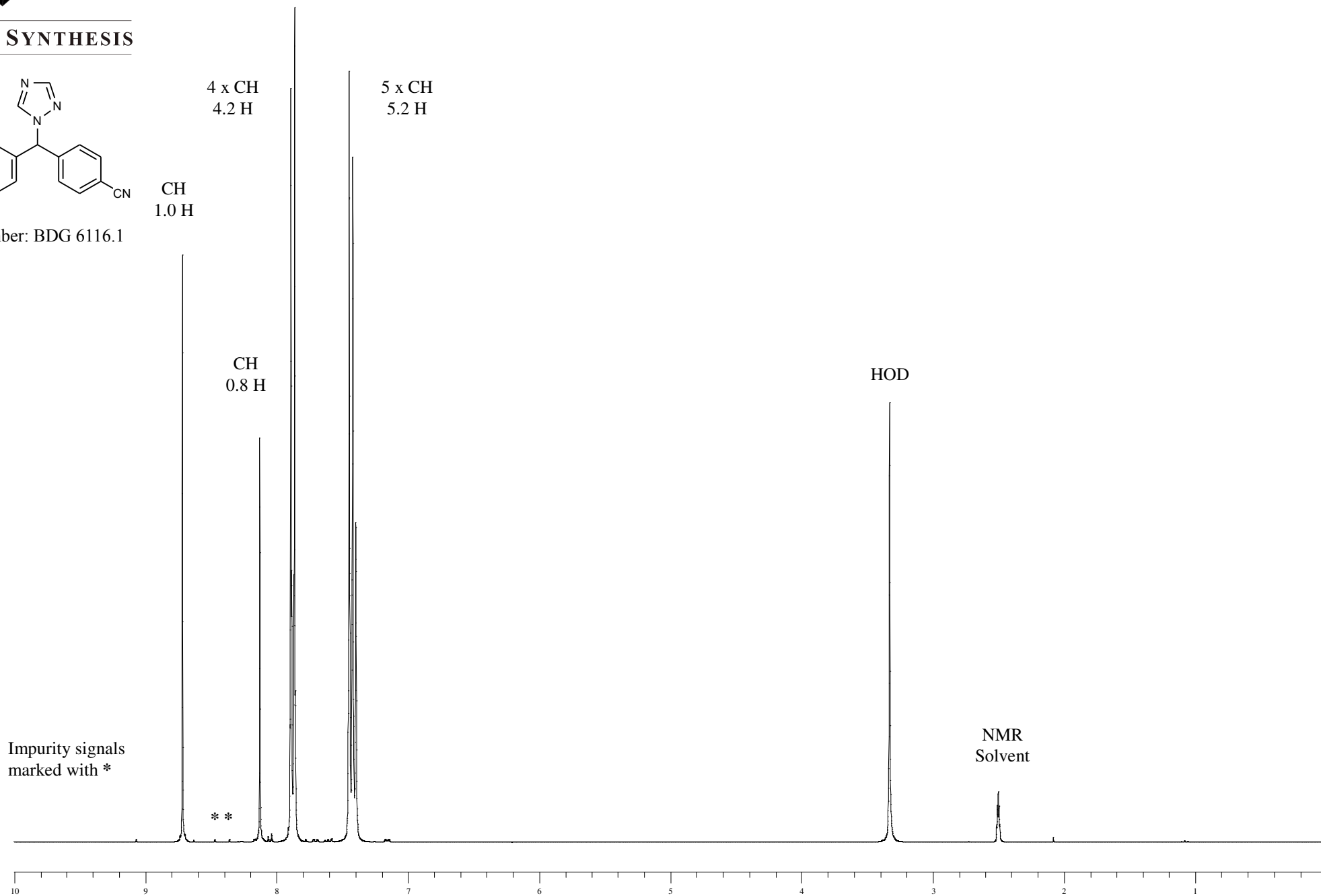


Proton NMR Spectrum of Letrozole in DMSO-d<sub>6</sub>

**BDG SYNTHESIS**



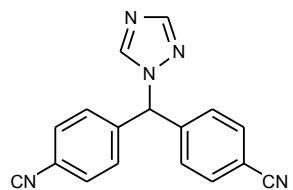
Lot Number: BDG 6116.1



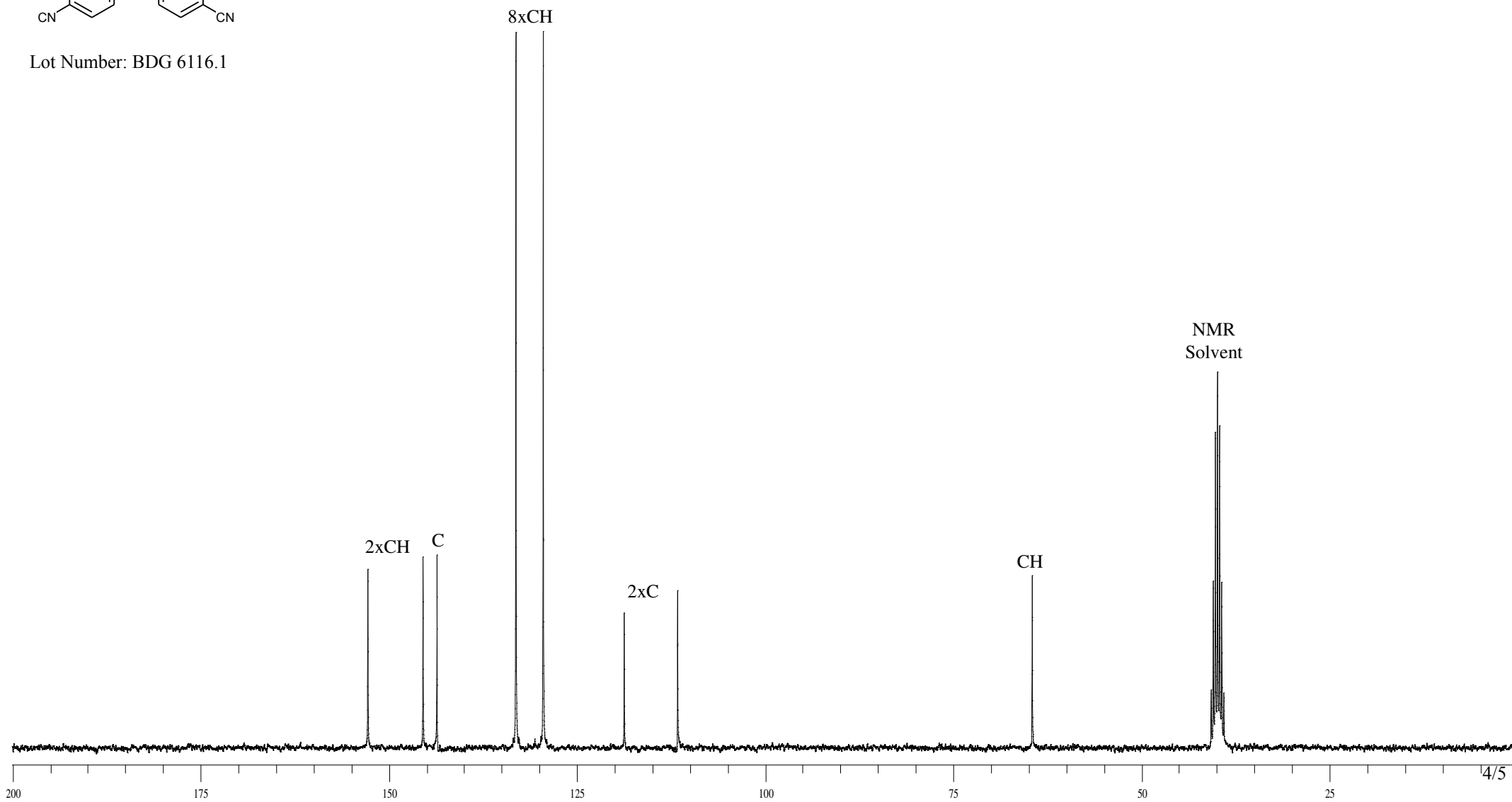


# Carbon-13 NMR Spectrum of Letrozole in DMSO-d<sub>6</sub>

**BDG SYNTHESIS**



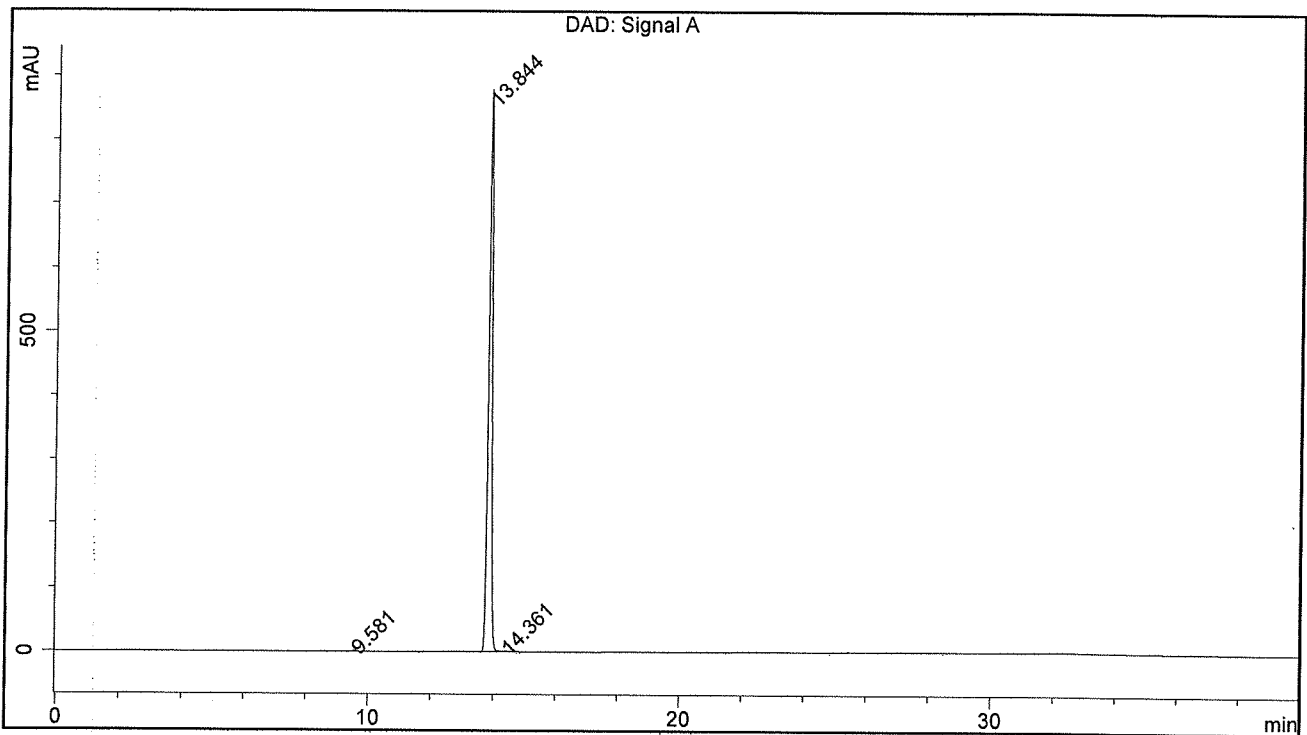
Lot Number: BDG 6116.1



BDG - Analysis of Letrozole

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm  
 Guard : Phenomenex Security Guard C18 4 x 3 mm  
 Mobile Phase A : Water  
 Mobile Phase B : Acetonitrile  
 Gradient ( A:B ) : T0 = 70:30, T25 = 30:70, T30 = 30:70, T35 = 70:30, T40 = 70:30  
 Flow Rate : 1.0 mL/min  
 Sample Solvent : Mobile Phase  
 Column Temperature : 20C  
 Injection Volume : 10 uL  
 Detection : UV at 230 nm

<b>Sample Name</b>	BDG 6116.1	<b>Instrument</b>	AnalyticalLC01
<b>Acquisition</b>	08/10/2008, 10:26:16	<b>Method (rev.)</b>	LC10212a ( 2)
<b>Sequence</b>	BDG_08Oct2008a	<b>Vial Position</b>	3
<b>Operator</b>	solvation010\cerityadmin	<b>Injection</b>	2 of 2



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	9.58 min	1.5523	10.8230	0.1053 min	0.157 %
2	13.84 min	879.2046	6856.6129	0.1210 min	99.354 %
3	14.36 min	1.0918	33.7537	0.3907 min	0.489 %