

BDG SYNTHESIS

Certificate of Analysis

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

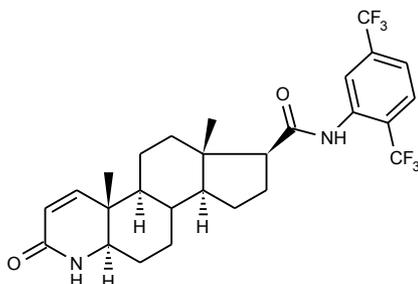
Barry Dent

Barry R. Dent, PhD, Director
20 May 2011

Name: Dutasteride

CAS Number: 164656-23-9

Structure:



Molecular Weight: $C_{27}H_{30}F_6N_2O_2 = 528.53$

Lot Number: BDG 10258.1

Appearance: White, crystalline solid

Corrected Purity: 99.6 % (HPLC) - 0.2 % (dichloromethane) - 0.1 % (dimethylformamide) = 99.3 %

Re-test Date: 20 May 2016

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: small amounts of dimethylformamide (0.1 % w/w) and dichloromethane (0.2 % w/w) and a trace (under 0.1 % w/w) of ethyl acetate 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 551.2087. $C_{27}H_{30}F_6N_2NaO_2$ $[M+Na]^+$ requires m/z 551.2104. The deviation of 3.1 ppm is within normally accepted limits for the establishment of identity by HRMS.

HPLC

A sharp, symmetrical peak is observed (99.6 %). 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

$C_{27}H_{30}F_6N_2O_2$	Found:	C 61.23, H 5.84, N 5.21 %
	Requires:	C 61.36, H 5.72, N 5.30 %

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).

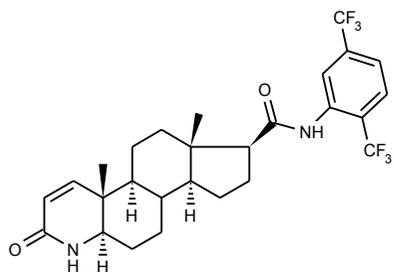
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

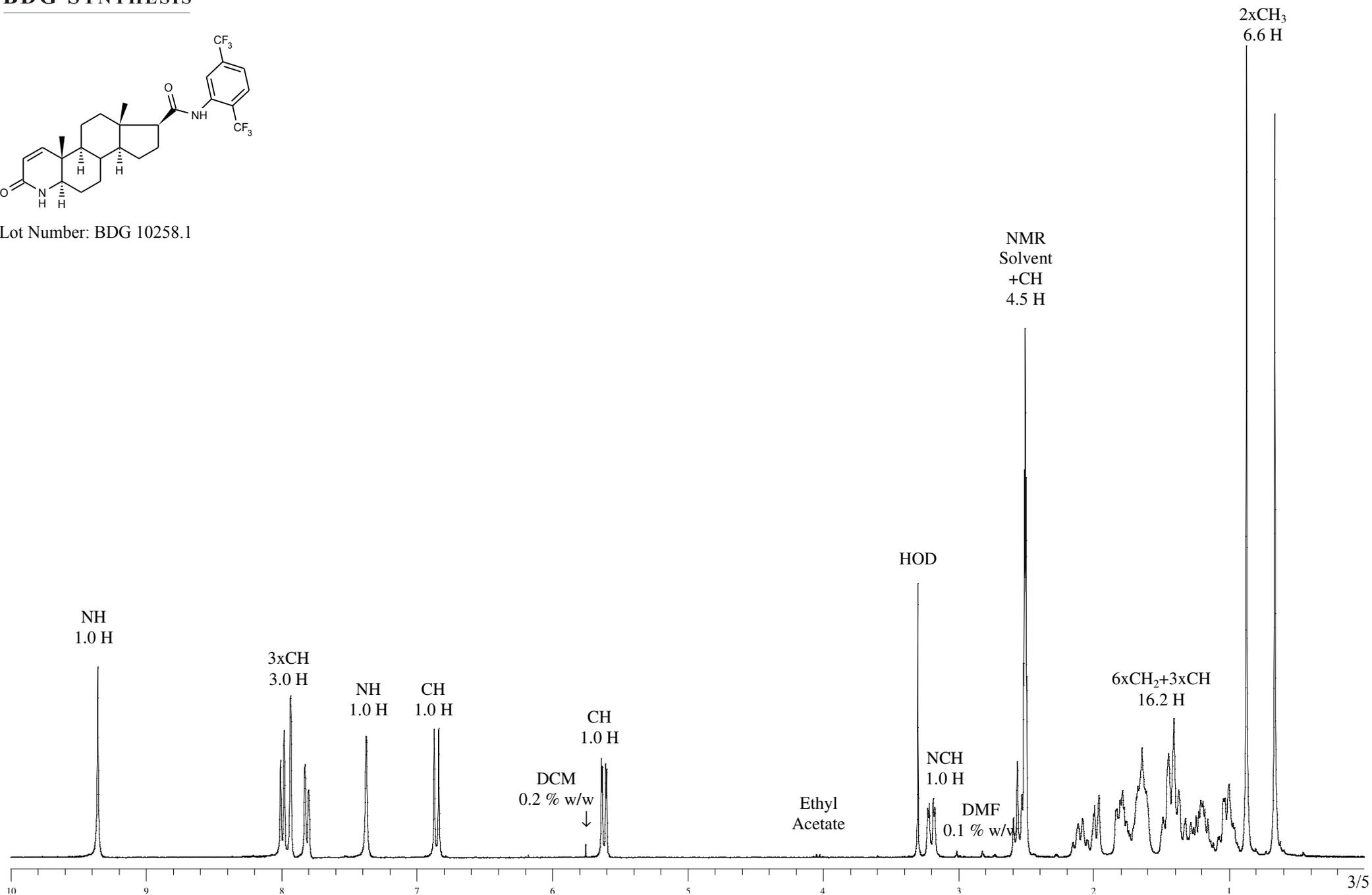


Proton NMR Spectrum of Dutasteride in DMSO-d₆

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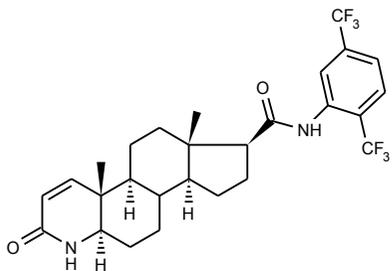
Lot Number: BDG 10258.1



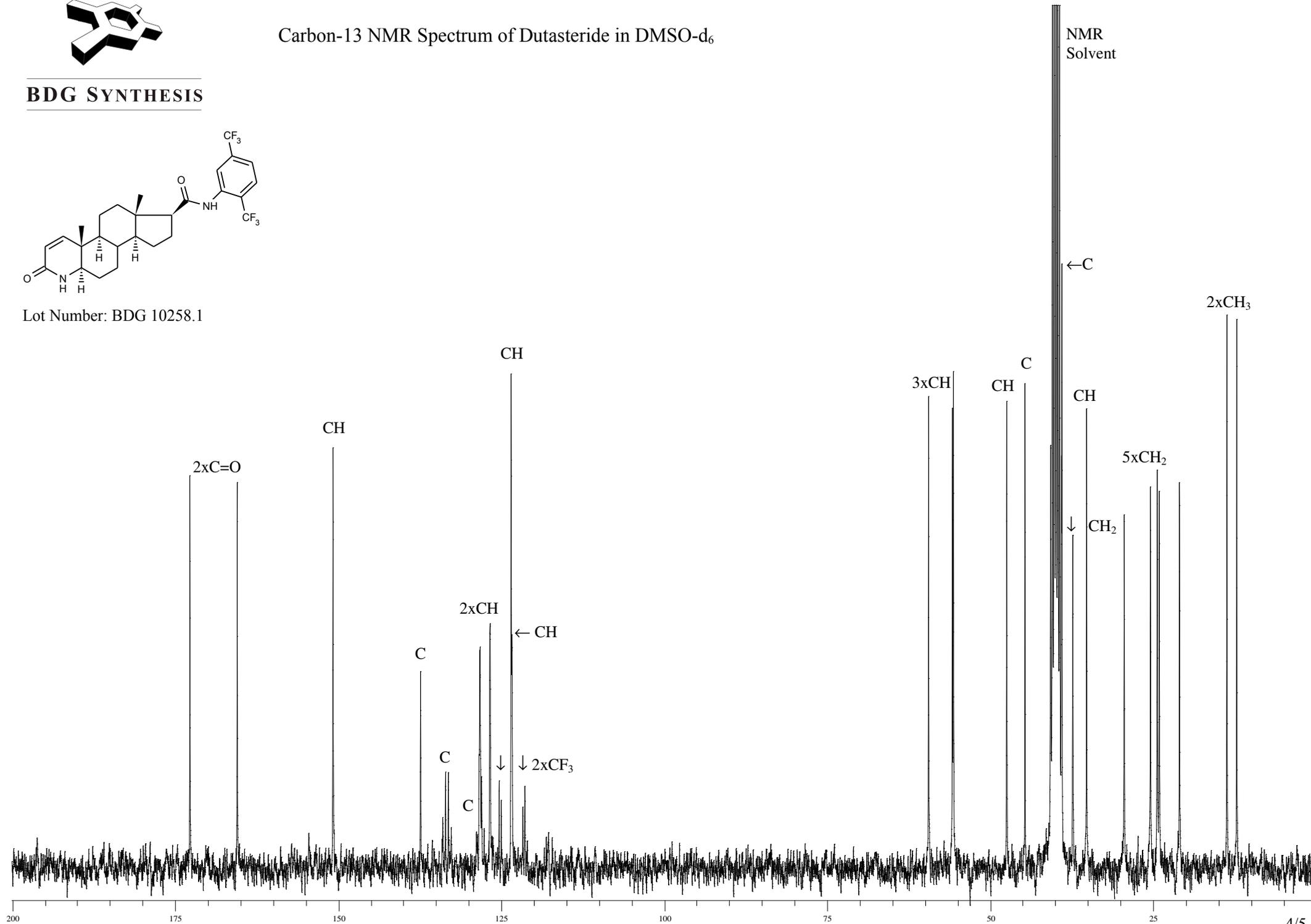


Carbon-13 NMR Spectrum of Dutasteride in DMSO-d₆

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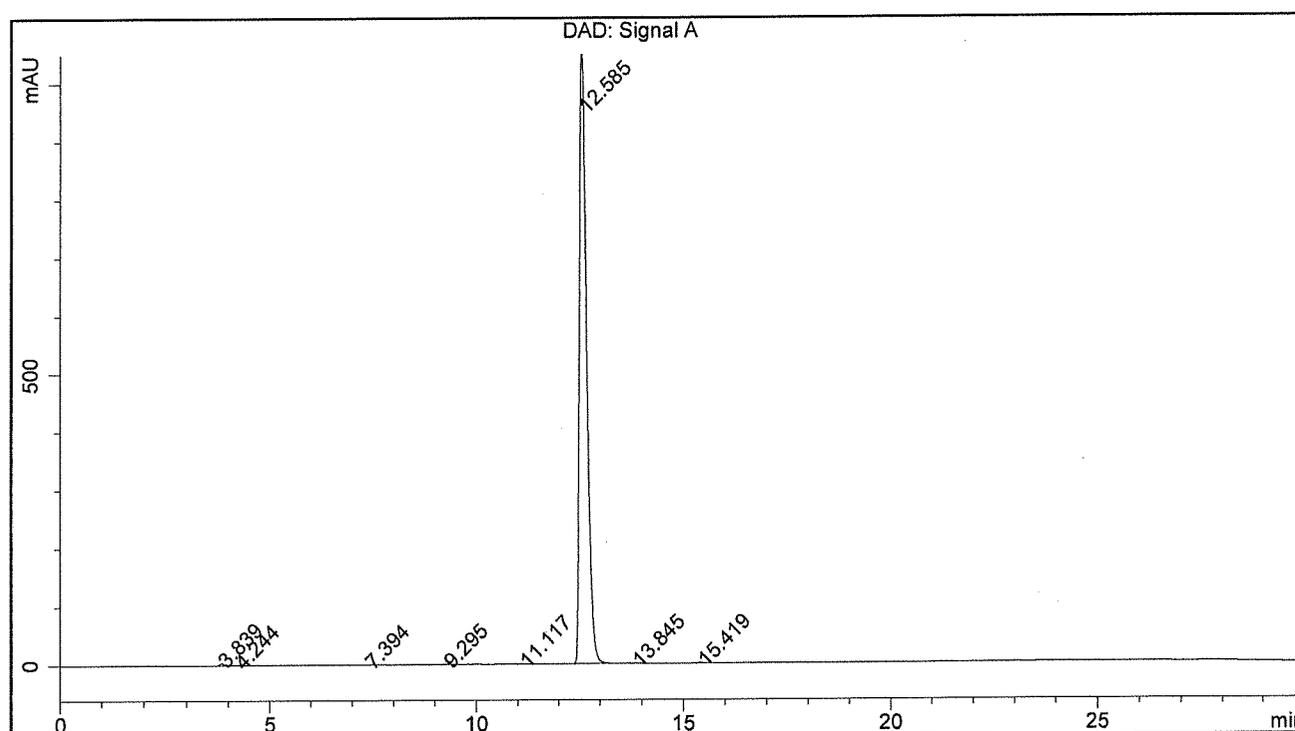
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BDG - Analysis of Dutasteride

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm
 Guard : Phenomenex Security Guard C18 RP 4 x 3 mm
 Mobile Phase A: Water
 Mobile Phase B: Acetonitrile
 Gradient (A:B) : T0=40:60, T20=10:90, T24=10:90, T27=40:60, T30=40:60
 Flow Rate : 1.0 mL/min
 Sample Solvent : Initial Mobile Phase
 Column Temperature : 20C
 Injection Volume : 10 uL
 Detection : UV at 242 nm

Sample Name	BDG 10258.1	Instrument	AnalyticalLC01
Acquisition	20/05/2011, 13:53:57	Method (rev.)	LC10286b (2)
Sequence	BDG_20May2011b	Vial Position	41
Operator	solvation010\cerityadmin	Injection	1 of 1



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	3.84 min	3.1775	22.5524	0.1048 min	0.178 %
2	4.24 min	0.4084	2.9199	0.1094 min	0.023 %
3	7.39 min	0.2447	1.9017	0.1167 min	0.015 %
4	9.30 min	0.4899	4.5986	0.1455 min	0.036 %
5	11.12 min	0.4673	4.5220	0.1429 min	0.036 %
6	12.59 min	1066.3645	12609.9612	0.1820 min	99.617 %
7	13.85 min	0.3688	3.9236	0.1621 min	0.031 %
8	15.42 min	0.7078	8.0549	0.1688 min	0.064 %