



## BDG SYNTHESIS

### Certificate of Analysis

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

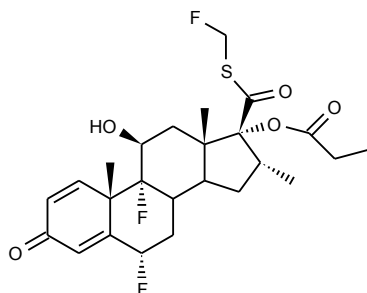
*Barry Dent*

Barry R. Dent, PhD, Director  
28 January 2010

**Name:** Fluticasone Propionate

**CAS Number:** 80474-14-2

**Structure:**



**Molecular Weight:**  $C_{25}H_{31}F_3O_5S = 500.57$

**Lot Number:** BDG 7979.3

**Appearance:** White, powder

**Corrected Purity:** 98.2 % (HPLC) - 0.4 % (ethyl acetate) = 97.9 %

**Re-test Date:** 28 January 2011

**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: a small amount of ethyl acetate (0.35 % w/w) is 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  $m/z$  523.1743.  $C_{25}H_{31}F_3NaO_5S$   $[M+Na]^+$  requires  $m/z$  523.1737. The deviation of 1.2 ppm is within normally accepted limits for the establishment of identity by HRMS.

### HPLC

A sharp, symmetrical peak is observed (98.2 %). 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 60.23, H 6.29 %
$C_{25}H_{31}F_3O_5S$	Requires:	C 59.98, H 6.24 %

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).

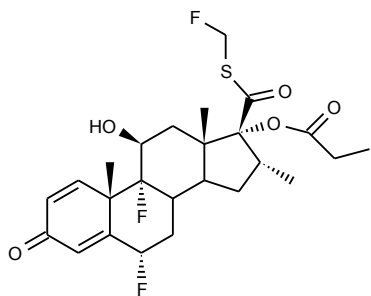
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

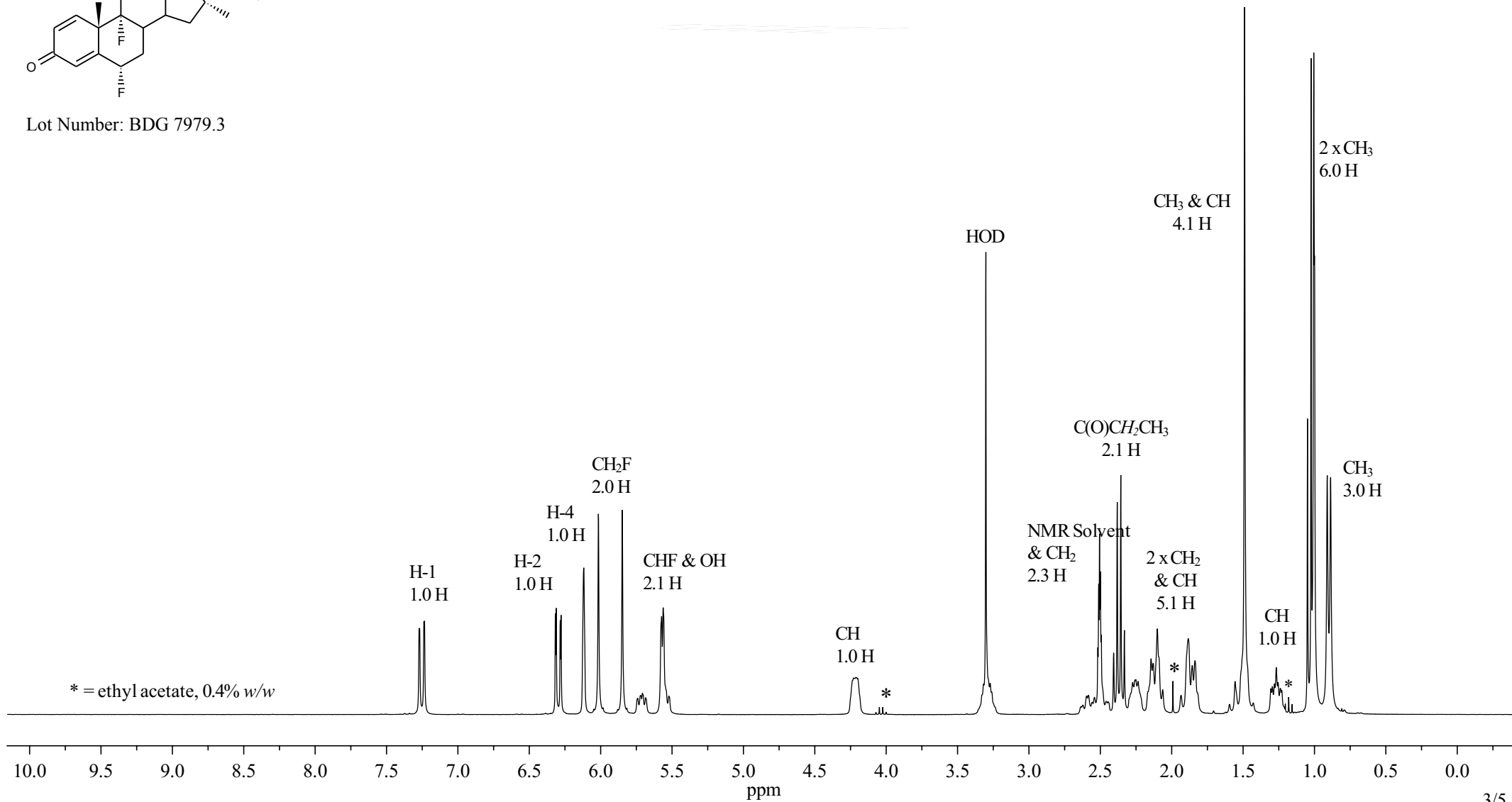


Proton NMR Spectrum of Fluticasone Propionate in DMSO-d<sub>6</sub>

**BDG SYNTHESIS**



Lot Number: BDG 7979.3

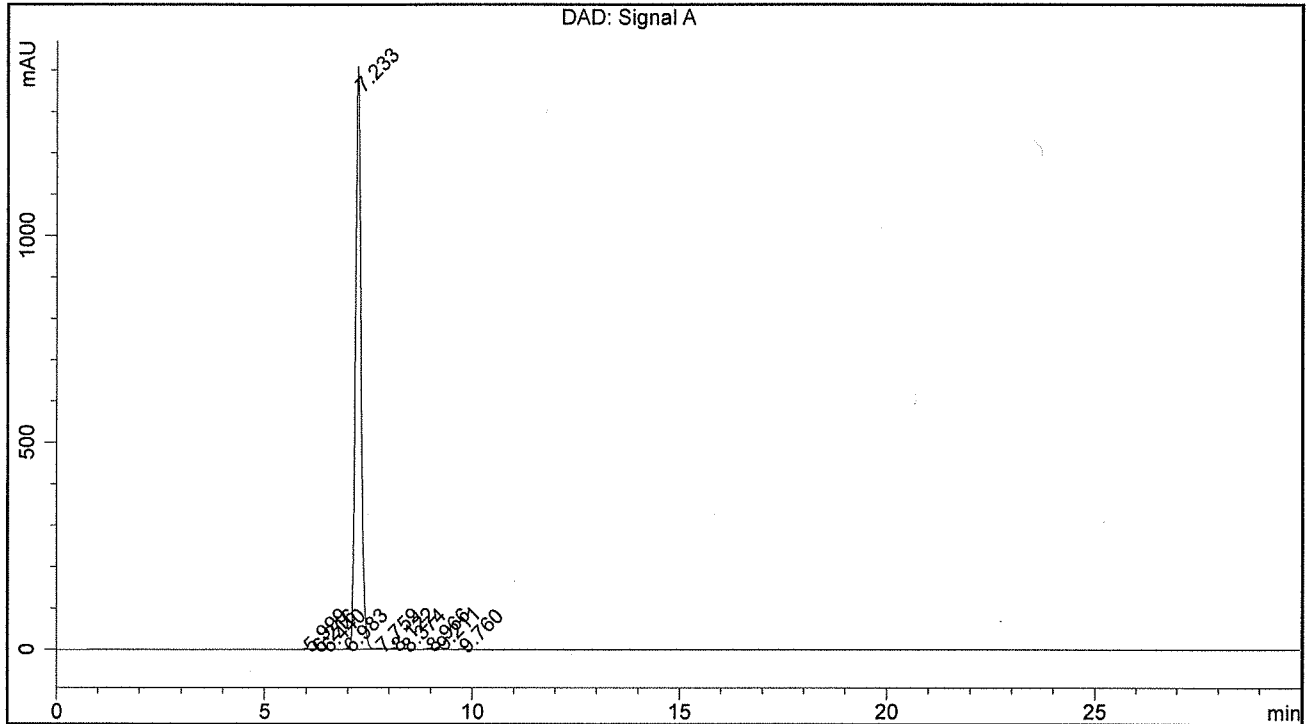




BDG - Analysis of Fluticasone propionate

Column : Phenomenex Luna C18 5um 250 x 4.6 mm  
 Guard : Phenomenex Security Guard C18 4 x 3 mm  
 Mobile Phase : 30:70 Water : Acetonitrile . . . . . Flow Rate : 1.0 mL/min  
 Sample Solvent : 30:70 Water : Acetonitrile . . . . . Injection Volume : 10 uL  
 Column Temperature : 20C . . . . . Detection : UV at 239 nm

<b>Sample Name</b>	BDG 7979.3	<b>Instrument</b>	AnalyticalLC01
<b>Acquisition</b>	28/01/2010, 11:33:59	<b>Method (rev.)</b>	LC10240c ( 4)
<b>Sequence</b>	BDG_28Jan2010a	<b>Vial Position</b>	2
<b>Operator</b>	solvation010\cerityadmin	<b>Injection</b>	2 of 2



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	6.00 min	2.7186	21.0797	0.1185 min	0.157 %
2	6.22 min	1.1546	10.0032	0.1291 min	0.074 %
3	6.44 min	1.6189	14.5850	0.1351 min	0.108 %
4	6.98 min	1.6091	9.9795	0.0964 min	0.074 %
5	7.23 min	1407.9676	13205.2069	0.1434 min	98.186 %
6	7.76 min	2.4250	26.7948	0.1609 min	0.199 %
7	8.12 min	3.1567	28.5120	0.1414 min	0.212 %
8	8.37 min	2.2624	24.0801	0.1622 min	0.179 %
9	8.97 min	3.0550	29.7088	0.1495 min	0.221 %
10	9.21 min	5.8369	70.0688	0.1781 min	0.521 %
11	9.76 min	0.5746	9.2233	0.2613 min	0.069 %