



BDG SYNTHESIS

Certificate of Analysis

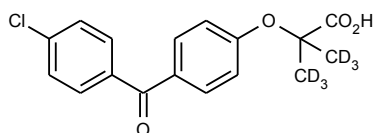
BDG Synthesis certifies that this reference material meets or exceeds the specifications stated herein.

Barry Dent

Barry R. Dent, PhD, Director
17 November 2006

Name: Fenofibric Acid- d_6
CAS Number: 42017-89-0 (unlabelled)

Structure:



Molecular Weight: $C_{17}H_9D_6ClO_4 = 324.79$

Lot Number: BDG 6609.1

Appearance: Off-white, crystalline solid

Corrected Purity: 98.5 % (HPLC) - 0.4 % (methanol) - 1.1 % (water) = 97.0 %

Isotopic Purity: Under 0.5 % d_0

Re-test Date: 17 November 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.

Isotopic Labelling: the signal at the site of deuteration is still present at about 4 % of the intensity which would be expected for unlabelled material, indicating that some H/D exchange has occurred.

Residual Solvents: a small amount of methanol (0.4 % 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.

Isotopic Labelling: the signal at the site of deuteration has collapsed into a small multiplet compared with what would be expected for unlabelled material indicating almost complete label incorporation.

High-resolution Mass Spectrum (FAB+)

Found m/z 325.1112. $C_{17}H_{10}D_6^{35}ClO_4$ $[M+H]^+$ requires m/z 325.1114. The deviation of 0.6 ppm is within normally accepted limits for the establishment of identity by HRMS. No signal for d_0 material was seen (detection limit about 0.5 %).

HPLC

A sharp, slightly tailing peak is observed (98.5 %). 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 62.30, H 2.85, D 3.81 %
$C_{17}H_9D_6ClO_4 \cdot 0.2H_2O$	Requires:	C 62.18, H 2.89, D 3.68 %, H_2O 1.10 %
$C_{17}H_9D_6ClO_4$	Requires:	C 62.87, H 2.79, D 3.72 %

The elemental analyses fall slightly 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. In the absence of a Karl-Fischer water analysis, we recommend that the “best-fit” water content be used when determining corrected purity.

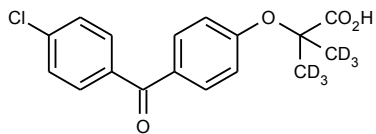
The available quantity of custom-synthesised material is always small, and this limits the extent and type of analytical data which can be obtained. This Certificate is presented in descriptive format for use by analytical chemists who are trained in the use of custom-synthesised materials. Custom materials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

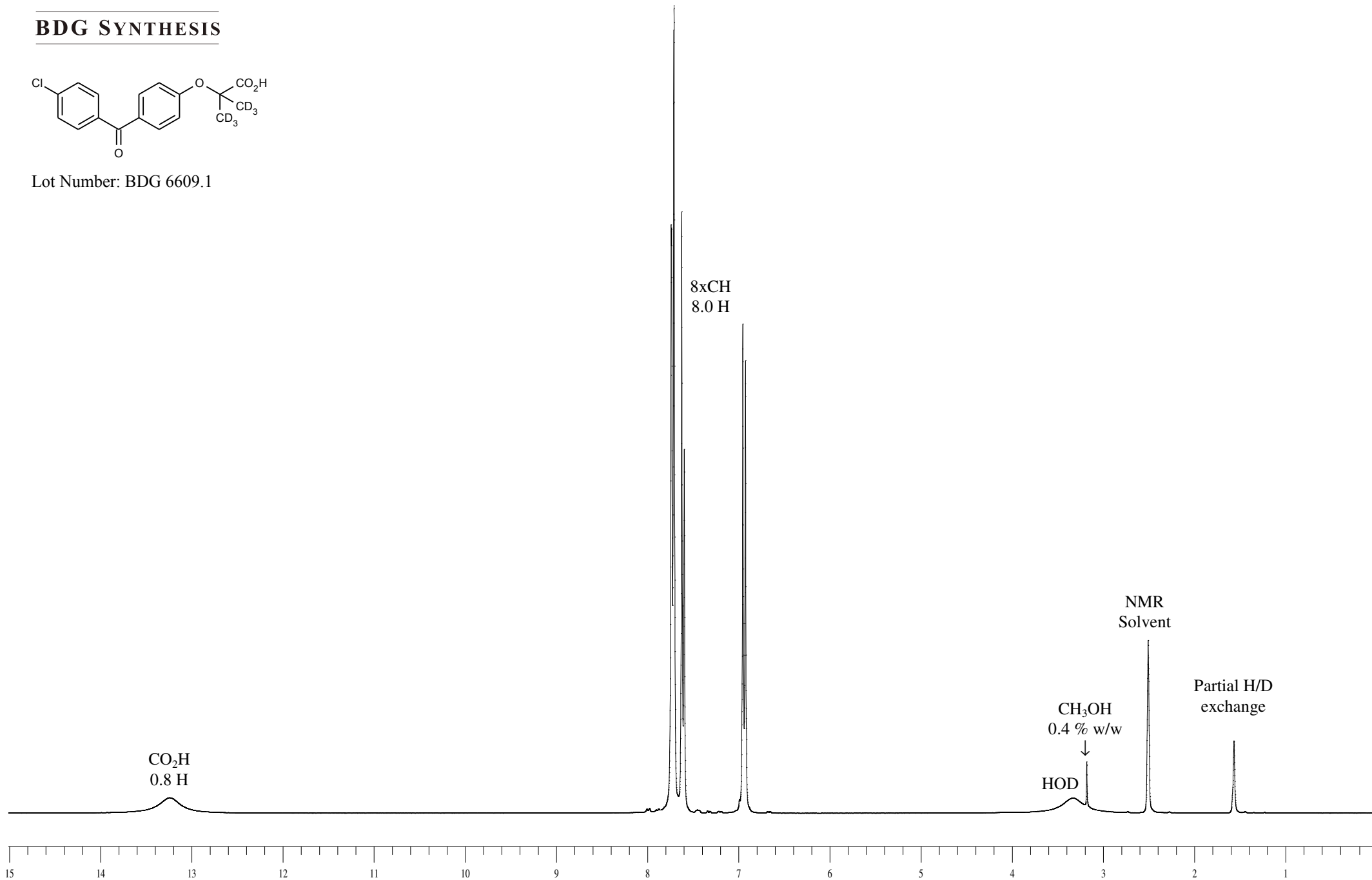


Proton NMR Spectrum of Fenofibric Acid-d₆ in DMSO-d₆

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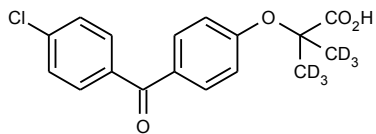
Lot Number: BDG 6609.1



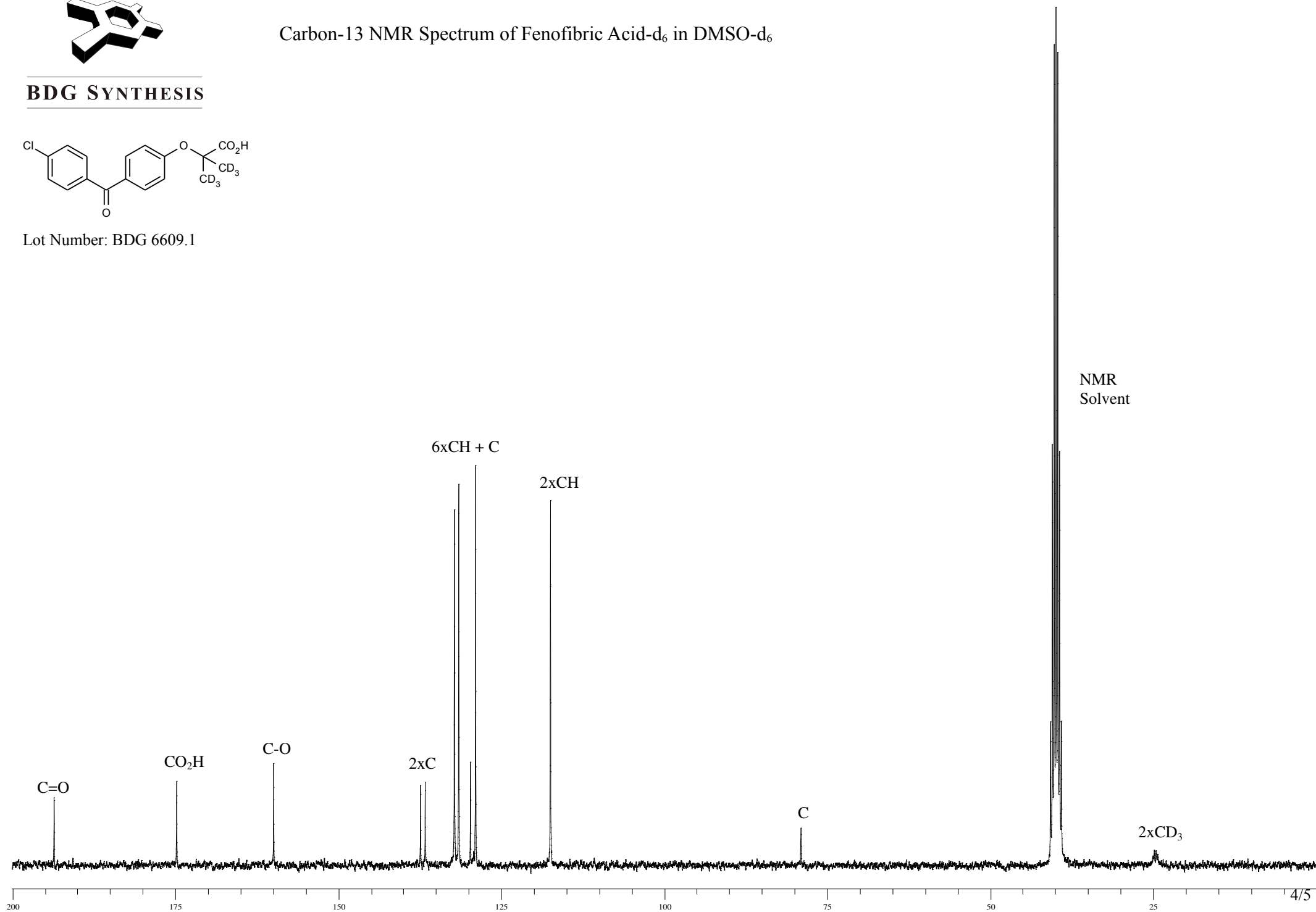


Carbon-13 NMR Spectrum of Fenofibric Acid-d₆ in DMSO-d₆

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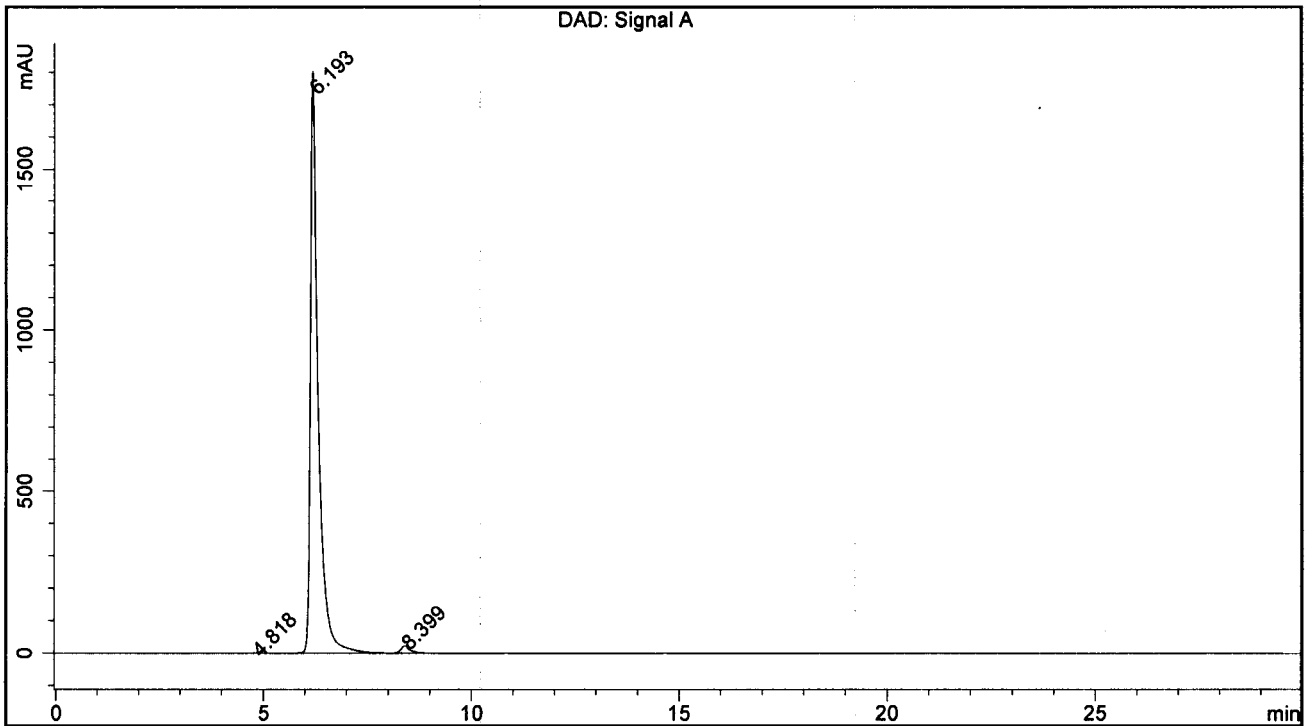
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BDG - Analysis of Fenofibric Acid-d6

Column : Phenomenex Luna C18(2) 5um 250 x 4.6 mm
 Guard : Phenomenex Security Guard C18 RP 4 x 3 mm
 Mobile Phase : 70:30 Acetonitrile : Water + Phosphoric Acid to pH 2.5
 Flow Rate : 1.0 mL/min
 Sample Solvent : Mobile Phase
 Column Temperature : 20C
 Injection Volume : 10 uL
 Detection : UV at 286 nm

Sample Name	BDG 6609.1	Instrument	AnalyticalLC01
Acquisition	09/11/2006, 11:10:34	Method (rev.)	LC10103a (4)
Sequence	BDG_09Nov2006a - Reprocessed	Vial Position	1
Operator	solvation010\cerityadmin	Injection	2 of 2



Area Percent Report

Peak#	RT	Peak Height	Peak Area	Width	Area %
1	4.82 min	0.8667	7.4137	0.1238 min	0.031 %
2	6.19 min	1803.3714	23435.8555	0.1836 min	98.464 %
3	8.40 min	22.5641	358.0557	0.2251 min	1.504 %