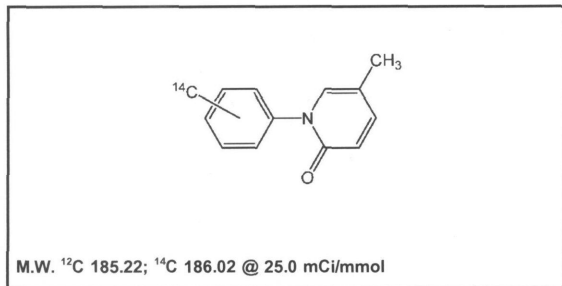




Product Data Sheet

MC-1435

Pirfenidone, [benzene ring-¹⁴C(U)]-



Lot #: 348-179-0250-A-20061213-JH

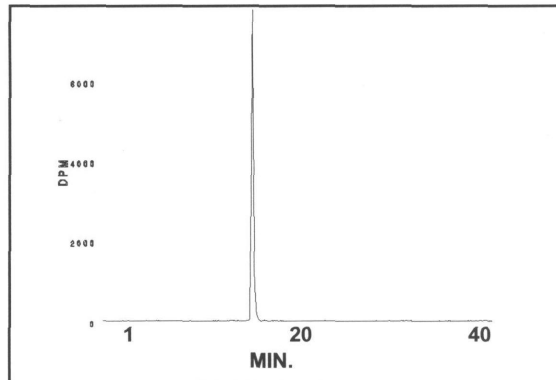
Specific Activity: 25.0 mCi/mmol

Concentration: 0.1 mCi/ml; 744.09 µg/ml

Packaged in: Ethanol solution

Date of Analysis: January 22, 2009

Radiochemical Purity: 99.8%



HPLC ANALYSIS LOT 348-179-0250-A-20061213-JH
File Name: intg1445 Date and Time: 1/22/2009 6:29:23 PM
Unit 16 Radio

Peak #	Area %	Time	Area
1	99.86	15.38000	12028.33077
2	0.14	16.67330	16.50994
Totals	100.00		12044.84071

Stability and Storage Recommendation: Store at -20°C.

Product Warranty: Stated on the reverse side of this Product Data Sheet.

Caution: Not For Use In Humans Or Clinical Diagnosis. This product is intended for investigational or manufacturing use only. It is pharmaceutically unrefined and is not intended for use in humans. Responsibility for its use in humans, as a diagnostic reagent, and compliance with federal laws rests solely with the purchaser.

MC-1435

Pirfenidone, [benzene ring-14C(U)]-

Lot 348-179-0250-A-20061213-JH

A) All chromatograms were run using the HPLC method described on the Product Data Sheet.

Concentrations and volumes:

Standard solution concentration was 3.5 mg/mL.

Pirfenidone, [benzene ring-14C(U)]- concentration was 0.1 mCi/mL.

Volume of standard alone injection was 7.5 μ L

Volume of **Pirfenidone, [benzene ring-14C(U)]-** alone injection was 2.0 μ L.

Co-injection solution consisted of 2.0 μ L **Pirfenidone, [benzene ring-14C(U)]-** + 7.5 μ L standard.

Volume of co-injection was 9.5 μ L.

Volume of blank injection was 2.0 μ L.

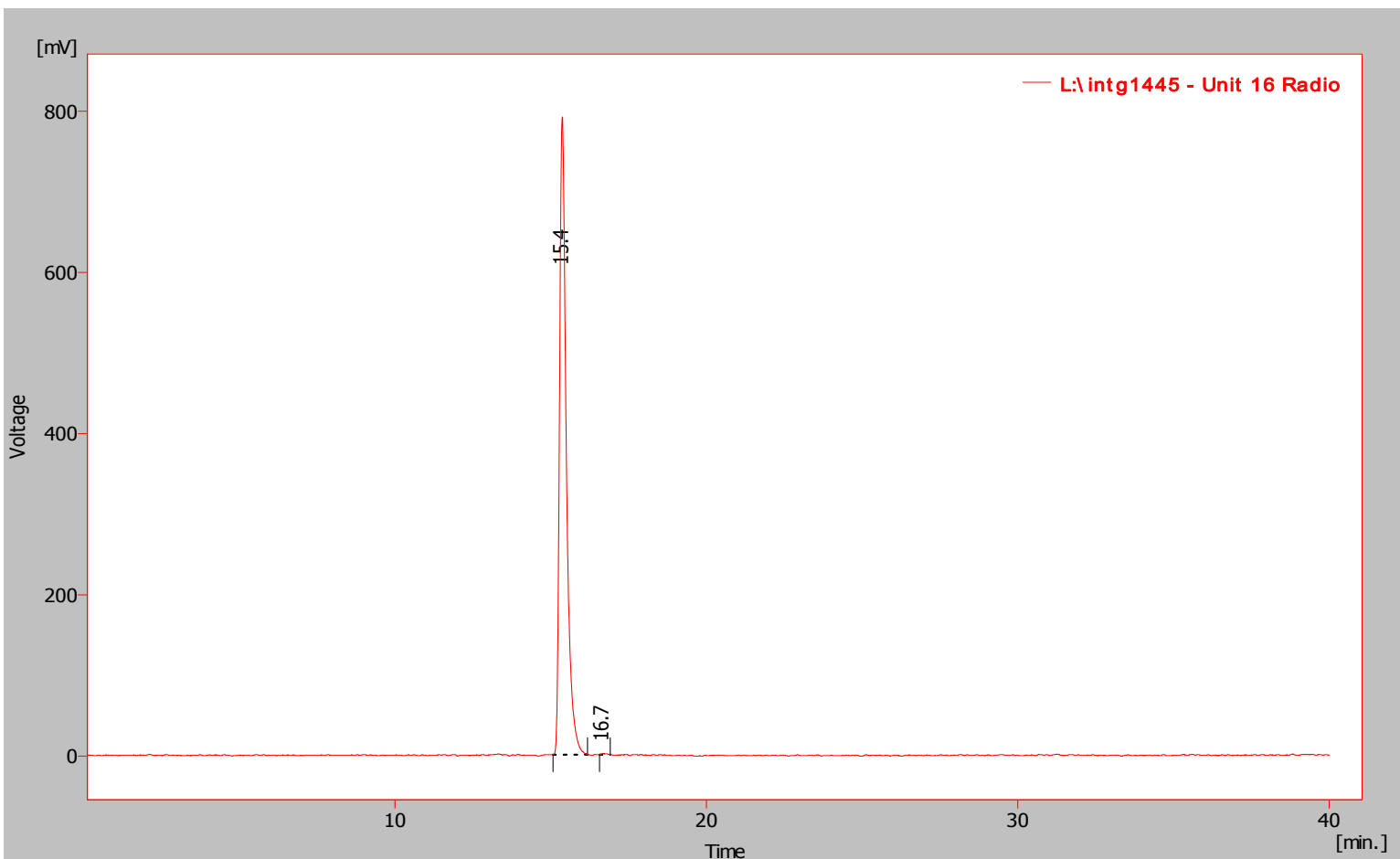
B) Mass spectrometry - Positive mode

C) NMR

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

File Name	: L:\intg1445	File Created	: 12/6/2013 10:48:17 AM
Origin	: Acquired, Acquisition started 1/22/2009 5:49:24 PM	Acquired Date	: 1/22/2009 6:29:23 PM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material alone	Modified	: 12/6/2013 11:01 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



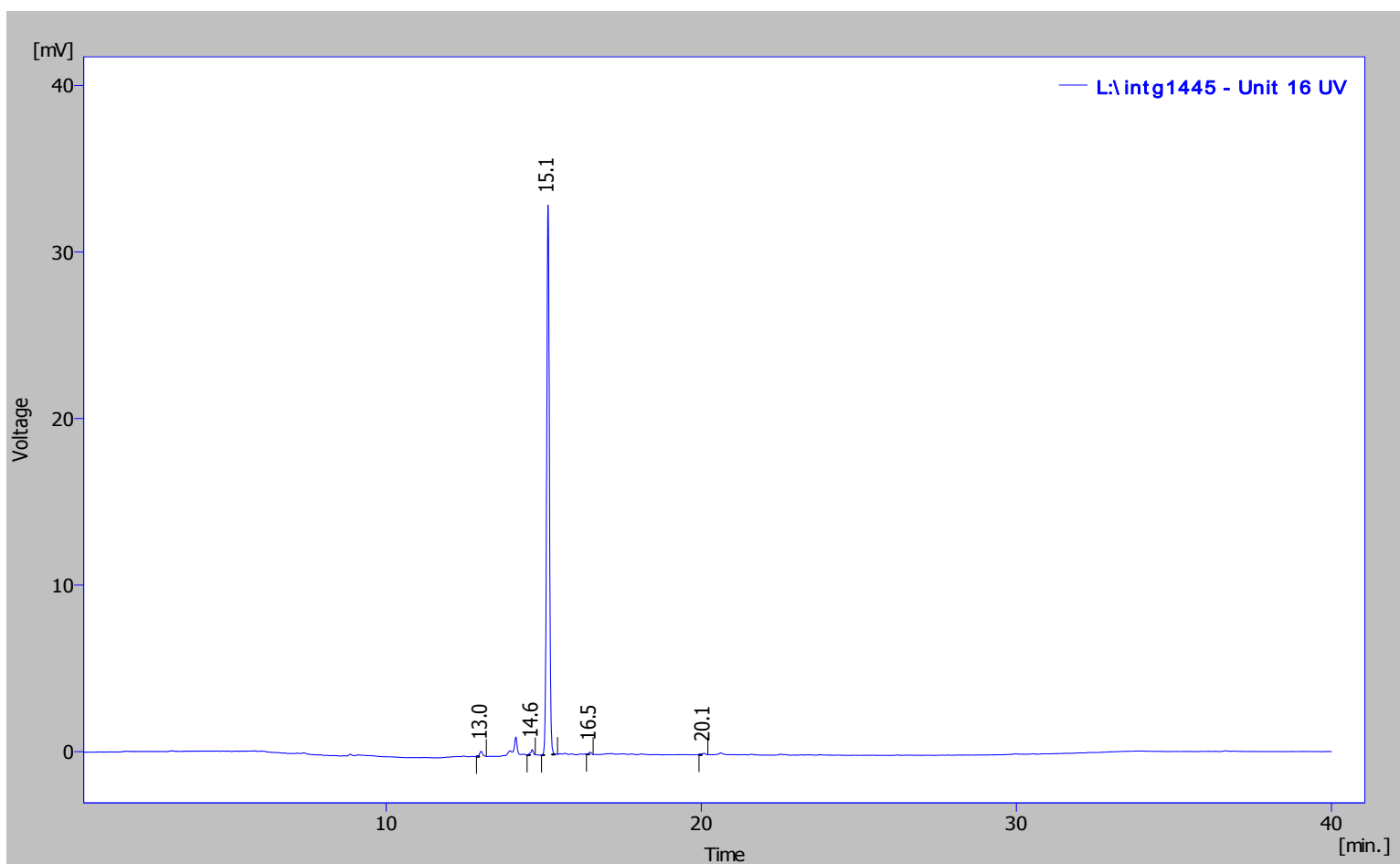
Result Table (Uncal - L:\intg1445 - Unit 16 Radio)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		15.380	99.86	12028.331	791.219	99.808	14411.660
2		16.673	0.14	16.510	1.523	0.192	55196.362
		Total	100.00	12044.841	792.742	100.000	

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

File Name	: L:\intg1445	File Created	: 12/6/2013 10:48:17 AM
Origin	: Acquired, Acquisition started 1/22/2009 5:49:24 PM	Acquired Date	: 1/22/2009 6:29:23 PM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: UV trace of 14C material alone	Modified	: 12/6/2013 11:04 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



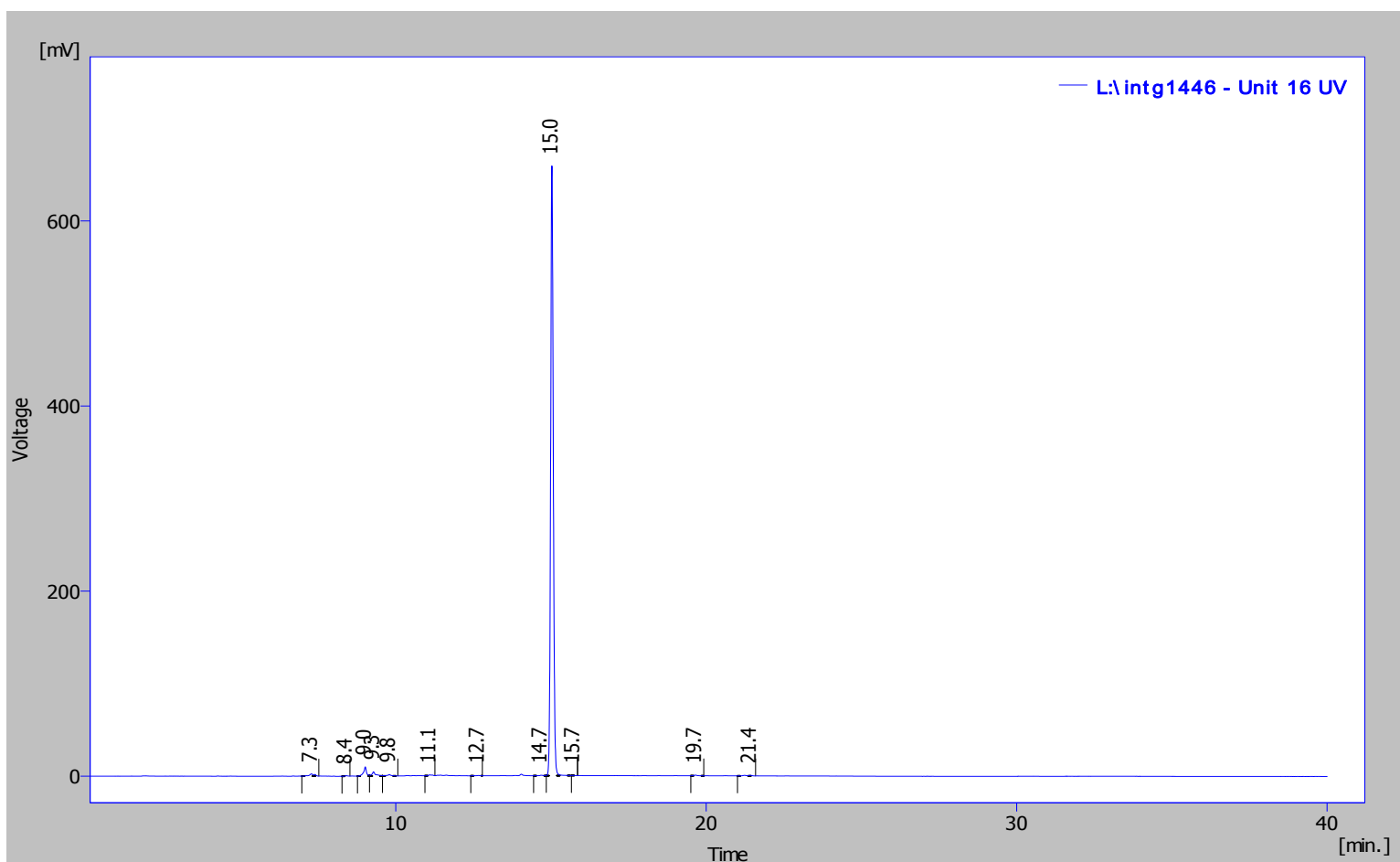
Result Table (Uncal - L:\intg1445 - Unit 16 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		13.020	1.01	2.083	0.311	0.918	74152.793
2		14.633	0.89	1.838	0.319	0.943	103268.988
3		15.137	97.39	200.812	33.005	97.463	125141.752
4		16.473	0.40	0.828	0.141	0.417	179147.008
5		20.083	0.31	0.630	0.088	0.259	174052.567
		Total	100.00	206.191	33.864	100.000	

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

File Name	: L:\intg1446	File Created	: 12/6/2013 10:48:17 AM
Origin	: Acquired, Acquisition started 1/23/2009 8:15:51 AM	Acquired Date	: 1/23/2009 8:55:50 AM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: UV trace of standard alone	Modified	: 12/6/2013 11:05 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



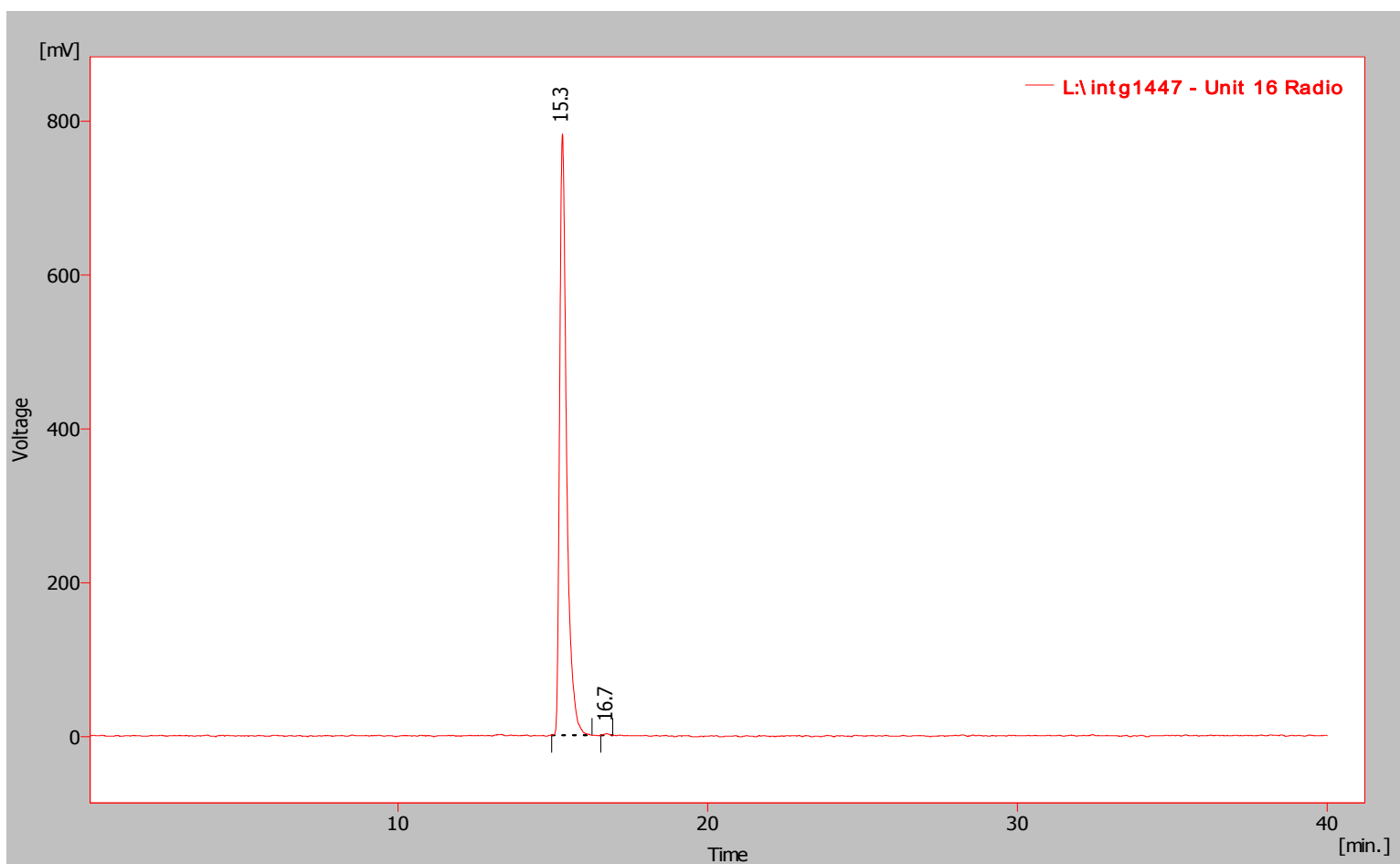
Result Table (Uncal - L:\intg1446 - Unit 16 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		7.283	0.68	27.910	2.442	0.358	5880.155
2		8.403	0.07	3.072	0.557	0.082	43563.883
3		9.017	1.62	66.422	10.039	1.474	21127.322
4		9.283	0.99	40.736	4.582	0.673	10339.334
5		9.790	0.37	15.340	1.436	0.211	10271.088
6		11.093	0.19	7.769	0.909	0.133	39501.923
7		12.660	0.07	2.805	0.312	0.046	26443.436
8		14.683	0.14	5.742	0.581	0.085	30473.263
9		15.027	95.51	3925.762	658.861	96.709	0.000
10		15.733	0.02	1.007	0.198	0.029	227837.830
11		19.653	0.13	5.195	0.701	0.103	118266.130
12		21.423	0.21	8.545	0.662	0.097	40137.371
		Total	100.00	4110.306	681.280	100.000	

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

File Name	: L:\intg1447	File Created	: 12/6/2013 10:48:13 AM
Origin	: Acquired, Acquisition started 1/23/2009 9:04:33 AM	Acquired Date	: 1/23/2009 9:44:31 AM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material co-injected with standard	Modified	: 12/6/2013 11:06 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



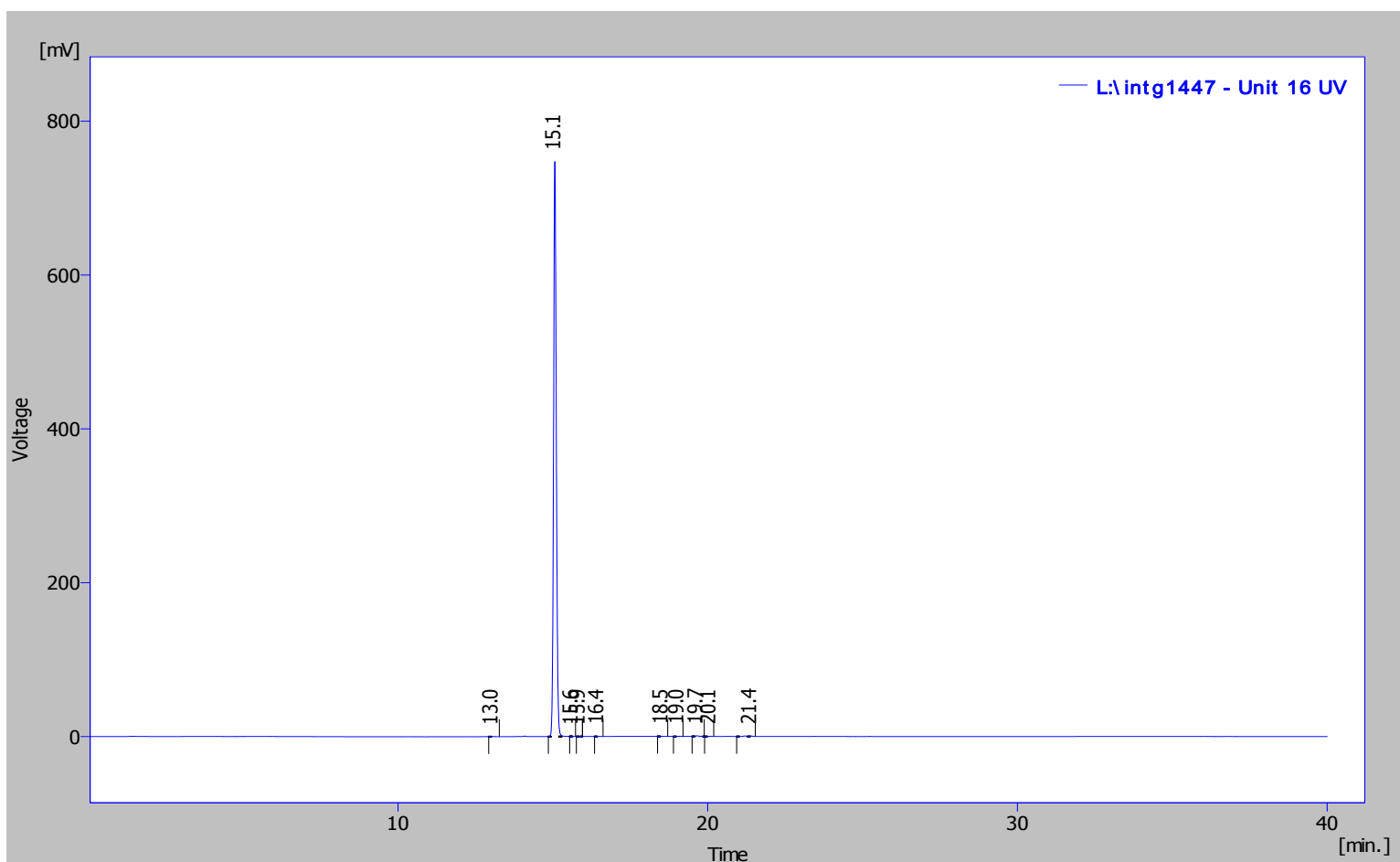
Result Table (Uncal - L:\intg1447 - Unit 16 Radio)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		15.310	99.81	12280.303	781.574	99.738	12809.086
2		16.743	0.19	23.602	2.054	0.262	54132.355
		Total	100.00	12303.905	783.629	100.000	

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

File Name	: L:\intg1447	File Created	: 12/6/2013 10:48:13 AM
Origin	: Acquired, Acquisition started 1/23/2009 9:04:33 AM	Acquired Date	: 1/23/2009 9:44:31 AM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: UV trace of 14C material co-injected with standard	Modified	: 12/6/2013 11:08 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



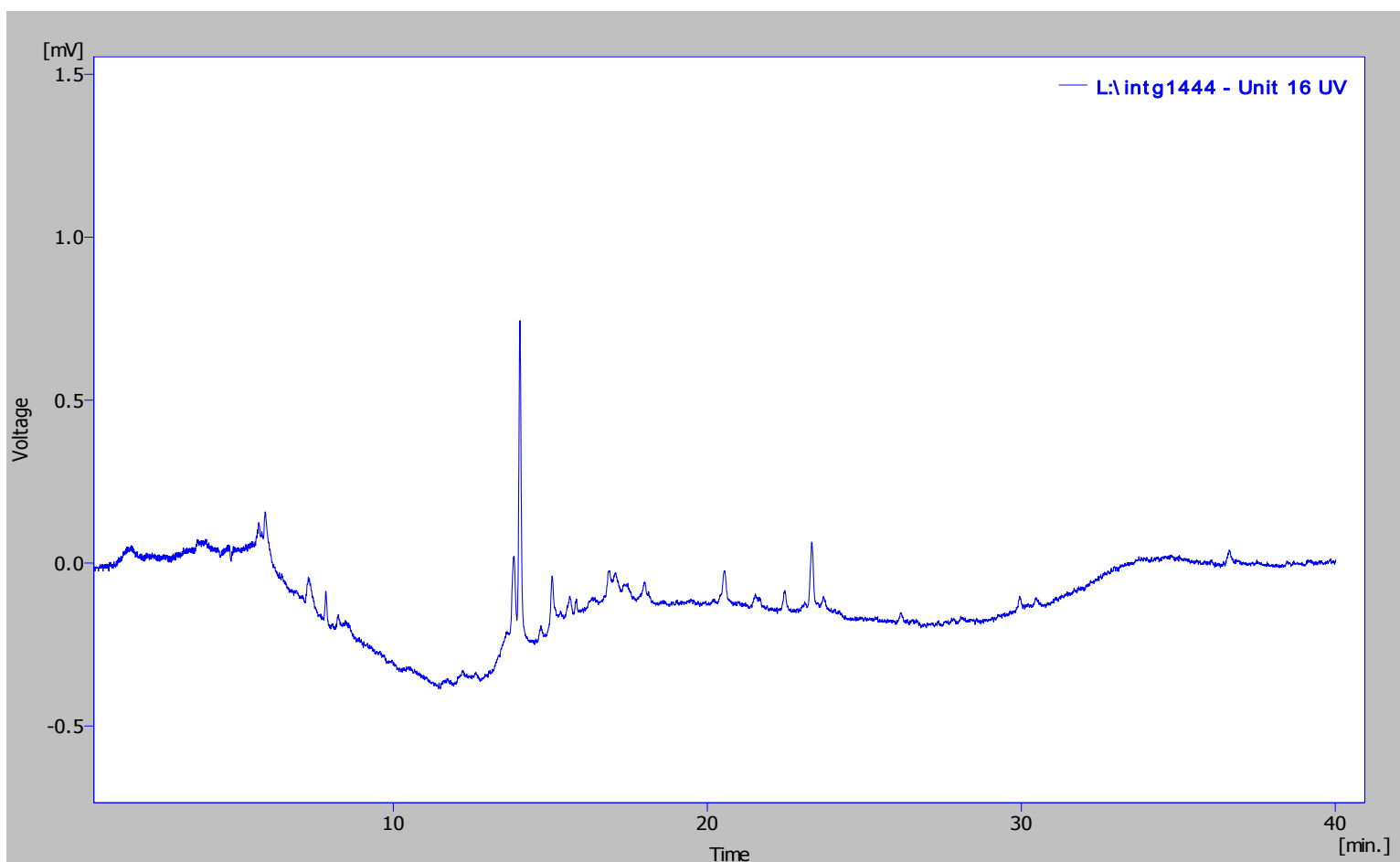
Result Table (Uncal - L:\intg1447 - Unit 16 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.p]
1		13.033	0.05	2.144	0.331	0.044	61649.847
2		15.063	99.51	4594.093	747.452	99.641	0.000
3		15.620	0.01	0.272	0.046	0.006	173408.601
4		15.850	0.01	0.515	0.101	0.014	205644.840
5		16.450	0.02	1.061	0.170	0.023	139106.549
6		18.527	0.02	0.870	0.128	0.017	126911.496
7		19.037	0.02	1.096	0.149	0.020	149427.555
8		19.657	0.13	5.894	0.825	0.110	129026.682
9		20.063	0.03	1.155	0.164	0.022	179264.321
10		21.383	0.21	9.697	0.779	0.104	39477.520
		Total	100.00	4616.797	750.147	100.000	

MC-1435
Pirfenidone, [benzene ring-14C(U)]-
Lot 348-179-0250-A-20061213-JH

Chromatogram Info:

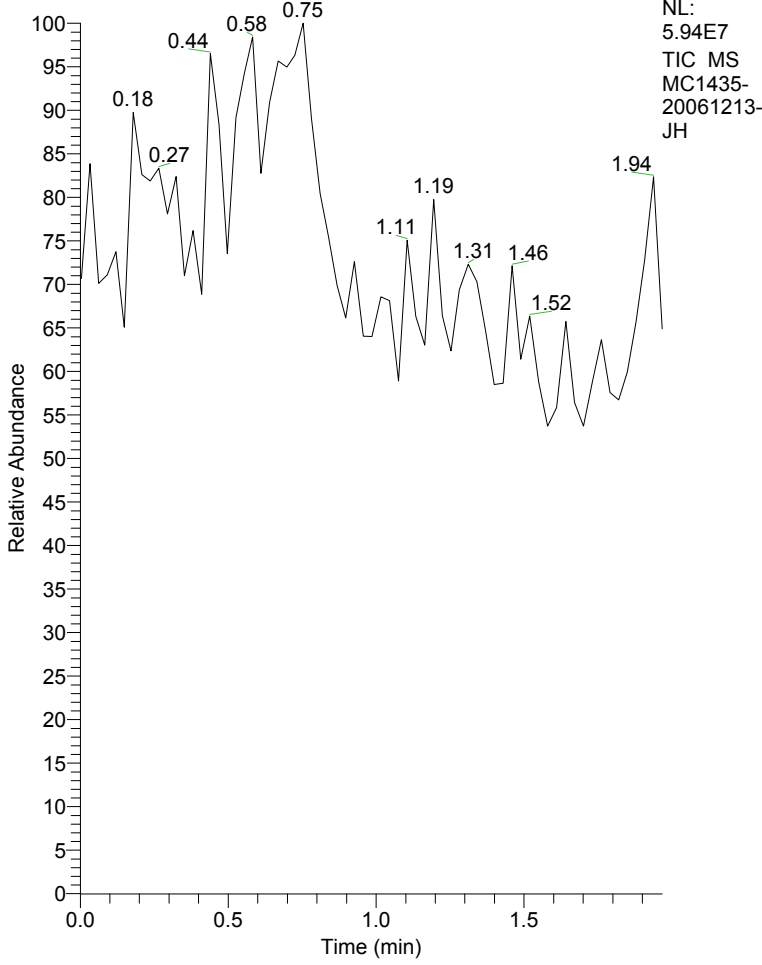
File Name	: L:\intg1444	File Created	: 12/6/2013 10:48:17 AM
Origin	: Acquired, Acquisition started 1/22/2009 4:59:23 PM	Acquired Date	: 1/22/2009 5:39:22 PM
Project	: Test	By	: Administrator
Method	: Unit16_40_min_run	By	: Administrator
Description	: UV trace of blank injection	Modified	: 12/6/2013 11:09 AM
Created	: 8/9/2007 8:59 AM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



Result Table (Uncal - L:\intg1444 - Unit 16 UV)

Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
No peak to report						

RT: 0.00 - 1.97



NL:
5.94E7
TIC MS
MC1435-
20061213-
JH

MC1435-20061213-JH#1-68 RT: 0.00-1.97 AV:

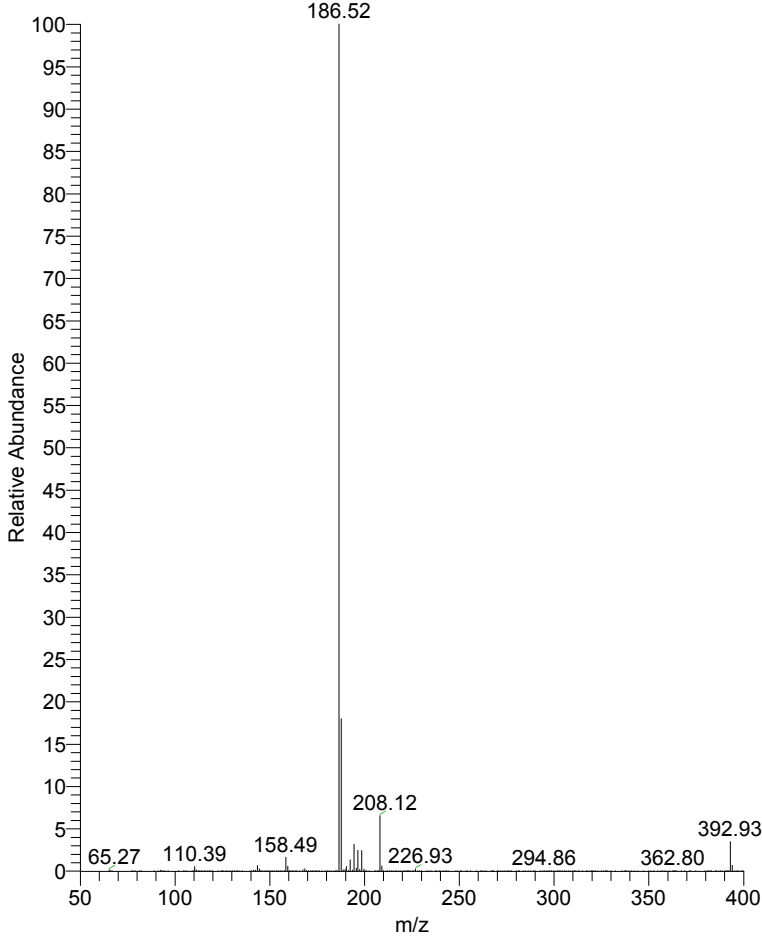
T: + c NSI Full ms [50.00-400.00]

m/z= 184.07-204.36

m/z	Intensity	Relative
184.75	1834.4	0.01
185.41	12943.1	0.04
186.52	29748549.9	100.00
187.75	5347749.6	17.98
188.71	36970.7	0.12
189.64	48331.1	0.16
190.45	151393.0	0.51
191.52	14517.9	0.05
192.46	392297.6	1.32
193.52	28341.1	0.10
194.45	933260.4	3.14
195.57	94806.2	0.32
196.43	722155.4	2.43
197.56	45112.0	0.15
198.43	718871.0	2.42
199.70	58036.5	0.20
200.38	4365.0	0.01
201.07	207.1	0.00
202.63	55.8	0.00

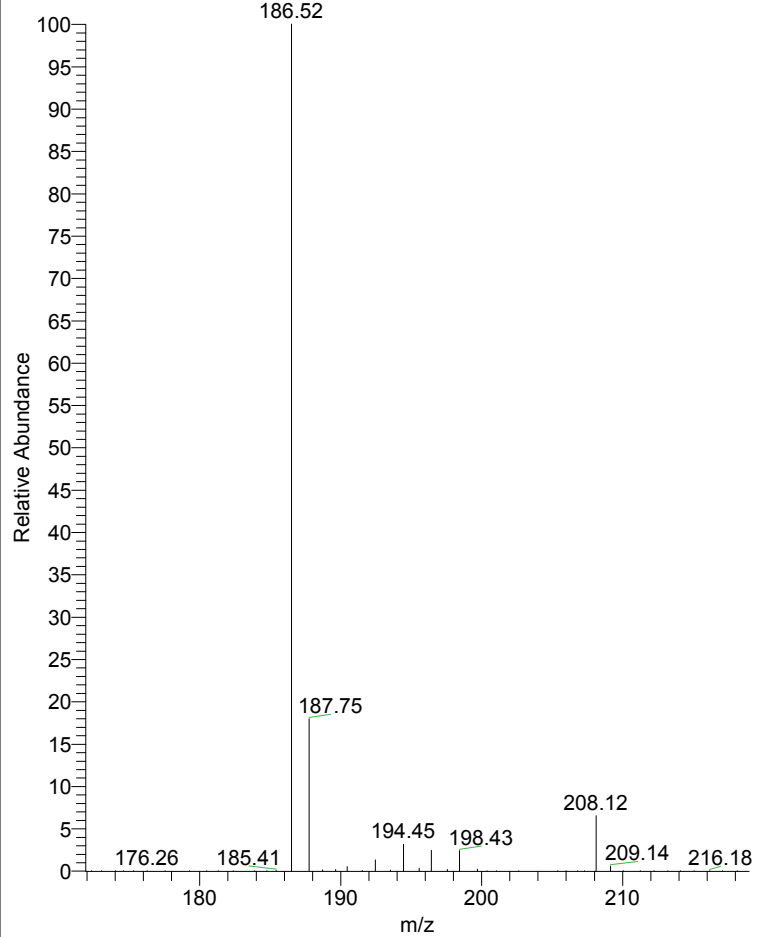
MC1435-20061213-JH #1-68 RT: 0.00-1.97 AV: 68 NL: 2.97E7

T: + c NSI Full ms [50.00-400.00]

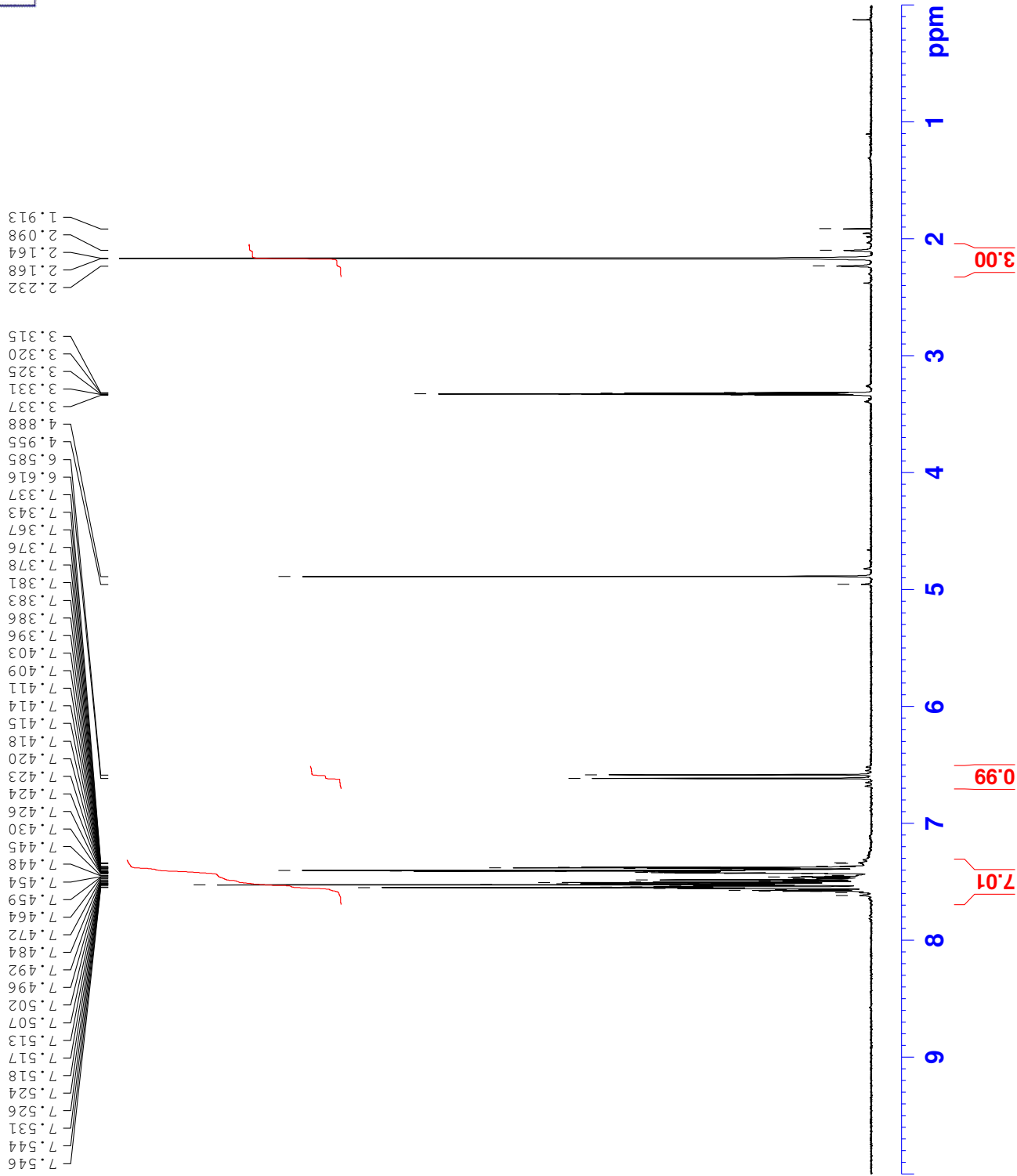


MC1435-20061213-JH #1-68 RT: 0.00-1.97 AV: 68 NL: 2.97E7

T: + c NSI Full ms [50.00-400.00]



MC1435 1H NMR in MeOD
Batch 20061213-JH



Current Data Parameters
NAME MC1435
EXPNO 1
PROCNO 1

F2 - Acquisition Parameter
Date_ 20090127
Time 16.41
INSTRUM spect
PROBHD 5 mm DUX 3H-1H
PULPROG zg30
TD 65536
SOLVENT MeOD
NS 791
DS 2
SWH 6172.839 Hz
FIDRES 0.094190 Hz
AQ 5.3084660 se
RG 362
DW 81.000 us
DE 6.00 us
TE 300.0 K
D1 1.00000000 se
TD0 1

==== CHANNEL f1 =====
NUC1 1H
P1 10.25 us
PL1 0.00 dB
SFO1 300.1318534 MH

F2 - Processing parameters
SI 32768
SF 300.1300000 MH
WDW no
SSB 0
LB 0.00 Hz
GB 0
PC 1.00