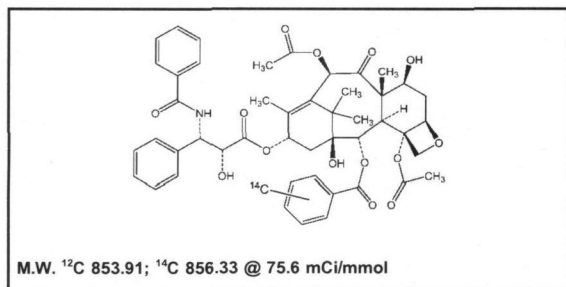




Product Data Sheet

MC-1446

Paclitaxel, [benzoyloxy ring-¹⁴C(U)]-



Lot #: 642-079-0756-A-20091009-SB

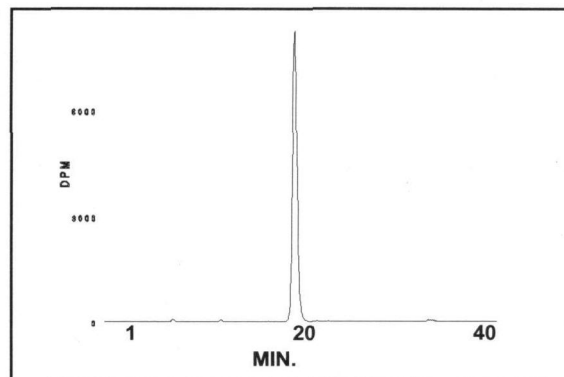
Specific Activity: 75.6 mCi/mmol

Concentration: 0.1 mCi/ml; 1.13 mg/ml

Packaged in: Ethyl acetate solution

Date of Analysis: October 12, 2009

Radiochemical Purity: 98.9%



HPLC ANALYSIS LOT 642-079-0756-A-20091009-SB
File Name: INTB3361 Date and Time: 10/12/2009 1:27:54 P
Unit 11 Radio

Peak #	Area %	Time	Area
1	0.41	6.97670	111.77760
2	0.25	11.92670	69.10510
3	98.90	19.46330	26835.08777
4	0.43	33.01670	116.54451
Totals	100.00		27132.51498

Note: Paclitaxel is the active ingredient in Taxol™ (Taxol™ is a registered trademark of Bristol-Myers Squibb)

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-1446

Paclitaxel, [benzoyloxy ring-¹⁴C]-

Lot 642-079-0756-A-20091009-SB

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

Concentrations and volumes:

Standard solution concentration was 1.0 mg/mL.

Paclitaxel, [benzoyloxy ring-¹⁴C]- concentration was 50.0 µCi/mL.

Volume of standard alone injection was 4.5 µL.

Volume of **Paclitaxel, [benzoyloxy ring-¹⁴C]-** alone injection was 1.5 µL.

Co-injection solution consisted of 1.5 µL **Paclitaxel, [benzoyloxy ring-¹⁴C]-** + 4.5 µL standard.

Volume of co-injection was 6.0 µL.

Volume of blank injection was 1.5 µL.

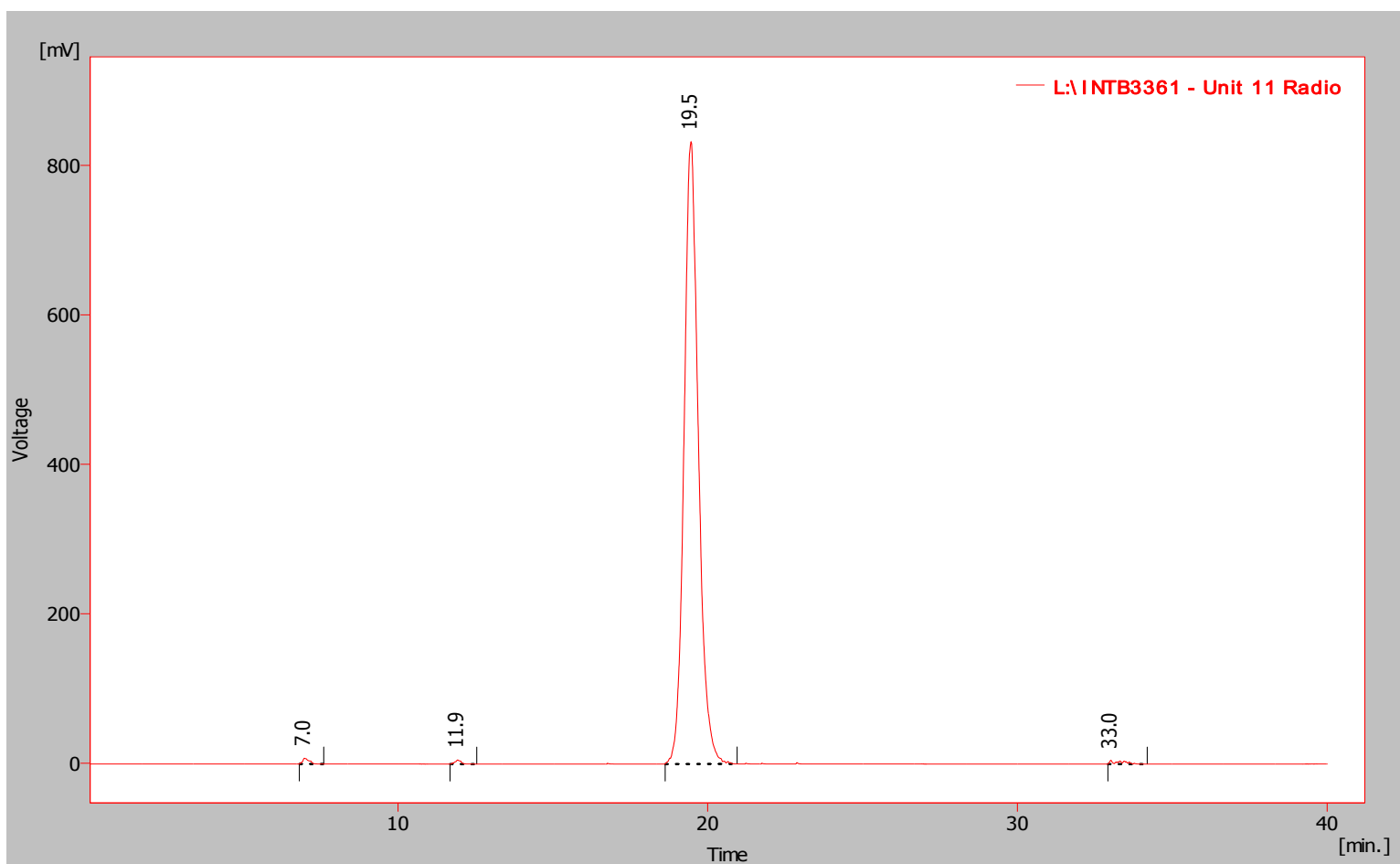
B) Mass spectrometry – Positive mode

C) NMR

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

File Name	: L:\INTB3361	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 12:47:56 PM	Acquired Date	: 10/12/2009 1:27:54 PM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material alone	Modified	: 12/6/2013 4:16 PM
Created	: 11/6/2007 2:08 PM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



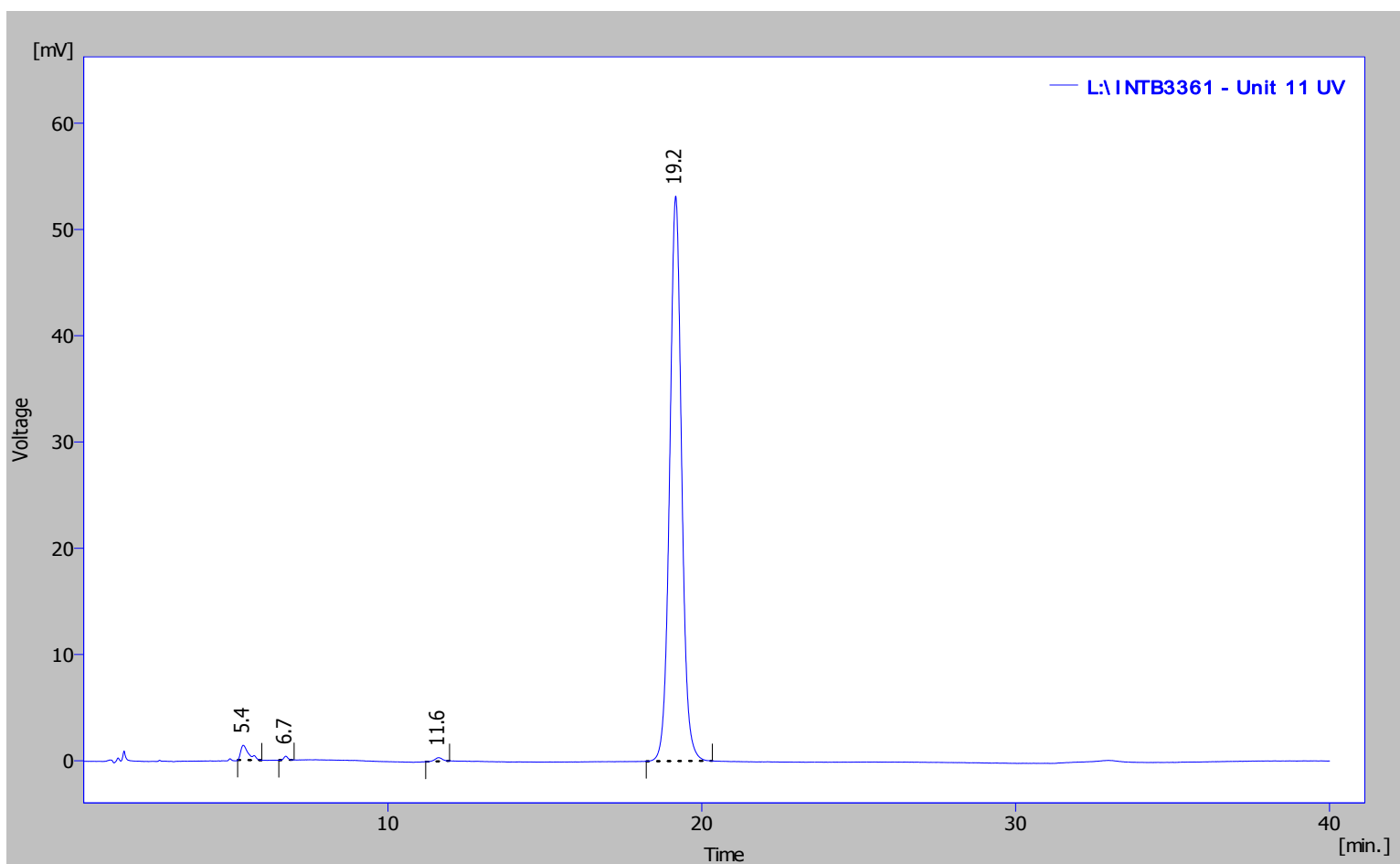
Result Table (Uncal - L:\INTB3361 - Unit 11 Radio)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		6.977	0.41	111.778	7.827	0.919	4674.524
2		11.927	0.25	69.105	5.583	0.656	17407.834
3		19.463	98.90	26835.088	832.962	97.821	6510.039
4		33.017	0.43	116.545	5.143	0.604	21421.610
		Total	100.00	27132.515	851.516	100.000	

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

File Name	: L:\INTB3361	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 12:47:56 PM	Acquired Date	: 10/12/2009 1:27:54 PM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: UV trace of 14C material alone	Modified	: 12/6/2013 4:18 PM
Created	: 11/6/2007 2:08 PM		
Column	:	Detection	: UV 227nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



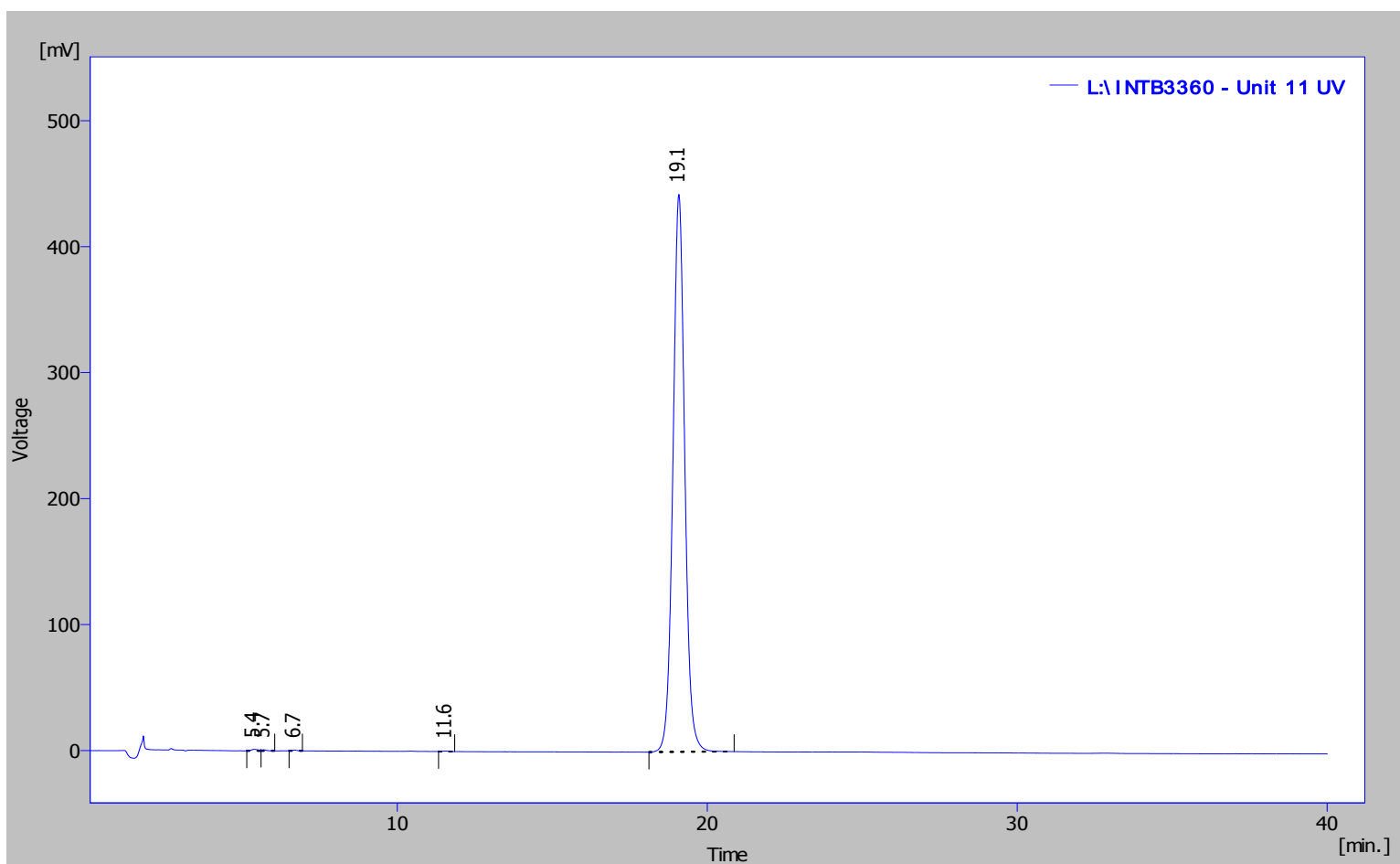
Result Table (Uncal - L:\INTB3361 - Unit 11 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		5.397	1.74	25.051	1.401	2.534	1350.605
2		6.740	0.23	3.314	0.370	0.670	11476.040
3		11.620	0.40	5.711	0.345	0.624	9887.218
4		19.167	97.63	1406.432	53.165	96.172	9724.718
		Total	100.00	1440.508	55.281	100.000	

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

File Name	: L:\INTB3360	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 11:13:51 AM	Acquired Date	: 10/12/2009 11:53:50 AM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: UV trace of standard alone	Modified	: 12/6/2013 4:08 PM
Created	: 11/6/2007 2:08 PM	Detection	: UV 227nm
Column	:	Temperature	:
Mobile Phase	:	Pressure	:
Flow Rate	:	Note	:



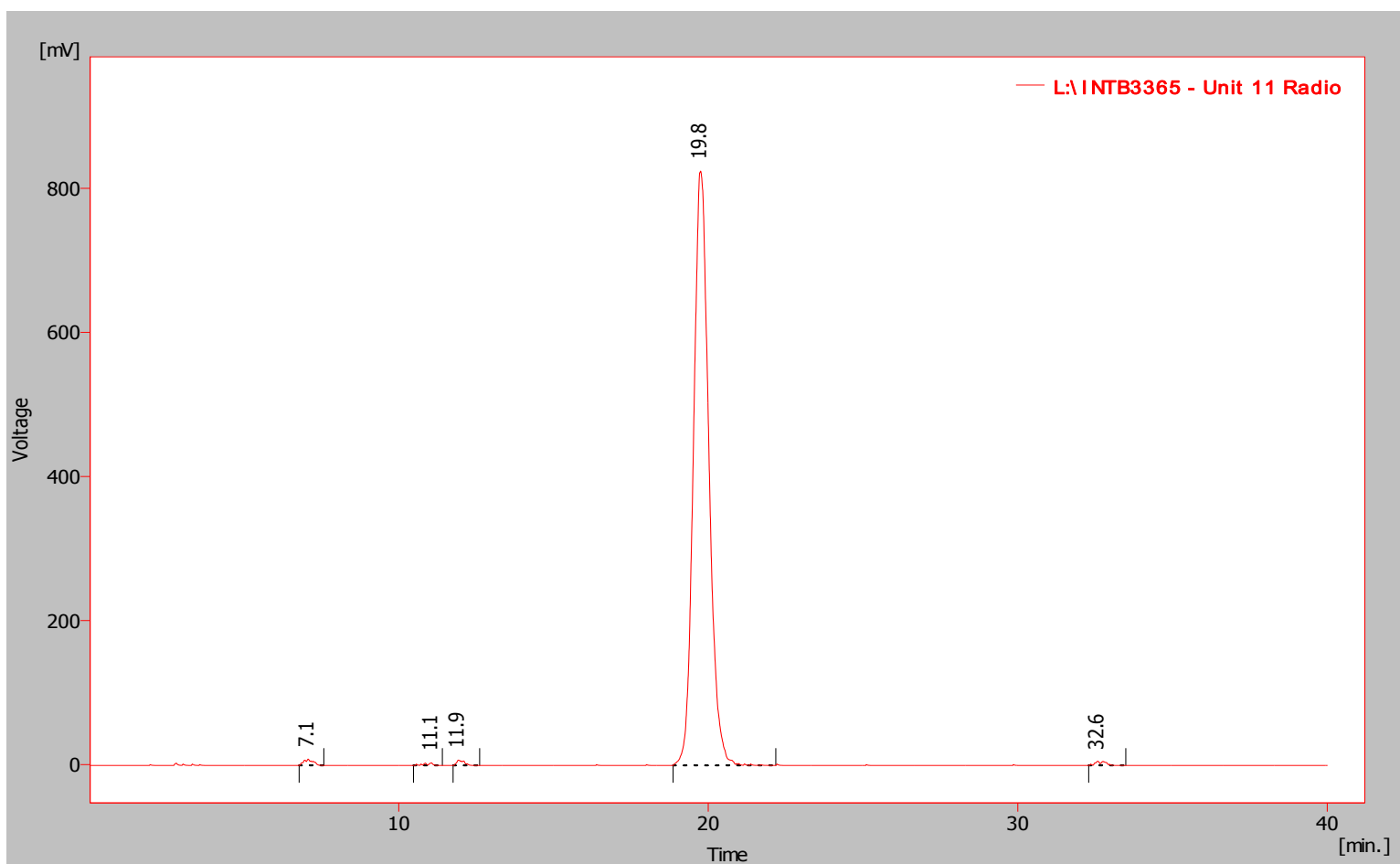
Result Table (Uncal - L:\INTB3360 - Unit 11 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		5.383	0.17	19.690	1.217	0.273	3229.590
2		5.693	0.08	9.638	0.913	0.205	4827.674
3		6.690	0.05	6.295	0.664	0.149	10482.968
4		11.560	0.04	5.277	0.353	0.079	14186.374
5		19.083	99.65	11714.064	442.610	99.294	9233.618
		Total	100.00	11754.963	445.758	100.000	

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

File Name	: L:\INTB3365	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 3:08:38 PM	Acquired Date	: 10/12/2009 3:48:36 PM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material co-injected with standard	Modified	: 12/6/2013 4:20 PM
Created	: 11/6/2007 2:08 PM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



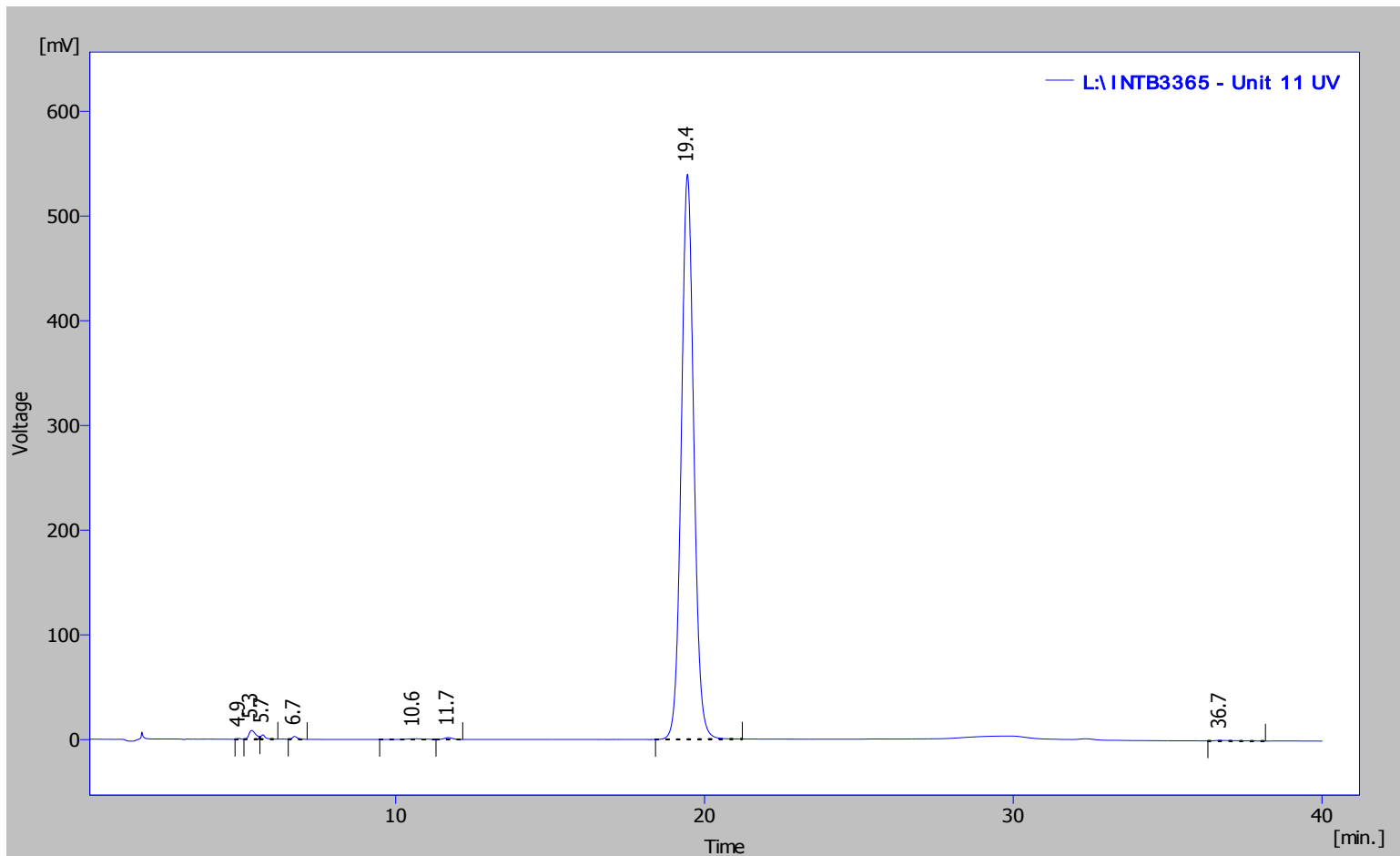
Result Table (Uncal - L:\INTB3365 - Unit 11 Radio)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		7.070	0.61	177.510	8.885	1.044	2507.325
2		11.067	0.21	60.172	3.510	0.413	4257.139
3		11.920	0.43	124.034	7.448	0.875	11084.978
4		19.753	98.31	28496.151	825.083	96.969	6136.791
5		32.590	0.44	128.229	5.948	0.699	43048.536
		Total	100.00	28986.096	850.875	100.000	

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

File Name	: L:\INTB3365	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 3:08:38 PM	Acquired Date	: 10/12/2009 3:48:36 PM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: UV trace of 14C material co-injected with standard	Modified	: 12/6/2013 4:21 PM
Created	: 11/6/2007 2:08 PM		
Column	:	Detection	: UV 227nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



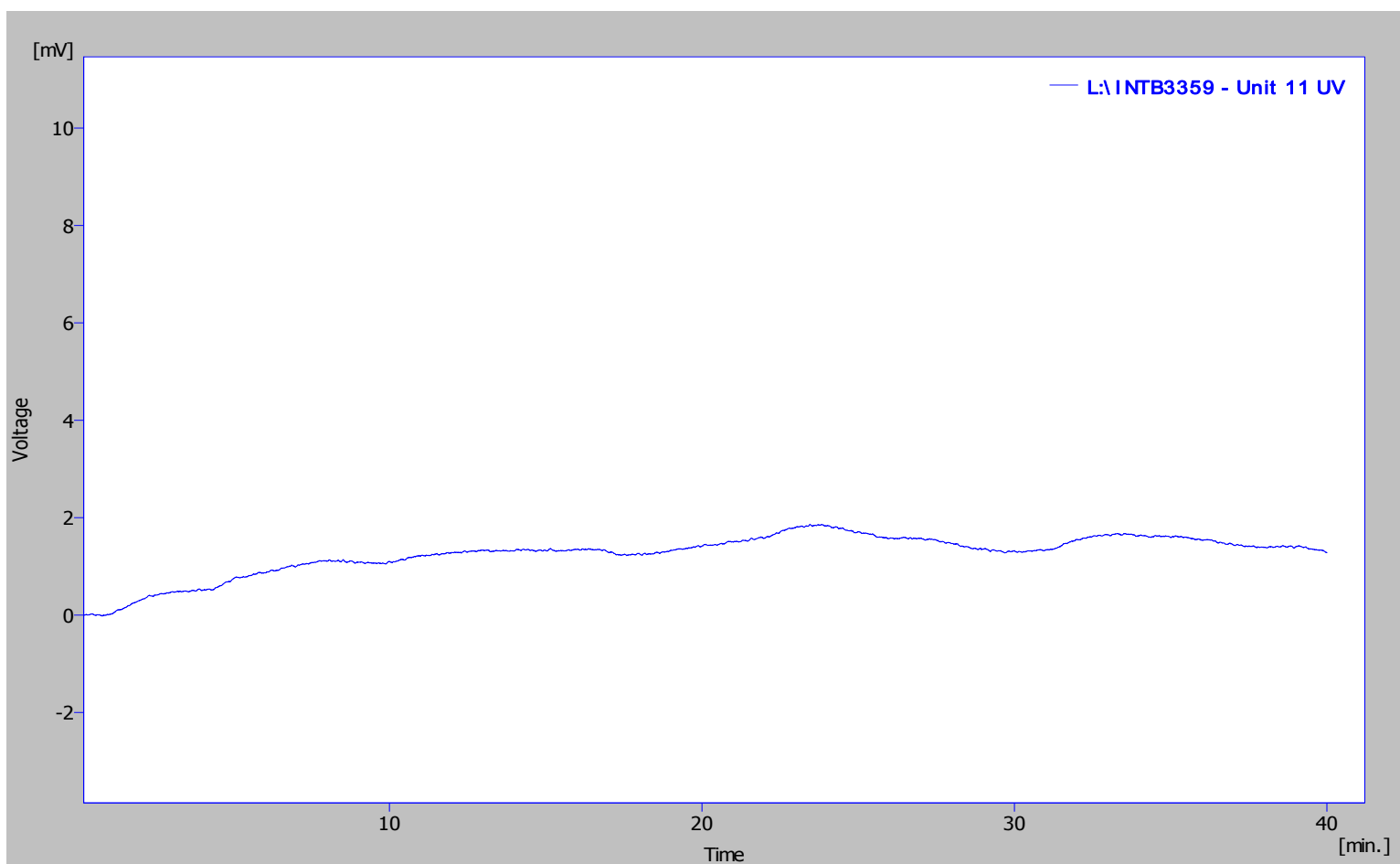
Result Table (Uncal - L:\INTB3365 - Unit 11 UV)

	Compound Name	Reten. Time [min]	Area [%]	Area [mV.s]	Height [mV]	Height [%]	Efficiency [th.pl]
1		4.927	0.03	4.765	0.822	0.147	14335.531
2		5.333	0.82	127.947	8.404	1.504	3009.334
3		5.697	0.26	41.170	4.164	0.745	4136.568
4		6.723	0.19	30.054	2.720	0.487	6179.276
5		10.580	0.17	27.197	0.667	0.119	1348.960
6		11.700	0.21	32.813	1.776	0.318	7643.242
7		19.447	98.13	15259.648	539.642	96.589	8905.042
8		36.710	0.17	27.119	0.505	0.090	9328.506
		Total	100.00	15550.712	558.699	100.000	

MC-1446
Paclitaxel, [benzoyloxy ring-14C]-
Lot 642-079-0756-A-20091009-SB

Chromatogram Info:

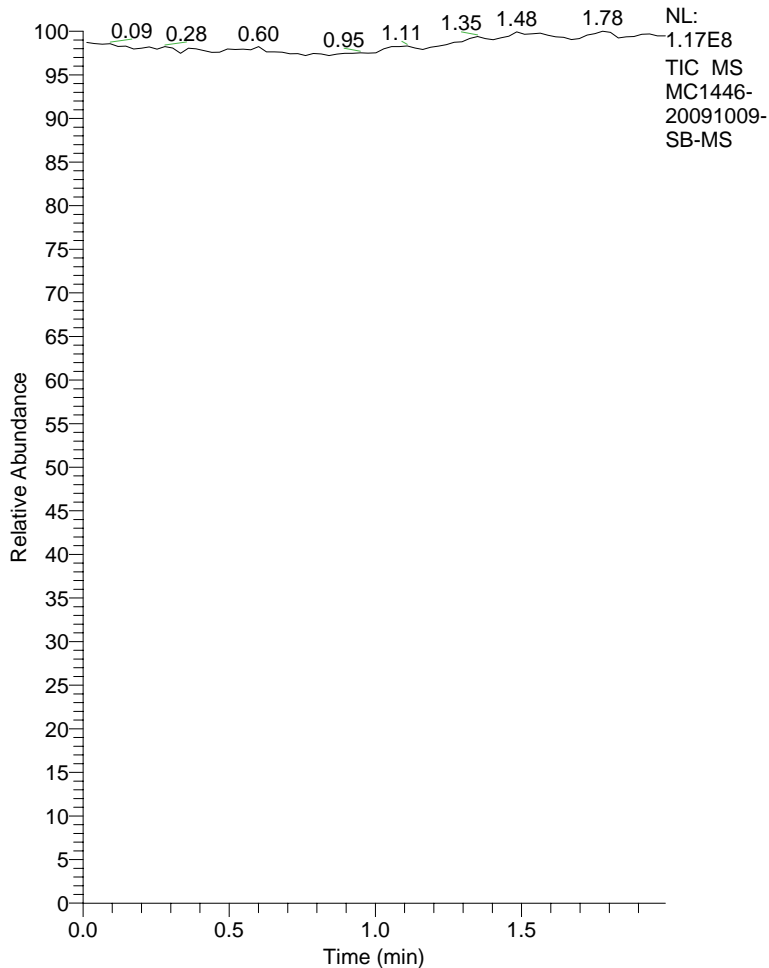
File Name	: L:\INTB3359	File Created	: 12/6/2013 4:07:12 PM
Origin	: Acquired, Acquisition started 10/12/2009 10:29:02 AM	Acquired Date	: 10/12/2009 11:09:01 AM
Project	: Test	By	: Administrator
Method	: Unit11_40_min_run	By	: Administrator
Description	: UV trace of blank injection	Modified	: 12/6/2013 4:22 PM
Created	: 11/6/2007 2:08 PM		
Column	:	Detection	: UV 227nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



Result Table (Uncal - L:\INTB3359 - Unit 11 UV)

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

RT: 0.00 - 1.99



MC1446-20091009-SB-MS#1-75 RT: 0.01-1.99

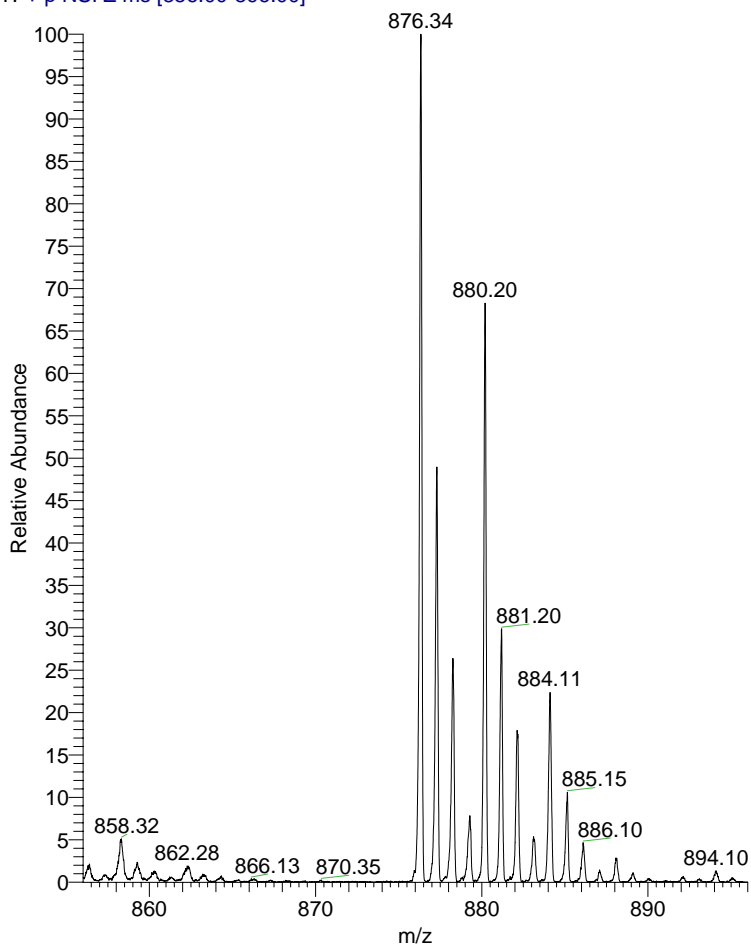
T: + p NSI Z ms [856.00-896.00]

m/z = 873.79-890.36

m/z	Intensity	Relative
874.16	107818.1	0.39
876.30	27386040.	100.00
877.26	14405088.	52.60
878.23	8558377.0	31.25
879.22	3020736.8	11.03
880.18	18046874.	65.90
881.16	8614283.0	31.46
882.12	5860735.5	21.40
883.11	2082546.4	7.60
884.09	7226012.0	26.39
885.10	3175179.8	11.59
886.08	1615499.6	5.90
887.08	528670.5	1.93
888.07	1031016.9	3.76
889.07	438432.4	1.60
890.06	234120.8	0.85

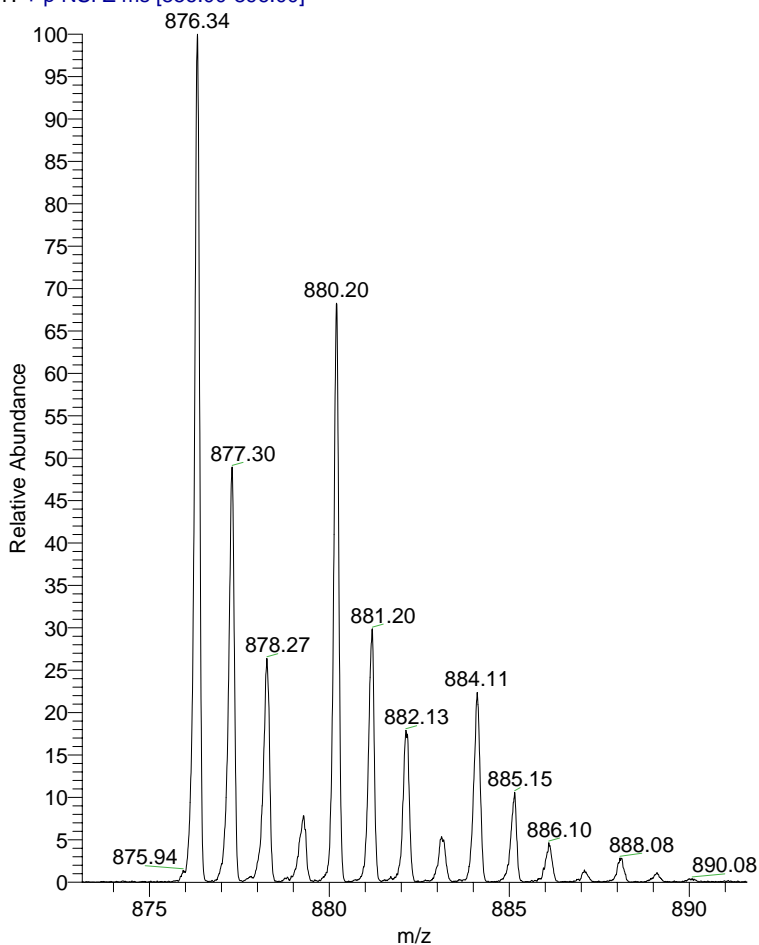
MC1446-20091009-SB-MS #1-75 RT: 0.01-1.99 AV: 75 NL: 7.74E5

T: + p NSI Z ms [856.00-896.00]



MC1446-20091009-SB-MS #1-75 RT: 0.01-1.99 AV: 75 NL: 7.74E5

T: + p NSI Z ms [856.00-896.00]



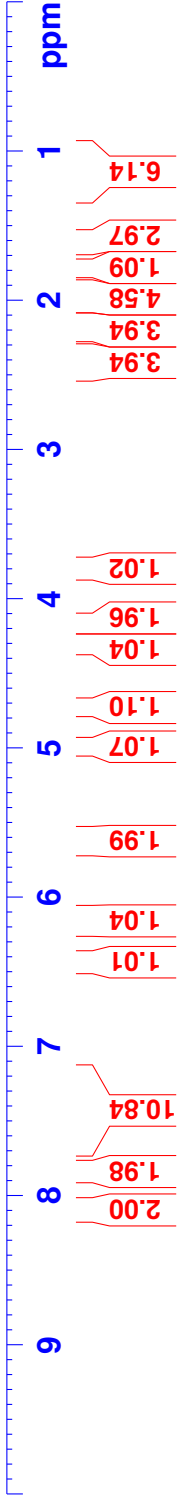
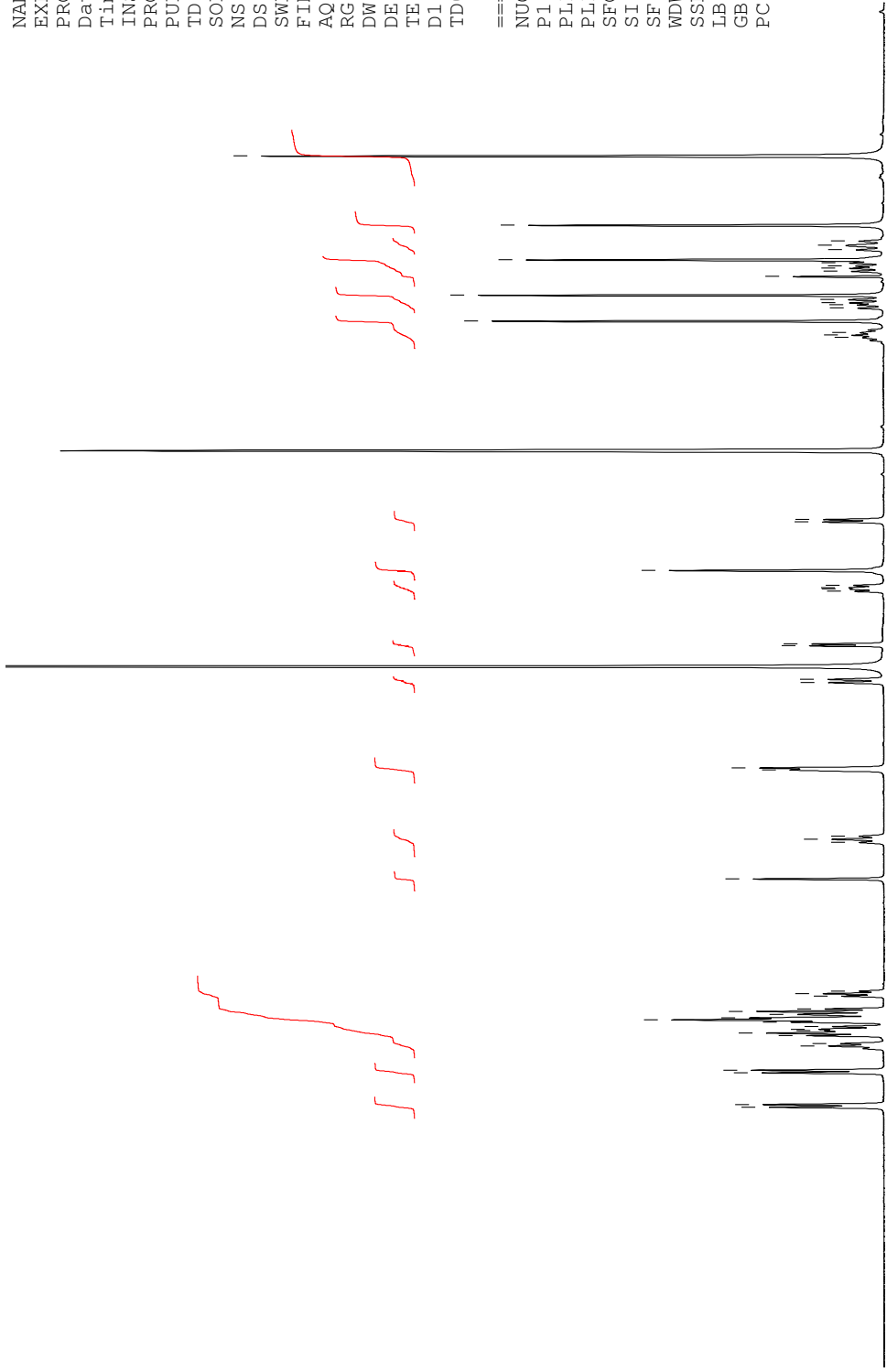
MC1446 1H NMR in MeOD
 Batch 20091009-SB



8.095
8.076
7.843
7.824
7.647
7.629
7.571
7.552
7.534
7.525
7.504
7.472
7.455
7.441
7.416
7.394
7.376
7.282
7.263
7.245
6.423
6.155
6.133
6.110
5.625
5.611
4.985
4.962
4.715
4.702
4.316
4.300
4.291
4.274
4.164
3.809
3.791
2.458
2.440
2.422
2.338
2.242
2.219
2.204
2.180
2.148
2.011
1.973
1.951
1.935
1.912
1.890
1.815
1.783
1.752
1.636
1.129

NAME MC1446
 EXPNO 2
 PROCNO 1
 Date_ 20091012
 Time 16.01
 INSTRUM spect
 PROBHD 5 mm PABBO BB-
 PULPROG zg30
 TD 65536
 SOLVENT MeOD
 NS 471
 DS 2
 SWH 8278.146 Hz
 FIDRES 0.126314 Hz
 AQ 3.9584243 sec
 RG 362
 DW 60.400 usec
 DE 6.50 usec
 TE 293.7 K
 D1 1.00000000 sec
 TD0 1

==== CHANNEL f1 =====
 NUC1 1H
 P1 14.50 usec
 PL1 -0.70 dB
 PL1W 10.03411102 W
 SF01 400.1324710 MHz
 SI 32768
 SF 400.1300168 MHz
 WDW no
 SSB 0
 LB 0.00 Hz
 GB 0
 PC 1.00



6.14
2.97
1.09
4.58
3.94
3.94
1.02
1.96
1.04
1.10
1.07
1.99
1.04
1.01
10.84
1.98
2.00