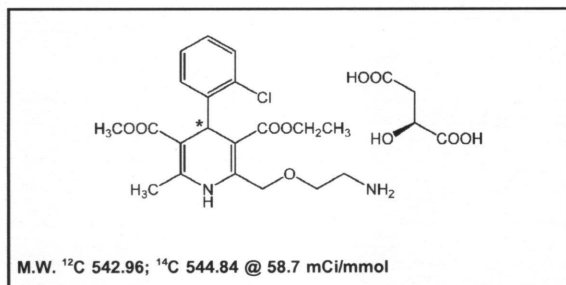




Product Data Sheet

MC-2155

(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-¹⁴C]-



Lot #: 198-075-0587-A-20090601-JH

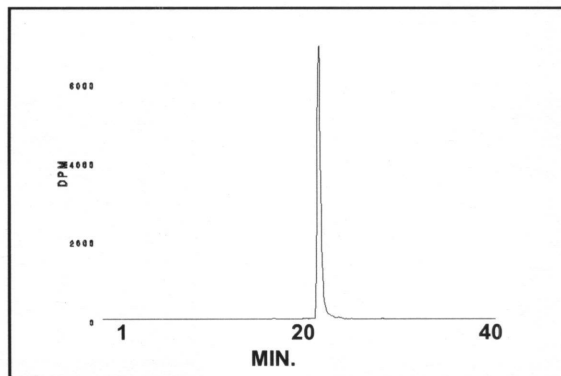
Specific Activity: 58.7 mCi/mmol

Concentration: 0.1 mCi/ml; 928.18 µg/ml

Packaged in: Ethanol : water (7 : 3) solution

Date of Analysis: December 28, 2010

Radiochemical Purity: 98.5%



HPLC ANALYSIS LOT 198-075-0587-A-20090601-JH
File Name: intj2112 Date and Time: 12/28/2010 3:33:31 P
Unit 19 Radio

Peak #	Area %	Time	Area
1	0.20	17.42330	36.80749
2	0.48	21.49670	89.38819
3	98.53	22.06000	18175.30098
4	0.13	23.00330	24.64623
5	0.15	23.42670	28.31918
6	0.32	24.09000	59.09994
7	0.06	25.42330	11.28393
8	0.12	28.53670	22.09862
Totals	100.00		18446.94456

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-2155

(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-¹⁴C]-

Lot 198-075-0587-A-20090601-JH

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.

¹⁴C material concentration was 0.1 mCi/ml.

Volume of standard alone injection was 2.0 µl.

Volume of ¹⁴C material alone injection was 2.0 µl.

Co-injection solution consisted of 2.0 µl ¹⁴C material + 2.0 µl standard.

Volume of co-injection was 4.0 µl.

Volume of blank injection was 2.0 µl.

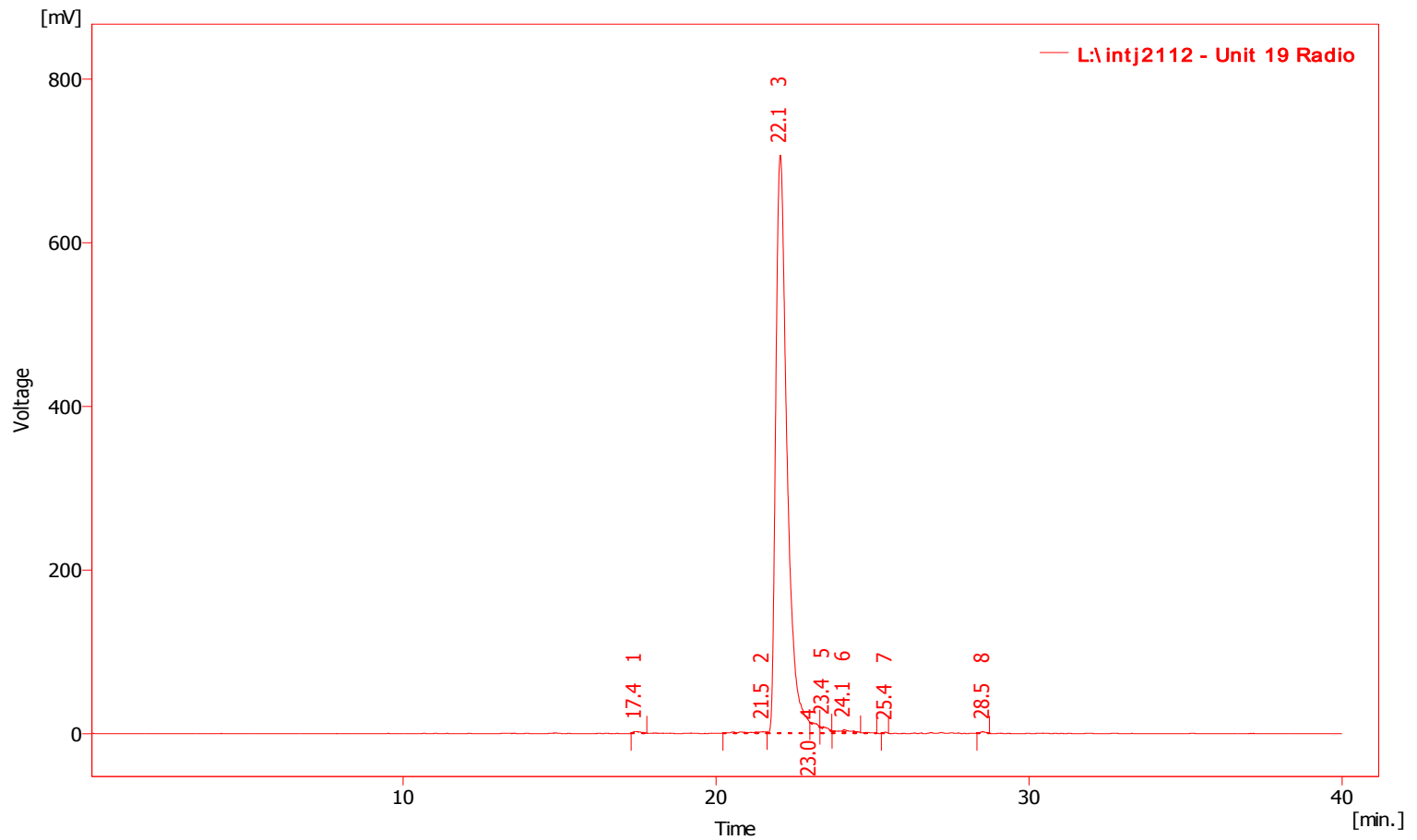
B) Mass spectrometry – Positive mode

C) NMR

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

File Name	: L:\intj2112	File Created	: 2/13/2014 3:42:19 PM
Origin	: Acquired, Acquisition started 12/28/2010 2:53:32 PM	Acquired Date	: 12/28/2010 3:33:31 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material alone	Modified	: 2/13/2014 3:56 PM
Created	: 8/9/2007 1:12 PM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



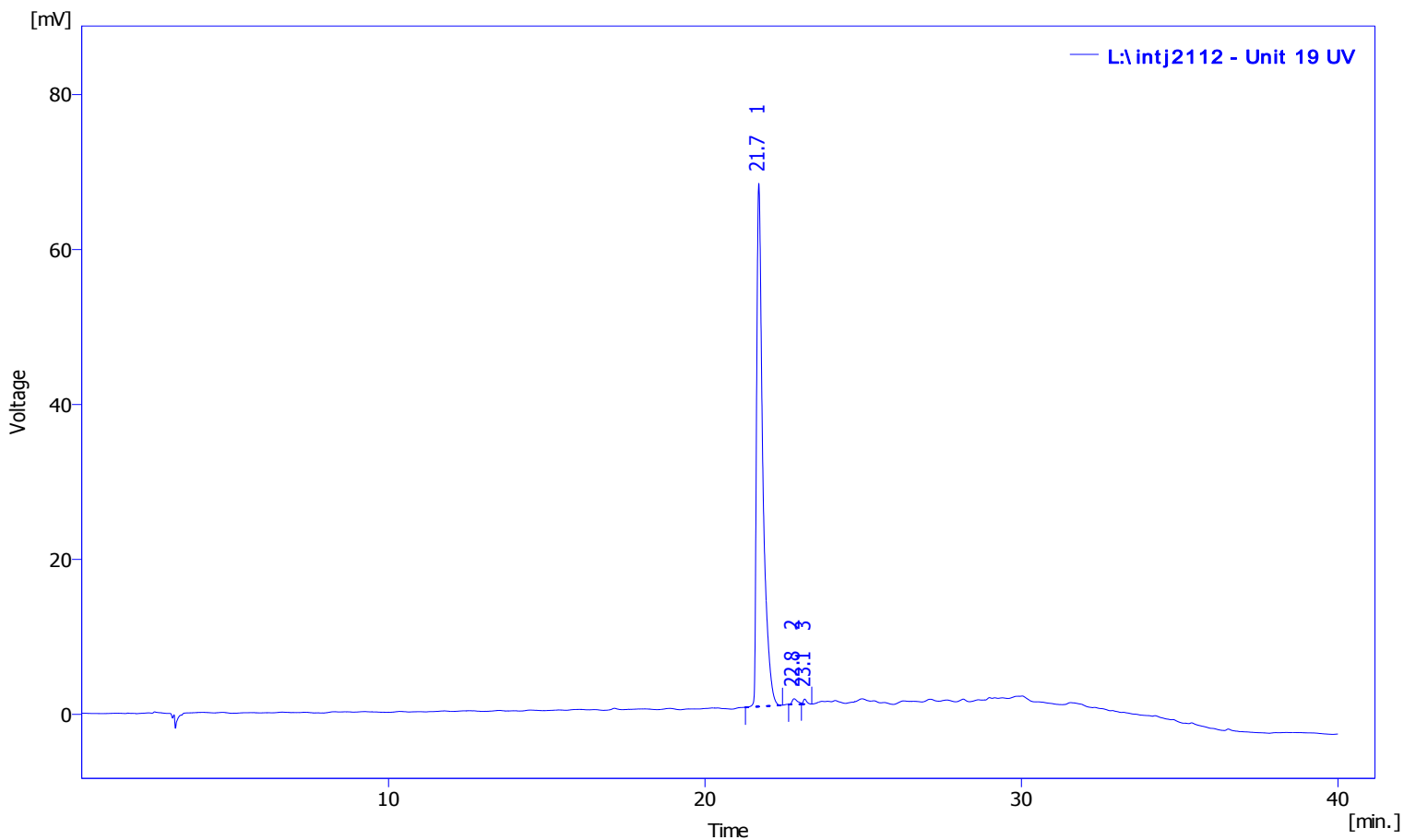
Result Table (Uncal - L:\intj2112 - Unit 19 Radio)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/l [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
1	17.42	36.807	2.03	0.20	0.28	22826.64	456532.81	1.83		
2	21.50	89.388	2.03	0.48	0.28	2919.88	58397.59	0.55		6.3
3	22.06	18175.301	706.39	98.53	98.23	0.00	0.00	3.99		0.9
4	23.00	24.646	0.12	0.13	0.02	99815.95	1996319.00	23.75		2.6
5	23.43	28.319	2.26	0.15	0.31	84044.58	1680891.69	1.81		2.4
6	24.09	59.100	2.82	0.32	0.39	16343.62	326872.39	1.31		2.7
7	25.42	11.284	1.49	0.06	0.21	264538.81	5290776.14	0.78		5.6
8	28.54	22.099	2.03	0.12	0.28	118349.05	2366981.00	1.10		9.8
Total		18446.945	719.16	100.00	100.00					

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

File Name	: L:\intj2112	File Created	: 2/13/2014 3:42:19 PM
Origin	: Acquired, Acquisition started 12/28/2010 2:53:32 PM	Acquired Date	: 12/28/2010 3:33:31 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: UV trace of 14C material alone	Modified	: 2/13/2014 3:57 PM
Created	: 8/9/2007 1:12 PM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



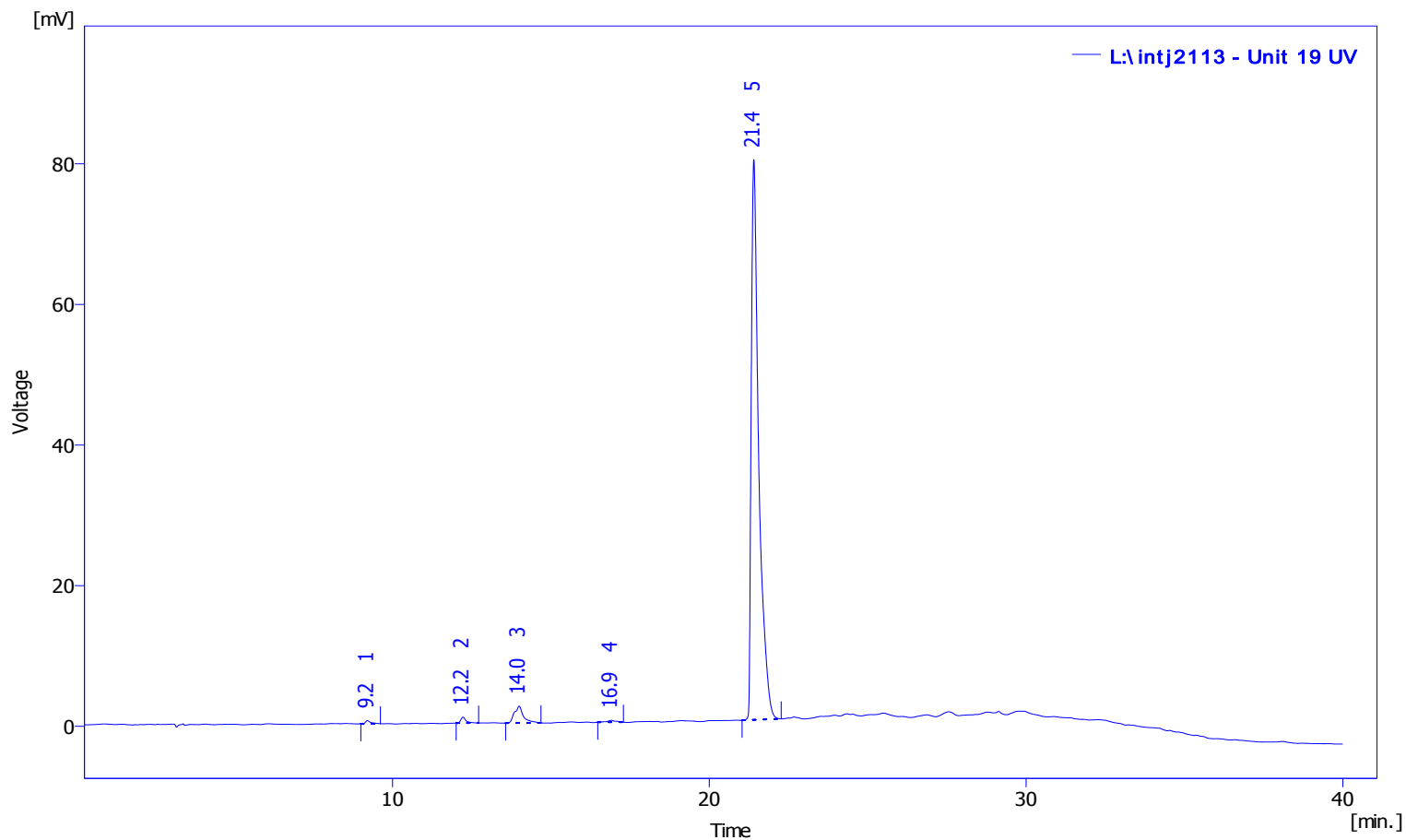
Result Table (Uncal - L:\intj2112 - Unit 19 UV)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/l [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
1		21.70	931.091	67.54	98.56	98.00	33671.79	673435.73	1.98		
2		22.81	8.428	0.72	0.89	1.04	84352.15	1687042.91	1.45		3.5
3		23.15	5.152	0.66	0.55	0.96	172456.69	3449133.86	1.34		1.3
		Total	944.671	68.91	100.00	100.00					

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

File Name	: L:\intj2113	File Created	: 2/13/2014 3:42:16 PM
Origin	: Acquired, Acquisition started 12/28/2010 3:47:17 PM	Acquired Date	: 12/28/2010 4:27:16 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: UV trace of standard alone	Modified	: 2/13/2014 3:47 PM
Created	: 8/9/2007 1:12 PM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



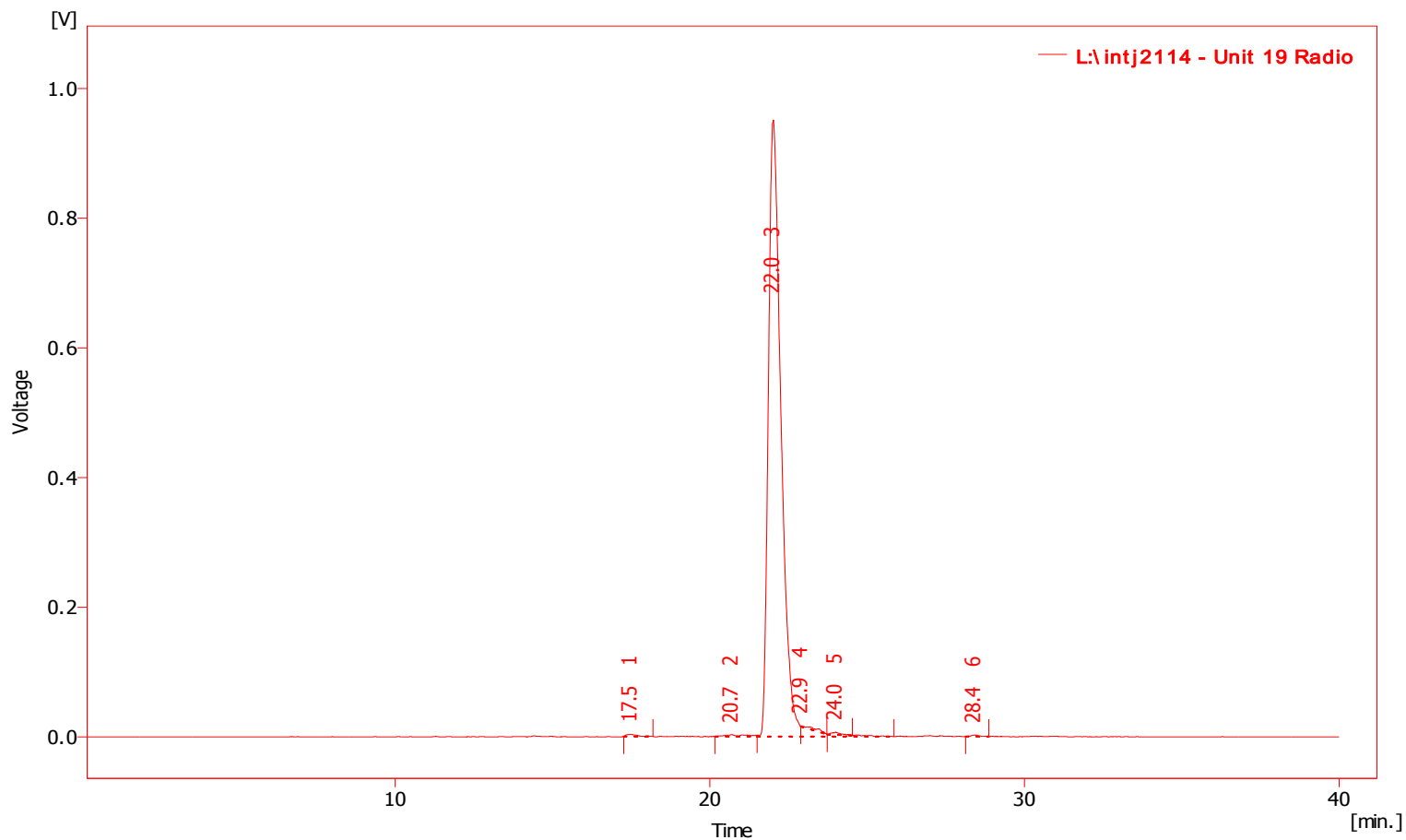
Result Table (Uncal - L:\intj2113 - Unit 19 UV)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/l [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
1		9.21	5.435	0.46	0.39	0.55	7201.36	144027.27	1.88		
2		12.22	9.582	0.85	0.69	1.02	13619.91	272398.27	1.59		11.6
3		14.00	47.534	2.40	3.42	2.87	6760.18	135203.54	1.39		4.6
4		16.91	5.459	0.28	0.39	0.33	10906.57	218131.50	0.94		6.3
5		21.41	1321.103	79.67	95.10	95.23	23090.85	461817.09	2.09		10.9
		Total	1389.114	83.66	100.00	100.00					

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

File Name	: L:\intj2114	File Created	: 2/13/2014 3:42:19 PM
Origin	: Acquired, Acquisition started 12/28/2010 4:47:17 PM	Acquired Date	: 12/28/2010 5:27:17 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material co-injected with standard		
Created	: 8/9/2007 1:12 PM	Modified	: 2/13/2014 3:59 PM
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



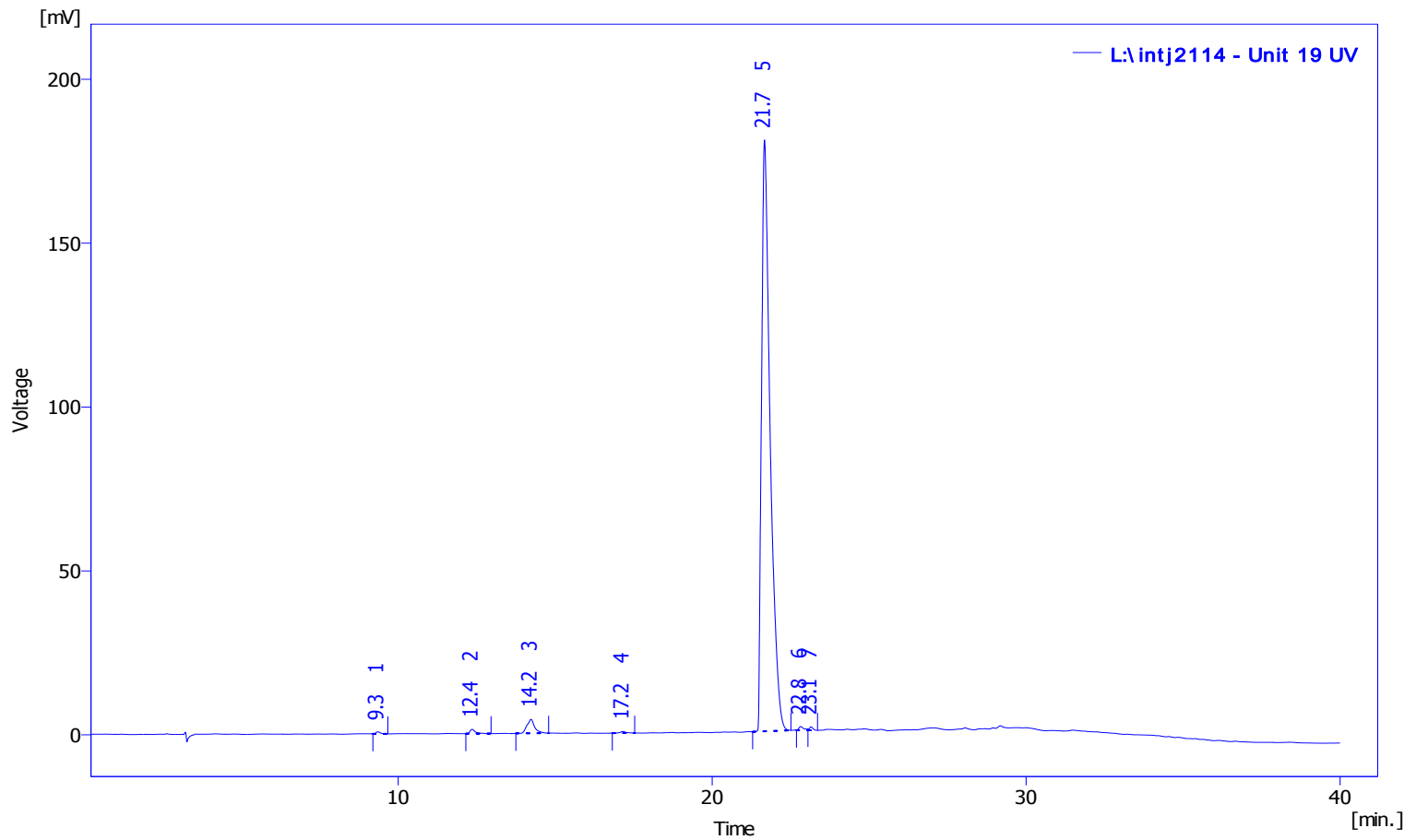
Result Table (Uncal - L:\intj2114 - Unit 19 Radio)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/l [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
1		17.50	86.716	3.44	0.31	0.36	6420.82	128416.50	2.03		
2		20.71	130.957	3.01	0.48	0.31	3632.79	72655.81	1.24		5.6
3		22.02	27061.011	950.77	98.26	98.47	0.00	0.00	4.14		2.2
4		22.91	120.557	1.38	0.44	0.14	14539.09	290781.85	20.58		2.3
5		24.00	96.373	4.44	0.35	0.46	17065.66	341313.15	1.55		3.9
6		28.42	44.066	2.50	0.16	0.26	37126.40	742528.01	1.22		10.0
		Total	27539.680	965.54	100.00	100.00					

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

File Name	: L:\intj2114	File Created	: 2/13/2014 3:42:19 PM
Origin	: Acquired, Acquisition started 12/28/2010 4:47:17 PM	Acquired Date	: 12/28/2010 5:27:17 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: UV trace of 14C material co-injected with standard	Modified	: 2/13/2014 3:50 PM
Created	: 8/9/2007 1:12 PM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



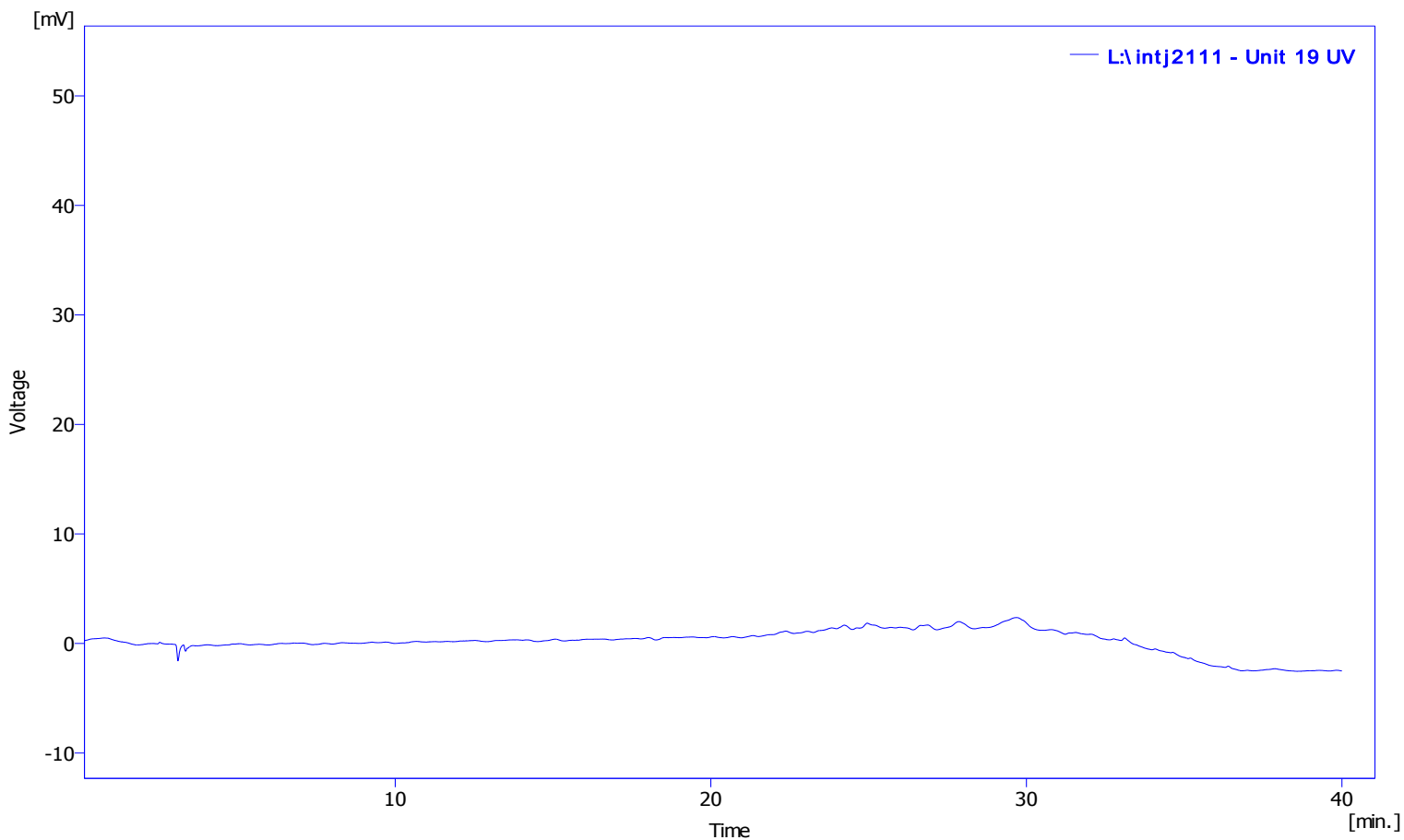
Result Table (Uncal - L:\intj2114 - Unit 19 UV)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/I [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
1		9.35	6.038	0.63	0.17	0.33	15799.86	315997.25	1.43		
2		12.35	15.786	1.33	0.44	0.70	10362.81	207256.11	1.95		11.8
3		14.23	72.359	4.27	2.02	2.25	11592.41	231848.24	1.19		5.4
4		17.16	6.322	0.49	0.18	0.26	24232.13	484642.62	1.02		8.0
5		21.67	3453.871	180.45	96.63	95.31	22083.24	441664.81	1.83		11.4
6		22.82	11.982	1.11	0.34	0.58	85097.81	1701956.26	1.55		3.1
7		23.15	8.000	1.06	0.22	0.56	198860.88	3977217.51	1.28		1.4
		Total	3574.358	189.33	100.00	100.00					

MC-2155
(R,S)-Amlodipine, malic acid salt, [dihydropyridine-4-14C]-
Lot 198-075-0587-A-20090601-JH

Chromatogram Info:

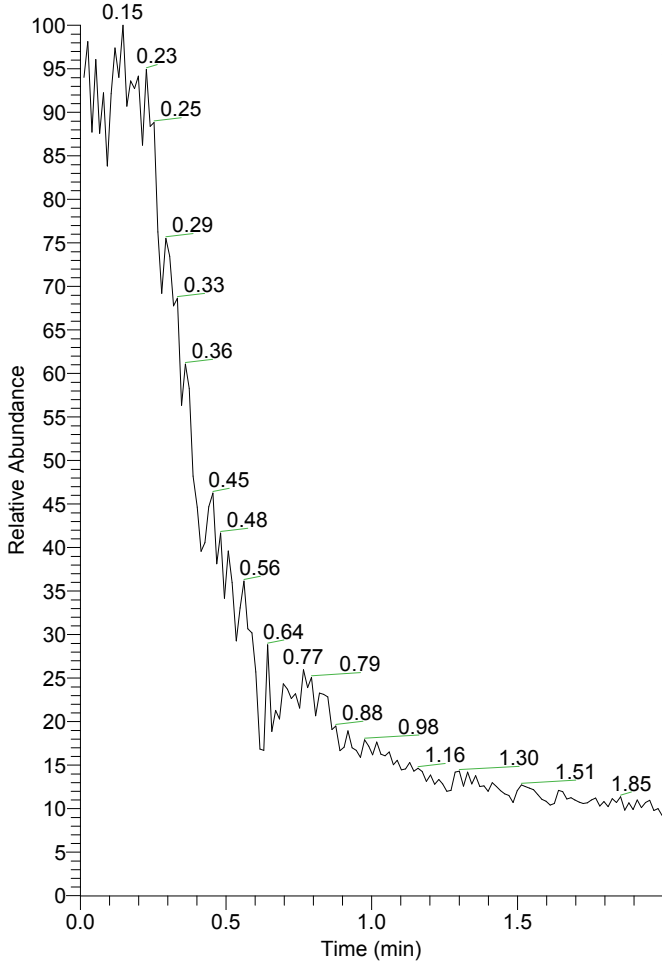
File Name	: L:\intj2111	File Created	: 2/13/2014 3:42:19 PM
Origin	: Acquired, Acquisition started 12/28/2010 1:41:19 PM	Acquired Date	: 12/28/2010 2:21:19 PM
Project	: Test	By	: Administrator
Method	: Unit19_40_min_run	By	: Administrator
Description	: UV trace of blank injection	Modified	: 2/13/2014 3:46 PM
Created	: 8/9/2007 1:12 PM		
Column	:	Detection	: UV 254nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



Result Table (Uncal - L:\intj2111 - Unit 19 UV)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	Efficiency [th.pl]	Eff/l [t.p./m]	Symmetry/Tailing [-]	Response Factor	Resolution [-]
No peak to report										

RT: 0.00 - 2.00



NL:
6.48E10
TIC MS
MC2155-
20090601-
JH_090608
110115

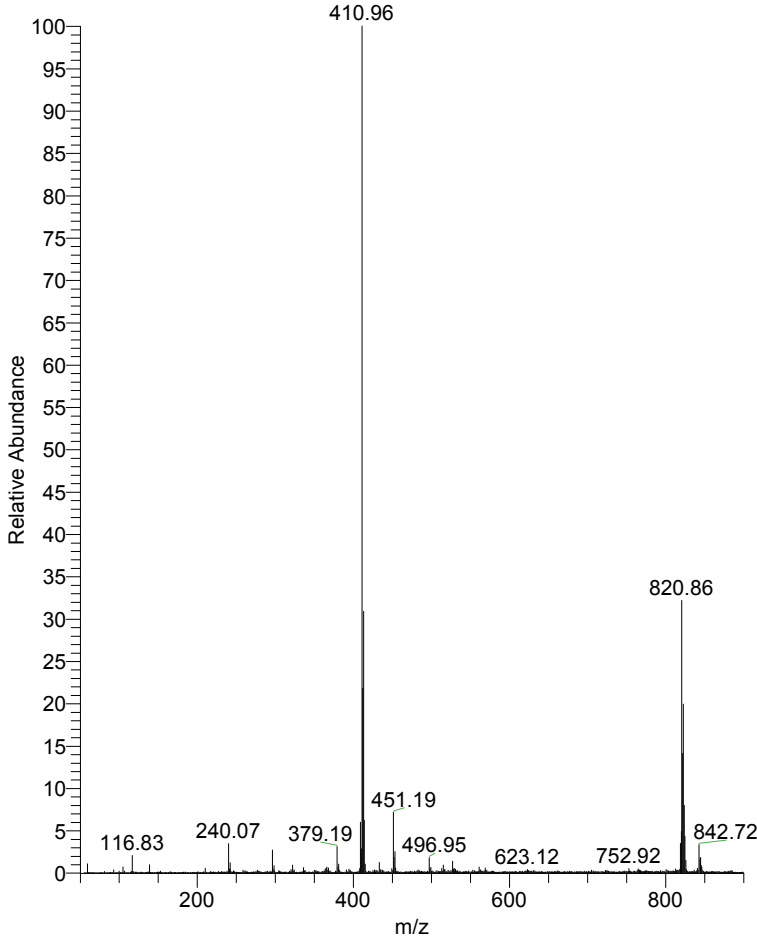
MC2155-20090601-JH_090608110115#1-144

T: + c NSI Full ms [50.00-900.00]

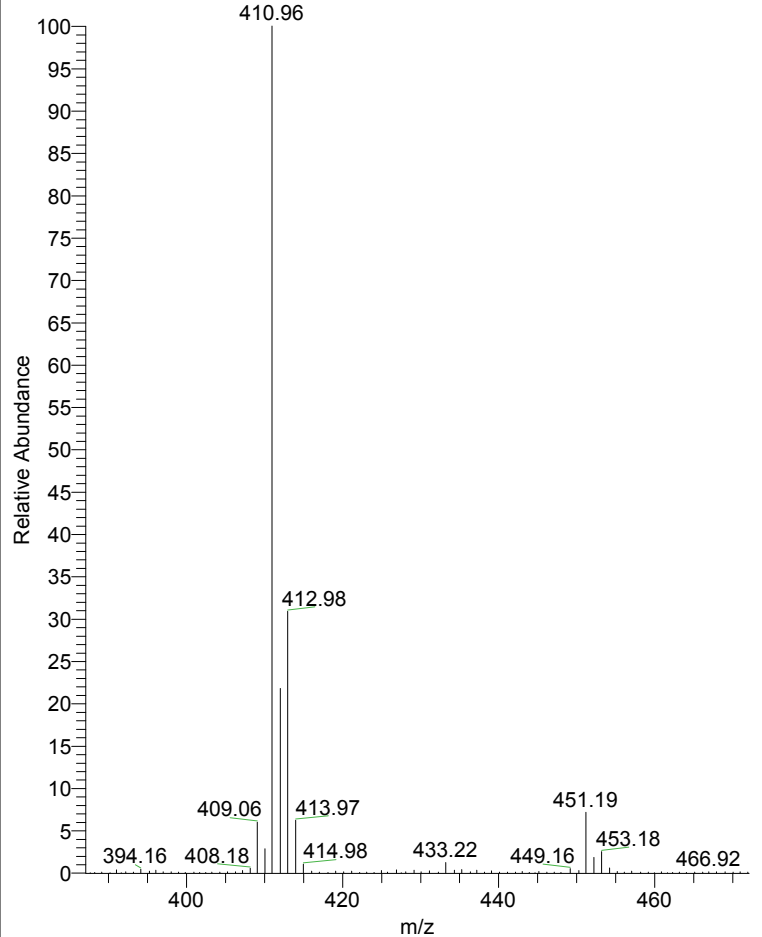
m/z = 405.83-418.72

m/z	Intensity	Relative
407.16	13061777.1	0.27
408.18	25782496.9	0.54
409.06	289433320.6	6.01
410.07	136860500.6	2.84
410.96	4818302684.4	100.00
412.03	1050423750.7	21.80
412.98	1489166696.9	30.91
413.97	298724259.6	6.20
414.98	49456441.3	1.03
416.04	10299954.0	0.21
417.02	4580919.5	0.10
418.12	3132862.4	0.07

MC2155-20090601-JH_090608110115 #1-144 RT: 0.01-2.00 AV: 144 NL:
T: + c NSI Full ms [50.00-900.00]



MC2155-20090601-JH_090608110115 #1-144 RT: 0.01-2.00 AV: 144 NL:
T: + c NSI Full ms [50.00-900.00]



MC2155 1H NMR in D2O
 Batch 20090601-JH



7.399
7.381
7.381
7.255
7.236
7.158
7.141
7.075
7.058

4.635
4.595

3.975
3.959
3.736
3.495
3.195

2.213

1.124
1.106
1.089
1.067
1.052
1.037

NAME MC2155
 EXPNO 1
 PROCNO 1
 Date_ 20090608
 Time 14.12
 INSTRUM spect
 PROBHD 5 mm PABBO BB-
 PULPROG zg30
 TD 65536
 SOLVENT D2O
 NS 256
 DS 2
 SWH 8278.146 Hz
 FIDRES 0.126314 Hz
 AQ 3.9584243 sec
 RG 256
 DW 60.400 usec
 DE 6.50 usec
 TE 294.3 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 400.1299790 MHz
 WDW EM
 SSB 0
 LB 0.30 Hz
 GB 0
 PC 1.00

