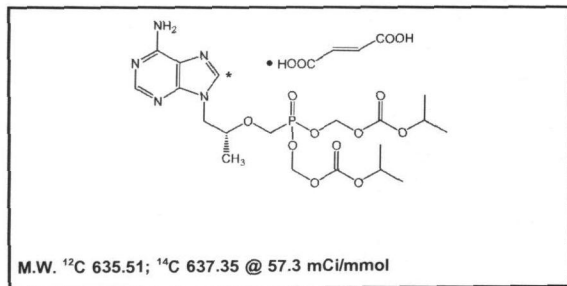




Product Data Sheet

MC-2023

Tenofovir disoproxil fumarate, [adenine-8-¹⁴C]-



Lot #: 194-040-0573-A-20080701-JZ

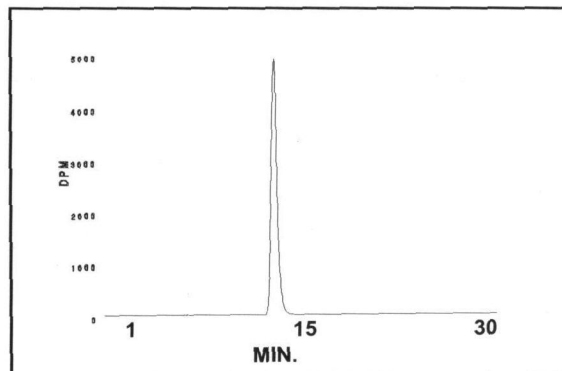
Specific Activity: 57.3 mCi/mmol

Concentration: 0.1 mCi/ml; 1.11 mg/ml

Packaged in: Ethanol solution

Date of Analysis: July 05, 2011

Radiochemical Purity: 99.7%



HPLC ANALYSIS LOT 194-040-0573-A-20080701-JZ
File Name: int43040 Date and Time: 7/5/2011 2:55:19 PM
Unit 4 Radio

Peak #	Area %	Time	Area
1	0.21	6.43000	33.60067
2	99.79	13.03000	15907.59484
Totals	100.00		15941.19551

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-2023

Tenofovir disoproxil fumarate, [adenine-8-¹⁴C]-

Lot 194-040-0573-A-20080701-JZ

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.

Tenofovir disoproxil fumarate, [adenine-8-¹⁴C]- concentration was 100 µCi/ml.

Volume of standard alone injection was 5.0 µl.

Volume of **Tenofovir disoproxil fumarate, [adenine-8-¹⁴C]-** alone injection was 1.0 µl.

Co-injection solution consisted of 1.0 µl **Tenofovir disoproxil fumarate, [adenine-8-¹⁴C]-** + 5.0 µl standard.

Volume of co-injection was 6.0 µl.

Volume of blank injection was 1.0 µl.

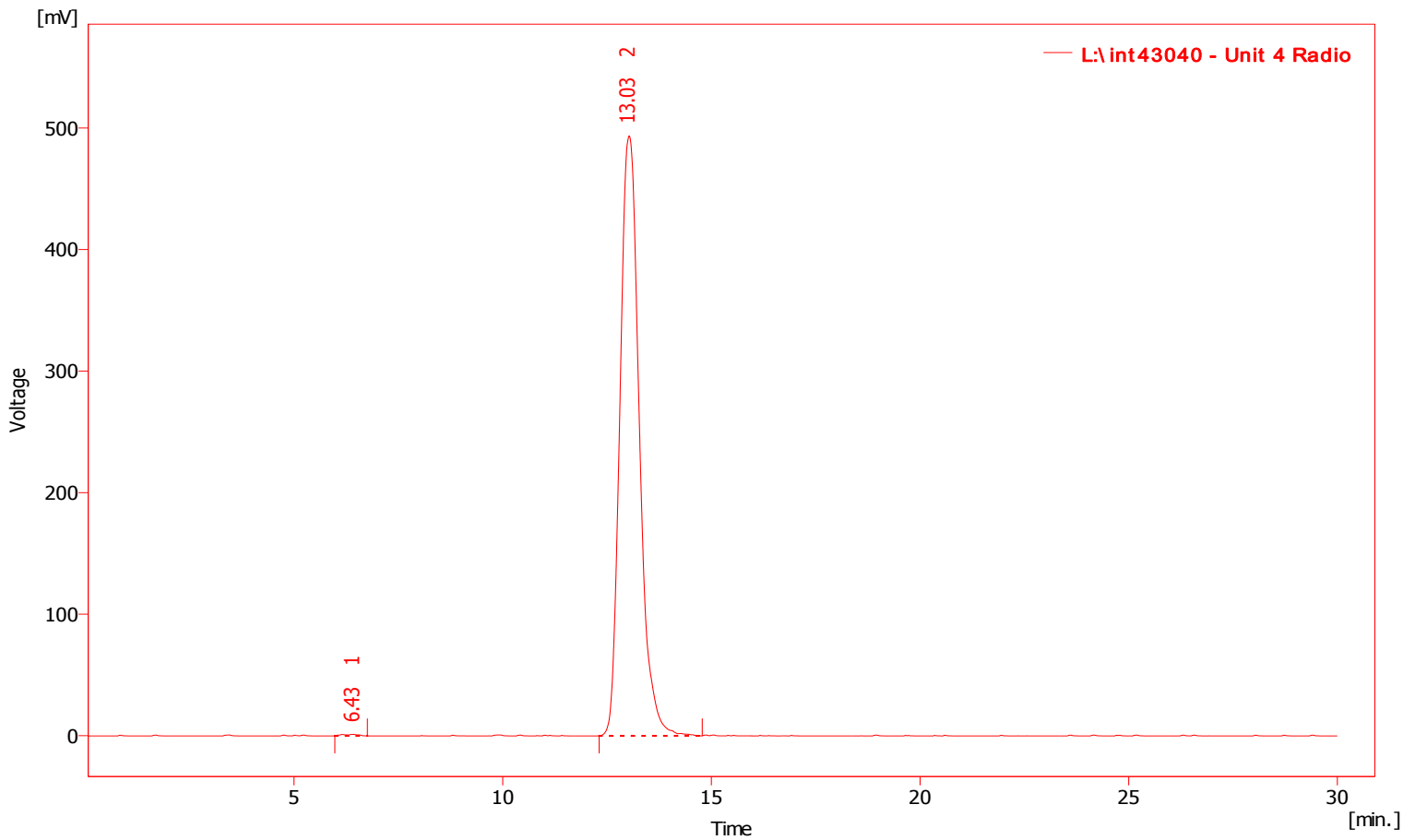
B) Mass spectrometry - Positive mode

C) NMR

MC-2023
Tenofovir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

File Name	: L:\int43040	File Created	: 2/11/2014 3:08:15 PM
Origin	: Acquired, Acquisition started 7/5/2011 2:25:20 PM	Acquired Date	: 7/5/2011 2:55:19 PM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: Radiochemical trace of 14C material alone	Modified	: 2/11/2014 3:08 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



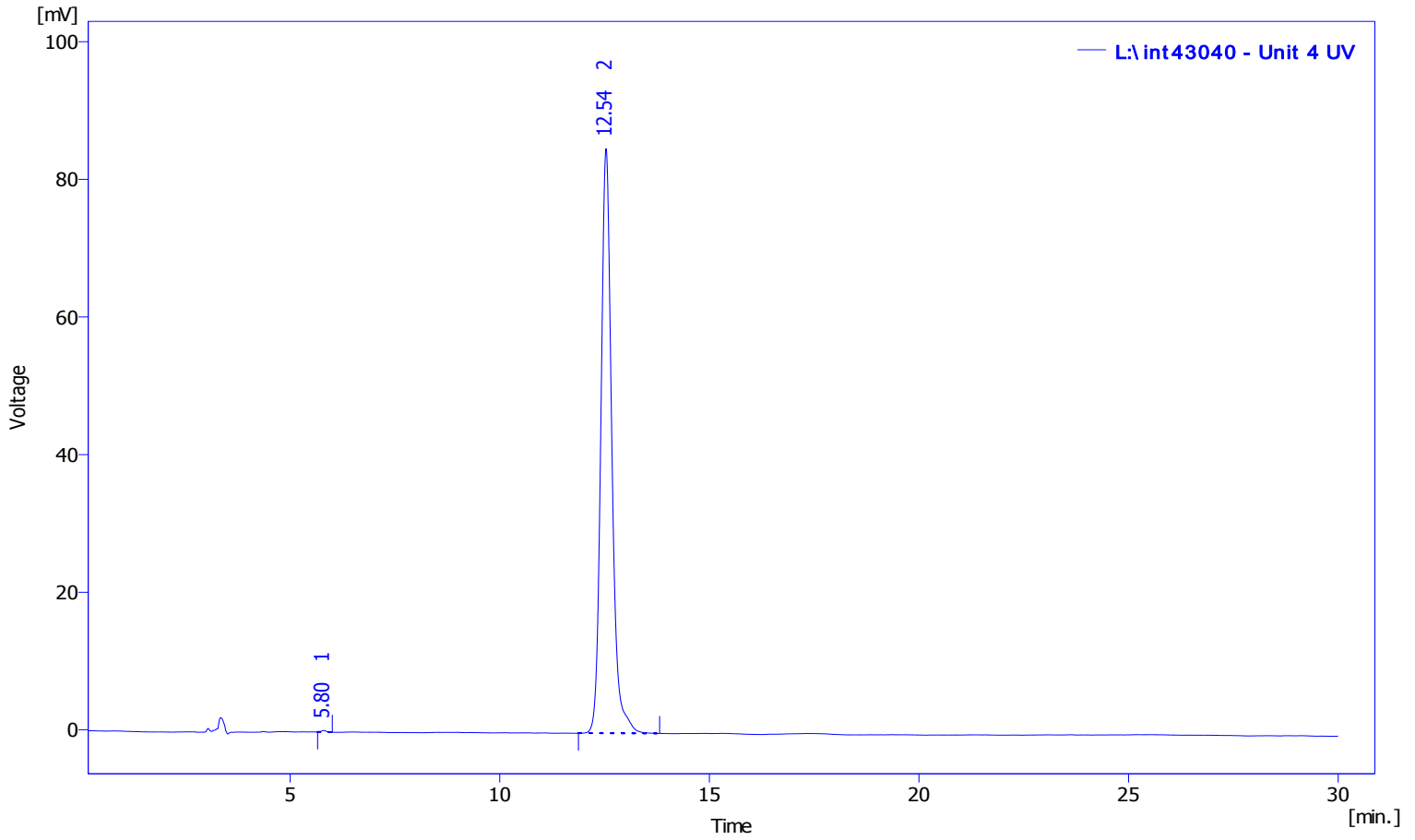
Result Table (Uncal - L:\int43040 - Unit 4 Radio)

	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		6.43	33.601	1.26	0.21	0.26	795.28	15905.69	0.79		
2		13.03	15907.595	493.61	99.79	99.74	3864.72	77294.34	1.22		7.6
		Total	15941.196	494.87	100.00	100.00					

MC-2023
Tenofovir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

File Name	: L:\int43040	File Created	: 2/11/2014 3:08:15 PM
Origin	: Acquired, Acquisition started 7/5/2011 2:25:20 PM	Acquired Date	: 7/5/2011 2:55:19 PM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: UV trace of 14C material alone	Modified	: 2/11/2014 3:09 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: UV 260nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



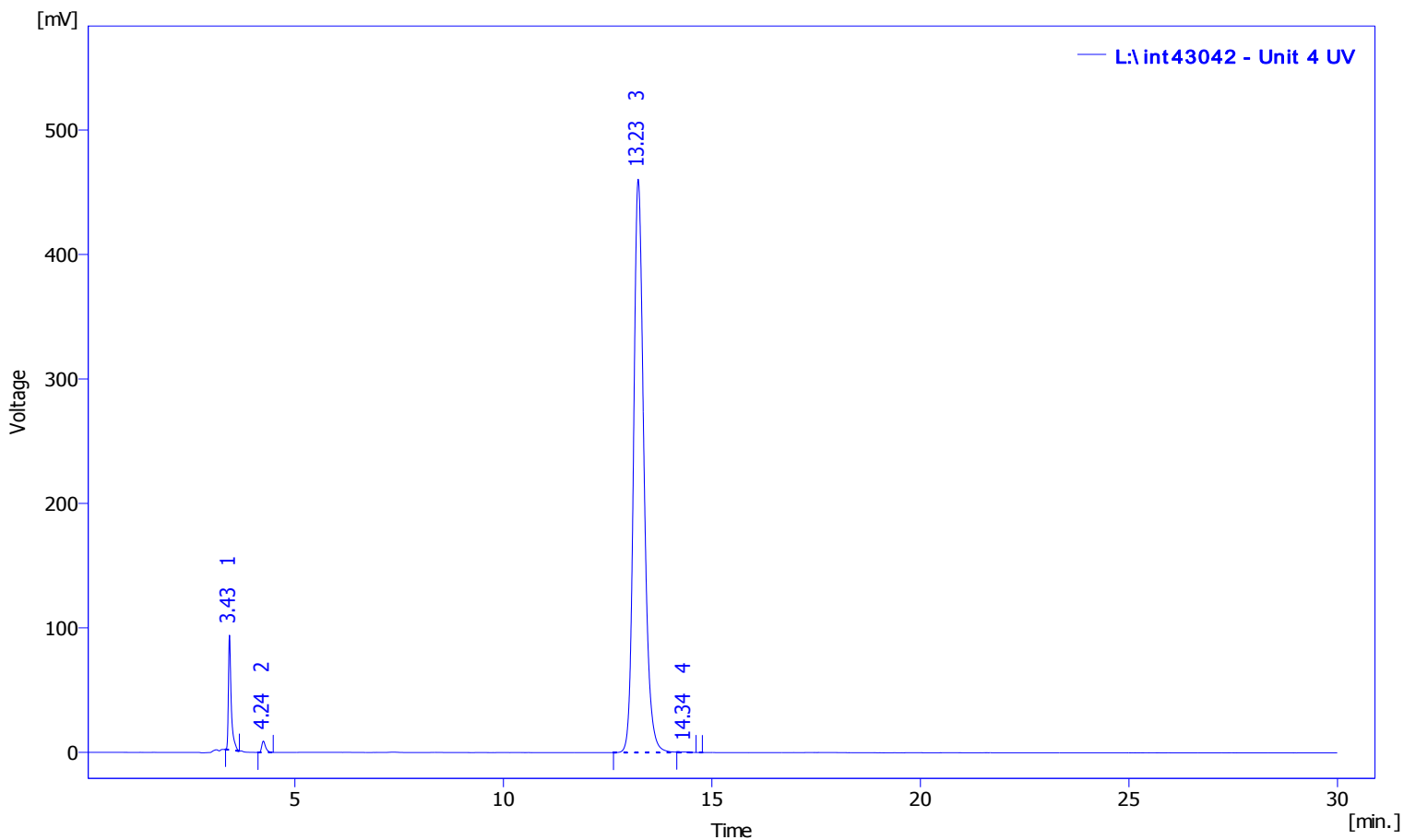
Result Table (Uncal - L:\int43040 - Unit 4 UV)

	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		5.80	1.858	0.23	0.12	0.27	12237.86	244757.20	1.29		
2		12.54	1535.862	84.97	99.88	99.73	11654.37	233087.36	1.16		20.1
		Total	1537.721	85.20	100.00	100.00					

MC-2023
Tenofovir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

File Name	: L:\int43042	File Created	: 2/11/2014 3:08:16 PM
Origin	: Acquired, Acquisition started 7/6/2011 11:32:05 AM	Acquired Date	: 7/6/2011 12:02:05 PM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: UV trace of standard alone	Modified	: 2/11/2014 2:24 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: UV 260nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



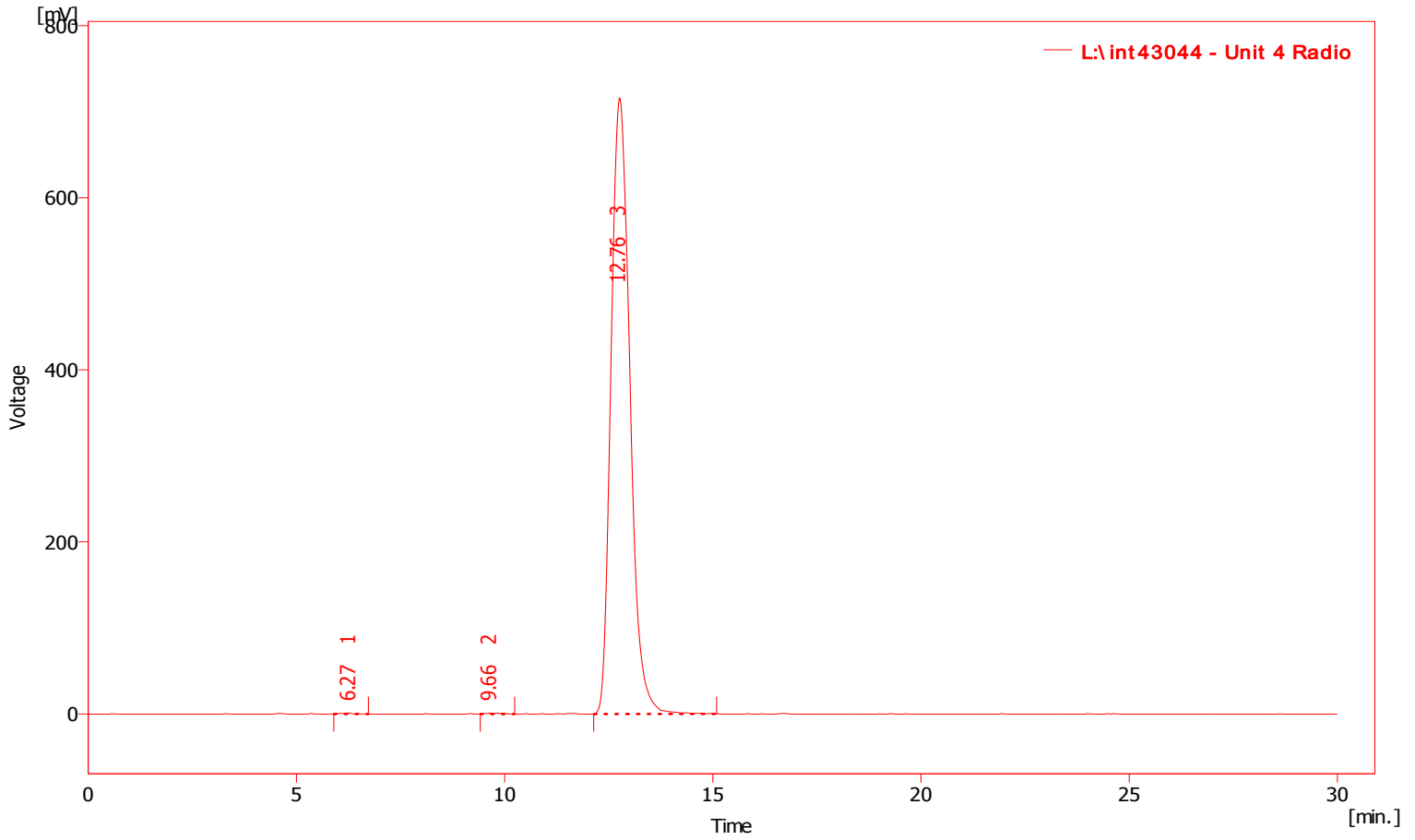
Result Table (Uncal - L:\int43042 - Unit 4 UV)

	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		3.43	429.017	92.24	5.08	16.41	14664.95	293298.96	1.91		
2		4.24	58.462	9.12	0.69	1.62	9975.26	199505.13	1.42		5.8
3		13.23	7952.629	460.61	94.19	81.94	13990.61	279812.16	1.81		29.2
4		14.34	2.722	0.20	0.03	0.04	15248.35	304967.01	1.24		2.4
		Total	8442.830	562.16	100.00	100.00					

MC-2023
Tenofvir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

File Name	: L:\int43044	File Created	: 2/11/2014 3:08:16 PM
Origin	: Acquired, Acquisition started 7/6/2011 2:22:33 PM	Acquired Date	: 7/6/2011 2:52:32 PM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: Radiochemical trace of 14C material co-injected with standard	Modified	: 2/11/2014 3:12 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



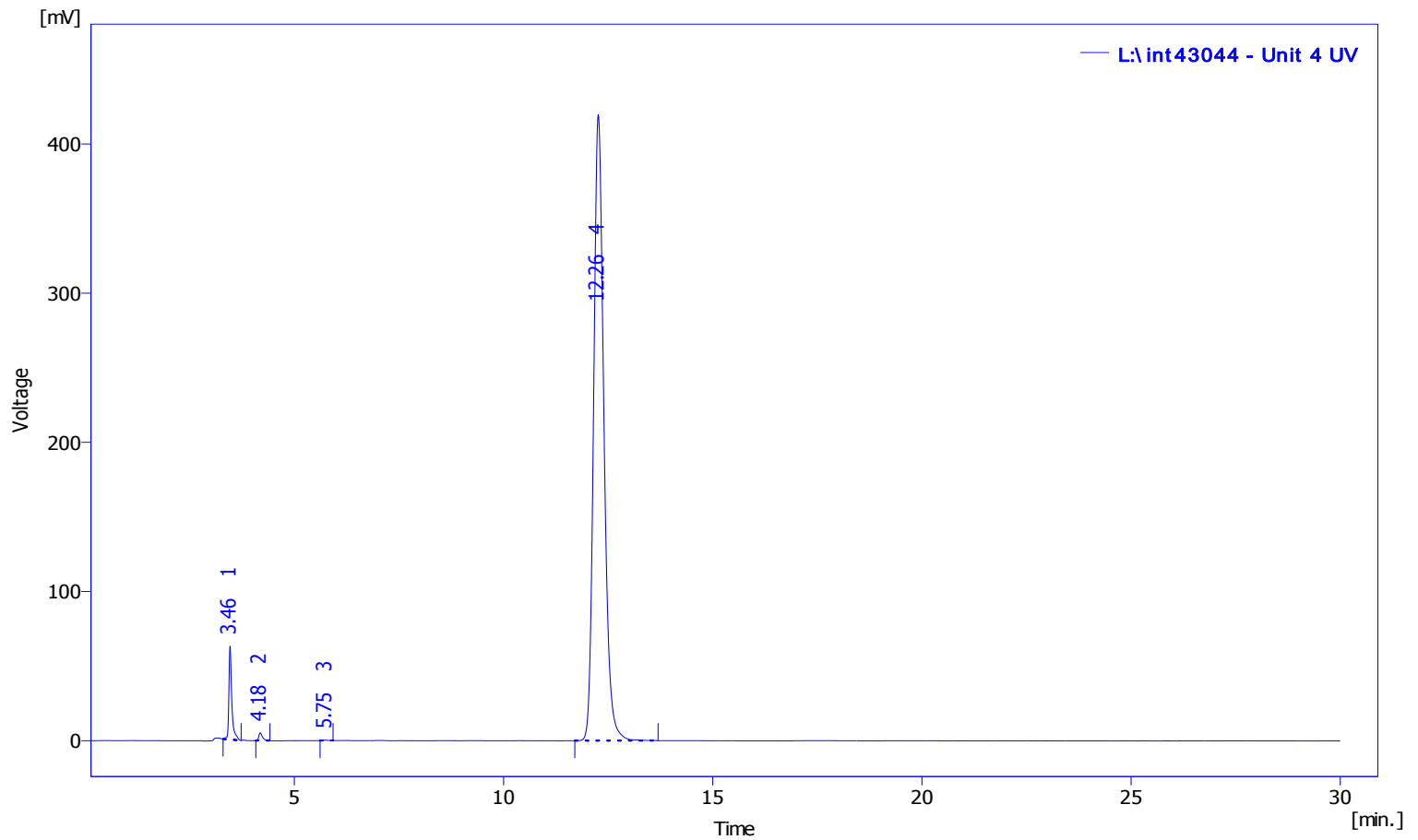
Result Table (Uncal - L:\int43044 - Unit 4 Radio)

	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		6.27	26.104	1.29	0.12	0.18	2043.13	40862.68	0.96		
2		9.66	31.064	1.22	0.14	0.17	2408.11	48162.27	1.53		5.1
3		12.76	22619.905	716.31	99.75	99.65	3656.63	73132.61	1.24		3.8
		Total	22677.074	718.82	100.00	100.00					

MC-2023
Tenofovir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

File Name	: L:\int43044	File Created	: 2/11/2014 3:08:16 PM
Origin	: Acquired, Acquisition started 7/6/2011 2:22:33 PM	Acquired Date	: 7/6/2011 2:52:32 PM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: UV trace of 14C material co-injected with standard	Modified	: 2/11/2014 3:15 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: UV 260nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	: The impurities were from standard material.		



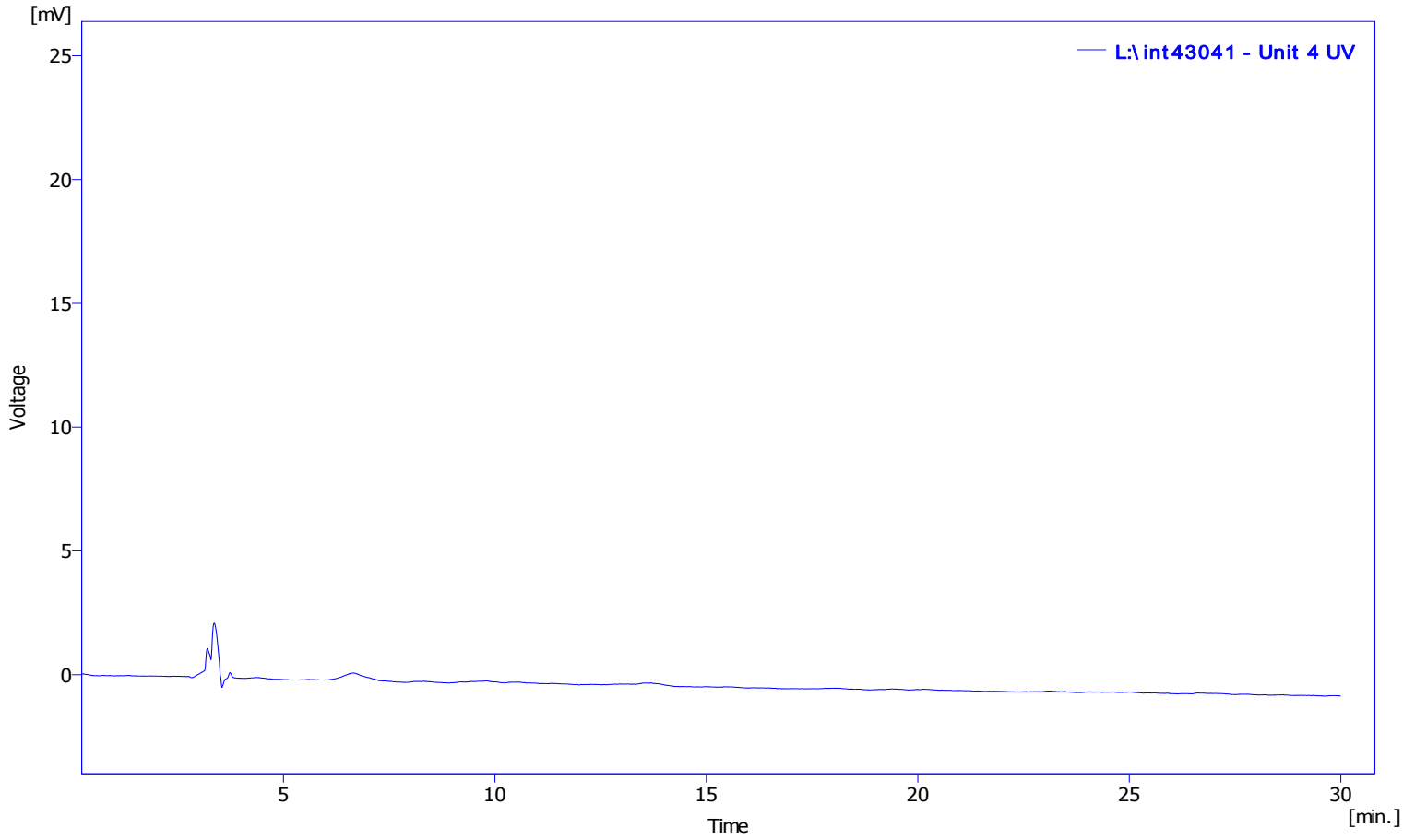
Result Table (Uncal - L:\int43044 - Unit 4 UV)

	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		3.46	302.055	62.58	4.03	12.83	13535.24	270704.75	1.71		
2		4.18	31.840	5.27	0.43	1.08	11129.64	222592.82	1.52		5.2
3		5.75	2.491	0.32	0.03	0.07	12041.61	240832.18	1.11		8.5
4		12.26	7149.496	419.52	95.51	86.02	12324.81	246496.14	1.20		20.0
		Total	7485.881	487.70	100.00	100.00					

MC-2023
Tenofovir disoproxil fumarate, [adenine-8-14C]-
Lot 194-040-0573-A-20080701-JZ

Chromatogram Info:

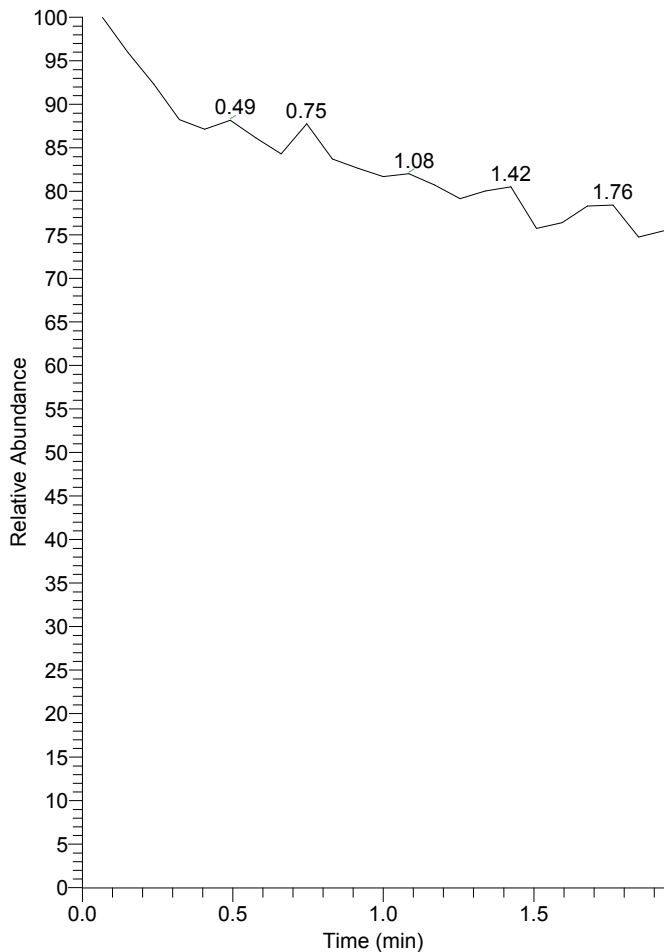
File Name	: L:\int43041	File Created	: 2/11/2014 3:08:15 PM
Origin	: Acquired, Acquisition started 7/6/2011 10:52:33 AM	Acquired Date	: 7/6/2011 11:22:32 AM
Project	: Test	By	: Administrator
Method	: Unit4-30minrun	By	: Administrator
Description	: UV trace of blank injection	Modified	: 2/11/2014 2:22 PM
Created	: 8/7/2007 9:44 AM		
Column	:	Detection	: UV 260nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



Result Table (Uncal - L:\int43041 - Unit 4 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 - 1.93



NL:
2.51E9
TIC MS
MC2023-
20080701-
JZ

MC2023-20080701-JZ#1-23 RT: 0.07-1.93 AV:

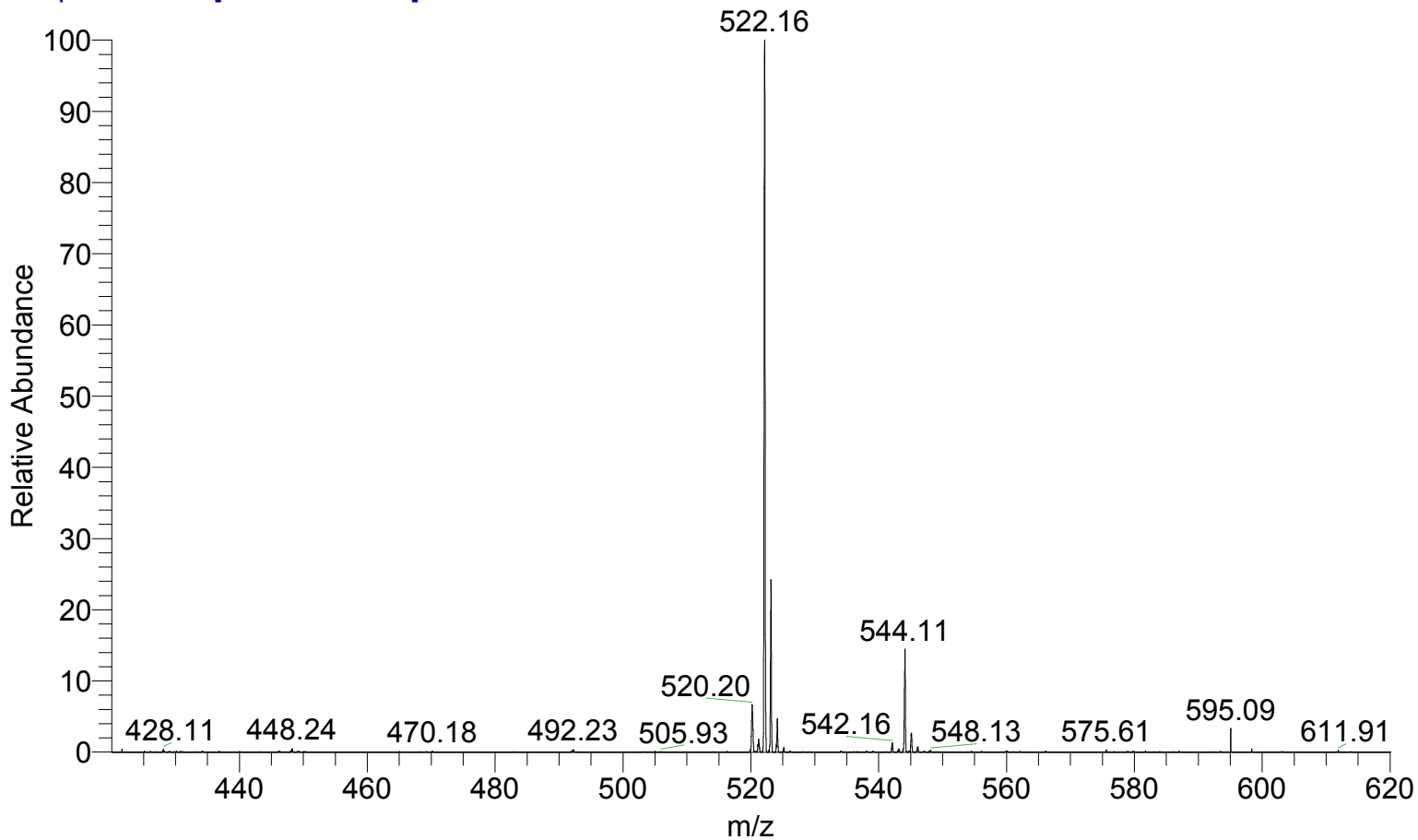
T: + p NSI Z ms [420.00-620.00]

m/z= 510.97-553.92

m/z	Intensity	Relative
520.22	116729240.0	8.90
521.20	26837224.0	2.05
522.16	1312082560.0	100.00
523.14	273571776.0	20.85
524.13	51442188.0	3.92
525.13	5304158.5	0.40
526.17	972992.2	0.07
528.14	492471.3	0.04
534.11	1441031.5	0.11
536.02	622132.8	0.05
538.09	966273.6	0.07
539.15	692189.7	0.05
541.10	352795.0	0.03
542.11	16949484.0	1.29
543.12	3972814.0	0.30
544.09	183474752.0	13.98
545.10	36901992.0	2.81
546.10	8415560.0	0.64
547.08	1211628.4	0.09
548.09	1709468.6	0.13

MC2023-20080701-JZ #1-23 RT: 0.07-1.93 AV: 23 NL: 3.52E7

T: + p NSI Z ms [420.00-620.00]



MC2023 1H NMR in MeOD
Batch 20080701-JZ



NAME MC2023-20080701-JZ
EXPNO 1
PROCNO 1
Date_ 20110706
Time 14.24
INSTRUM spect
PROBHD 5 mm FAPBO BB-
PULPROG zg30
TD 65536
SOLVENT MeOD
NS 512
DS 0
SWH 8278.146 Hz
FIDRES 0.126314 Hz
AQ 3.9584243 sec
RG 4
DW 60.400 usec
DE 6.50 usec
TE 300.0 K
D1 2.00000000 sec
TD0 1

==== CHANNEL f1 =====
NUC1 1H
P1 14.50 usec
PL1 -0.70 dB
PL1W 10.03411102 W
SFO1 400.1324710 MHz
SI 32768
SF 400.1300167 MHz
WDW no
SSB 0
LB 0.00 Hz
GB 0
PC 1.00

