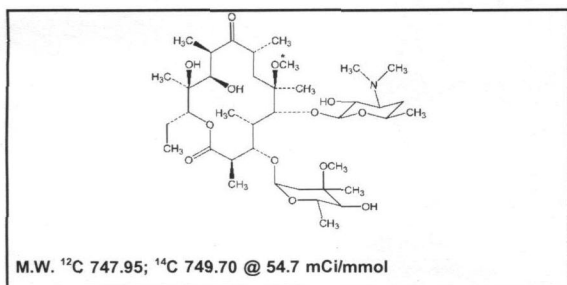




Product Data Sheet

MC-2295

Clarithromycin, [6-O-methyl-¹⁴C]-



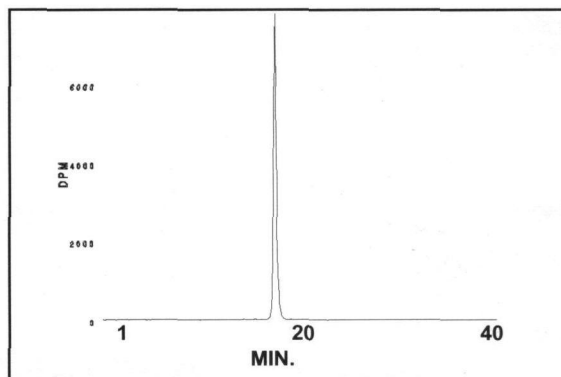
Lot #: 229-018-0547-A-20120620-JH

Specific Activity: 54.7 mCi/mmol

Packaged as: Solid

Date of Analysis: June 26, 2012

Radiochemical Purity: 99.4%



HPLC ANALYSIS LOT 229-018-0547-A-20120620-JH
File Name: intrn4282 Date and Time: 6/26/2012 1:38:54 PM
Unit 21 Radio

Peak #	Area %	Time	Area
1	0.16	14.42330	27.26041
2	0.32	15.52330	53.20957
3	99.41	17.52330	16703.26935
4	0.11	19.19330	18.02887
Totals	100.00		16801.76820

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-2295

Clarithromycin, [6-O-methyl-¹⁴C]-

Lot 229-018-0547-A-20120620-JH

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

Concentrations and volumes:

Standard solution concentration was 10.0 mg/ml.

Clarithromycin, [6-O-methyl-¹⁴C]- concentration was 0.1 mCi/ml.

Volume of standard alone injection was 15.0 µl.

Volume of **Clarithromycin, [6-O-methyl-¹⁴C]-** alone injection was 1.0 µl.

Co-injection solution consisted of 1.0 µl **Clarithromycin, [6-O-methyl-¹⁴C]-** + 15.0 µl standard.

Volume of co-injection was 16.0 µl.

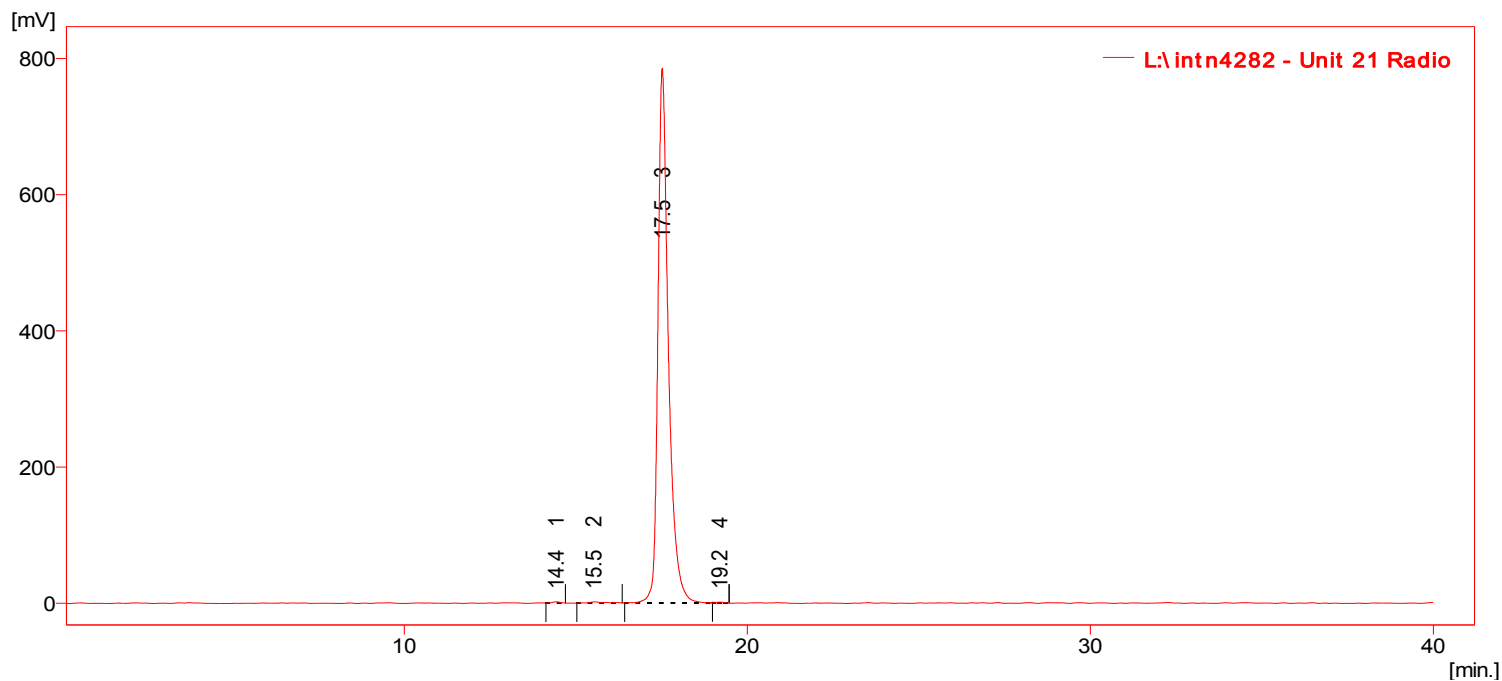
Volume of blank injection was 1.0 µl.

B) Mass spectrometry – Positive mode

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

File Name	: L:\intn4282	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 12:58:55 PM	Acquired Date	: 6/26/2012 1:38:54 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material alone	Modified	: 5/1/2014 3:17 PM
Created	: 4/17/2008 10:21 AM		
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



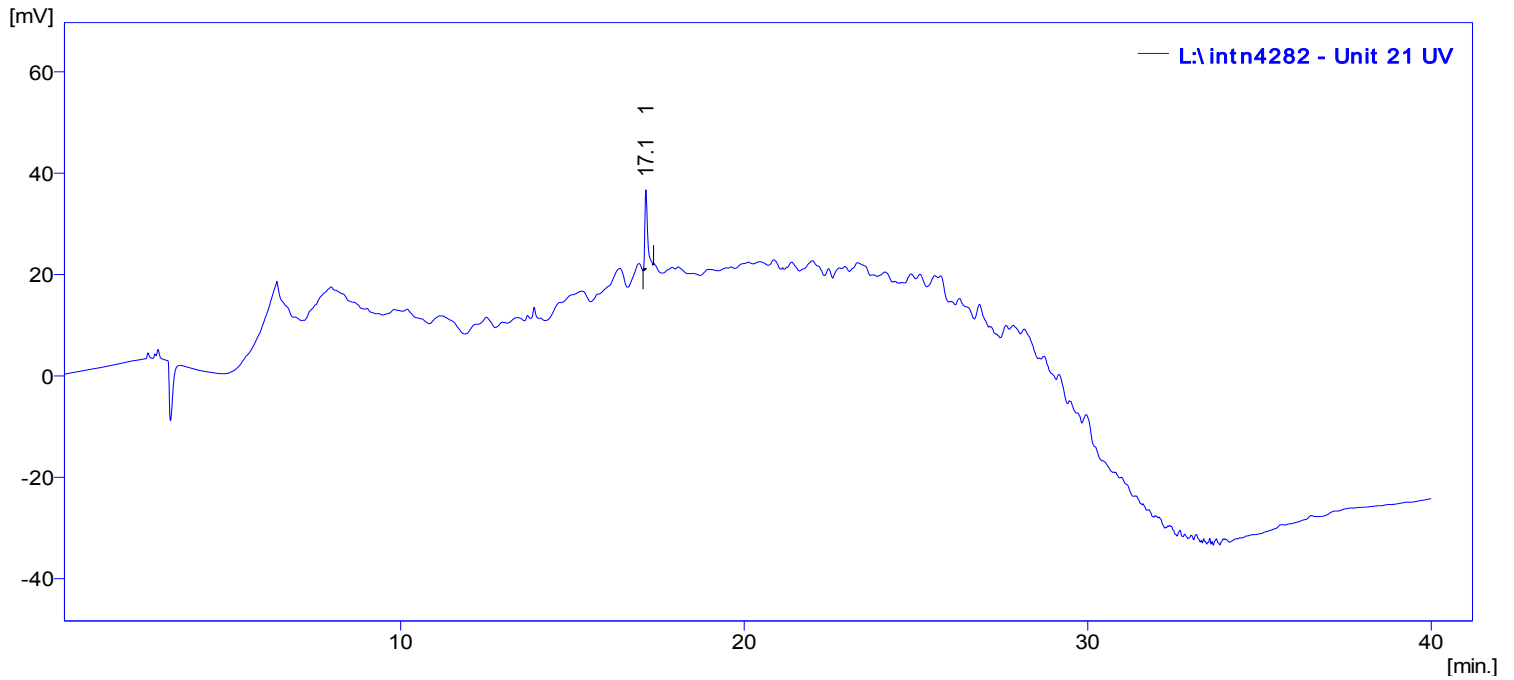
Result Table (Uncal - L:\intn4282 - Unit 21 Radio)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/I [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
1	14.42	27.260	1.89	0.16	0.2	0.22	23812	476240		1.12	
2	15.52	53.210	1.77	0.32	0.2	0.30	14509	290181	2.48	1.47	
3	17.52	16703.269	785.46	99.41	99.4	0.31	17327	346545	3.83	1.38	
4	19.19	18.029	1.14	0.11	0.1	0.26	30190	603801	3.44	1.18	
Total		16801.768	790.26	100.00	100.0						

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

File Name	: L:\intn4282	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 12:58:55 PM	Acquired Date	: 6/26/2012 1:38:54 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: UV trace of 14C material alone	Modified	: 5/1/2014 3:18 PM
Created	: 4/17/2008 10:21 AM		
Column	:	Detection	: UV 205nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



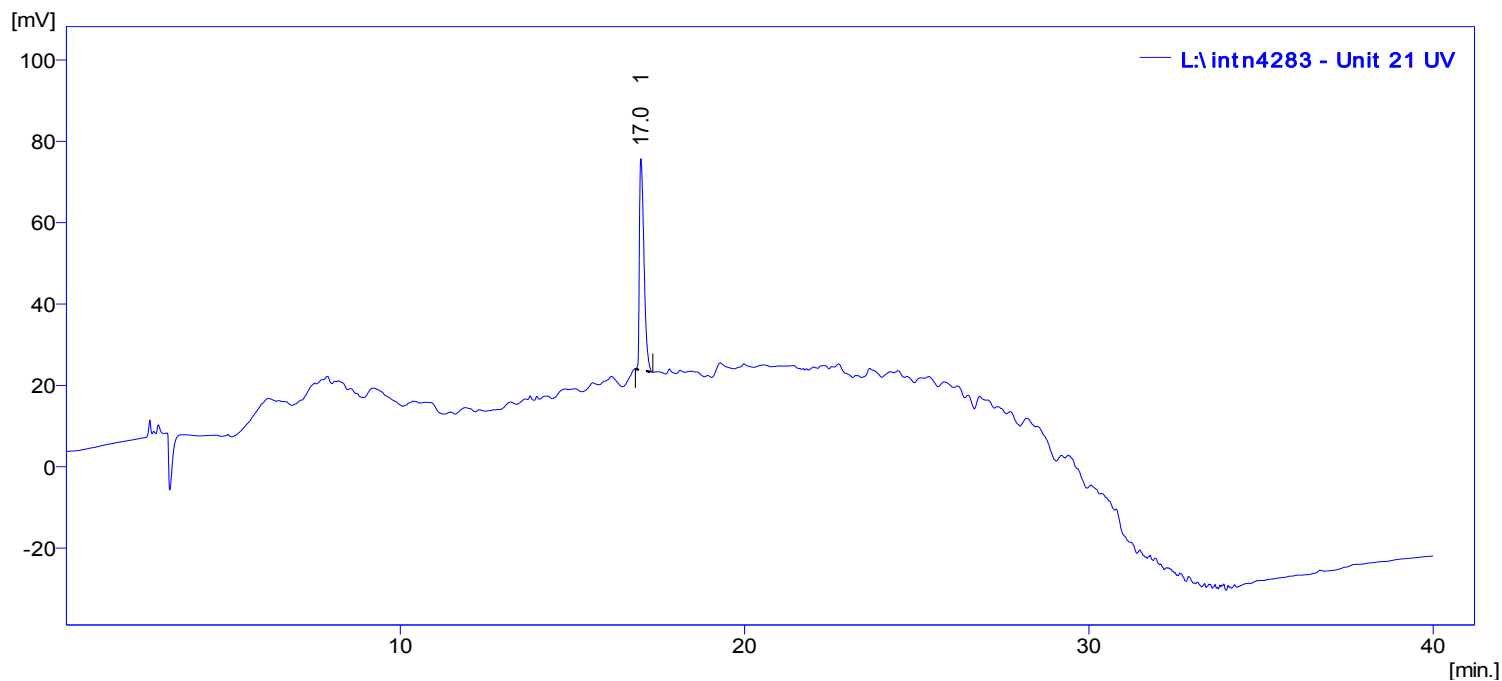
Result Table (Uncal - L:\intn4282 - Unit 21 UV)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/l [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
1	17.14	84.419	15.54	100.00	100.0	0.08	254204	5084081		1.86	
Total		84.419	15.54	100.00	100.0						

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

File Name	: L:\intn4283	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 1:46:14 PM	Acquired Date	: 6/26/2012 2:26:13 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: UV trace of standard alone	Modified	: 5/1/2014 3:12 PM
Created	: 4/17/2008 10:21 AM		
Column	:	Detection	: UV 205nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



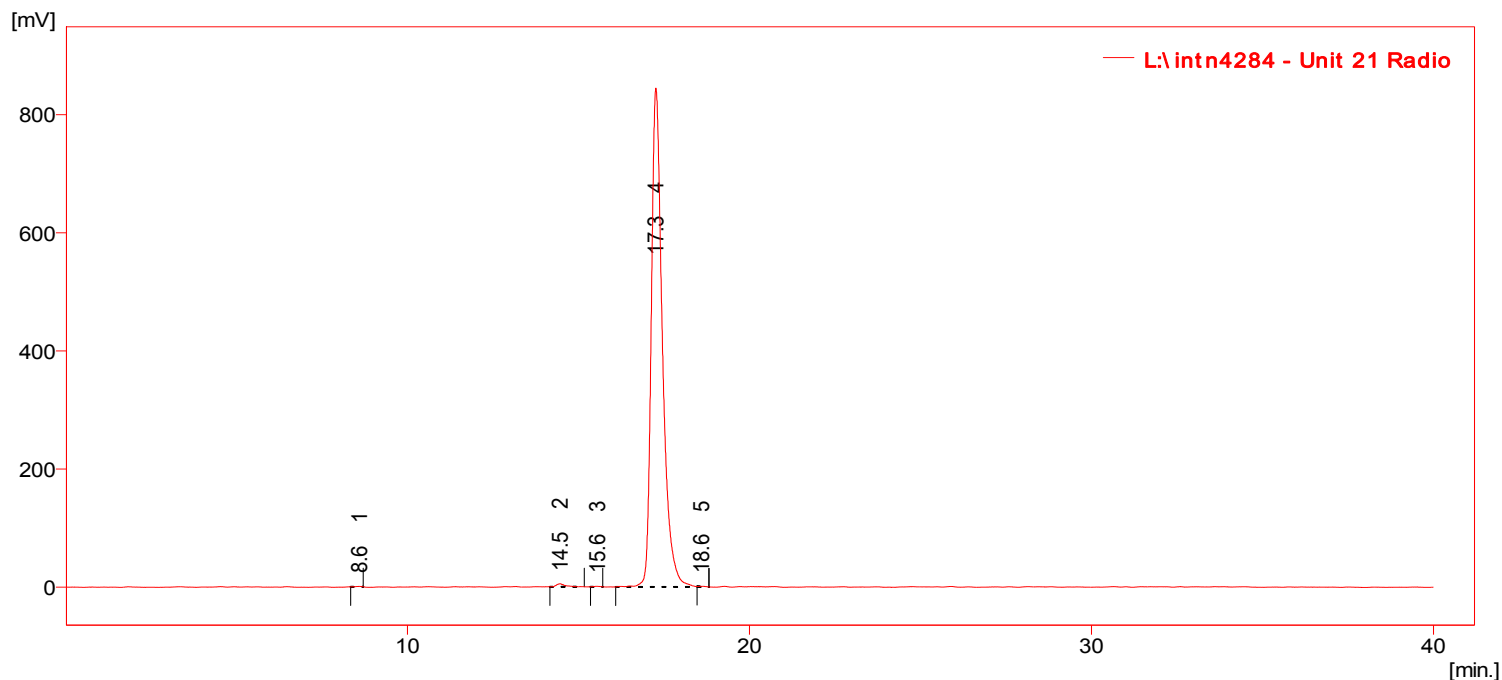
Result Table (Uncal - L:\intn4283 - Unit 21 UV)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/I [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
1		16.99	480.366	51.96	100.00	100.0	0.15	74313	1486255		1.94	
		Total	480.366	51.96	100.00	100.0						

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

File Name	: L:\intn4284	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 2:35:47 PM	Acquired Date	: 6/26/2012 3:15:46 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: Radiochemical trace of 14C material co-injected with standard		
Created	: 4/17/2008 10:21 AM	Modified	: 5/1/2014 3:21 PM
Column	:	Detection	: Radiochemical
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



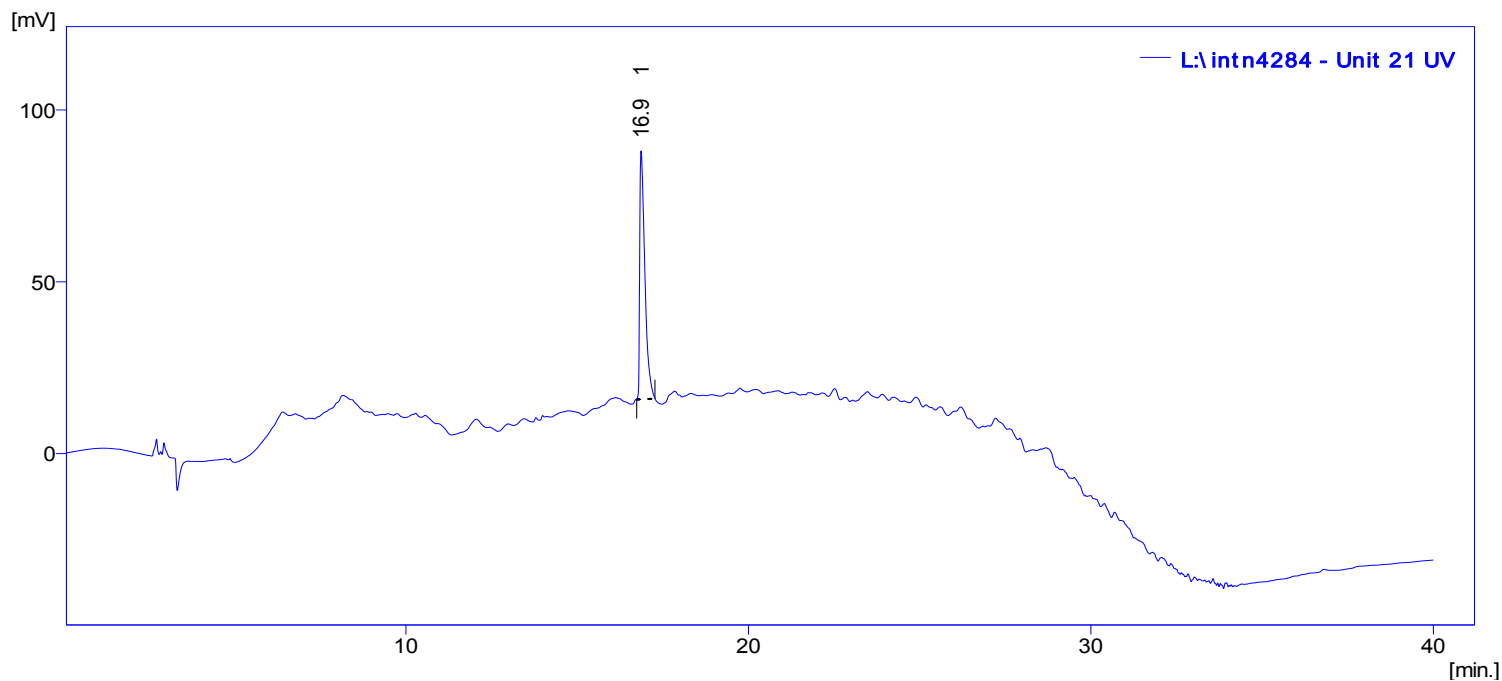
Result Table (Uncal - L:\intn4284 - Unit 21 Radio)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/I [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
1	8.60	8.248	0.79	0.04	0.1	0.14	19929	398571		0.77	
2	14.46	93.877	5.22	0.49	0.6	0.22	23224	464482	18.87	1.53	
3	15.56	11.239	0.93	0.06	0.1	0.19	35885	717704	3.12	0.85	
4	17.26	19193.421	844.75	99.37	99.1	0.34	14567	291332	3.79	1.16	
5	18.60	8.315	0.65	0.04	0.1	0.22	38413	768251	2.81	1.31	
Total		19315.100	852.33	100.00	100.0						

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

File Name	: L:\intn4284	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 2:35:47 PM	Acquired Date	: 6/26/2012 3:15:46 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: UV trace of 14C material co-injected with standard	Modified	: 5/1/2014 3:10 PM
Created	: 4/17/2008 10:21 AM		
Column	:	Detection	: UV 205nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



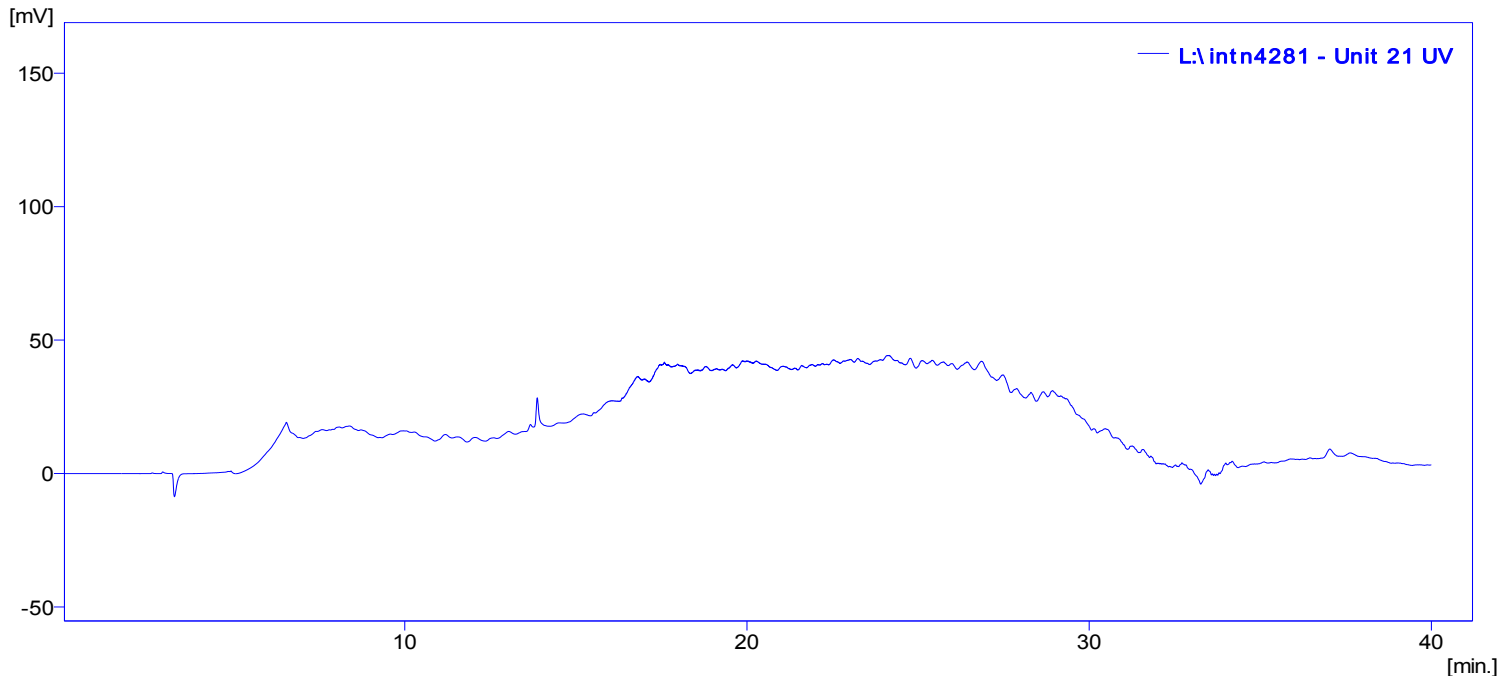
Result Table (Uncal - L:\intn4284 - Unit 21 UV)

	Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/I [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
1		16.87	757.468	72.25	100.00	100.0	0.16	61564	1231284		2.50	
		Total	757.468	72.25	100.00	100.0						

MC2295
Clarithromycin, [6-O-methyl-14C]-
Lot 229-018-0547-A-20120620-JH

Chromatogram Info:

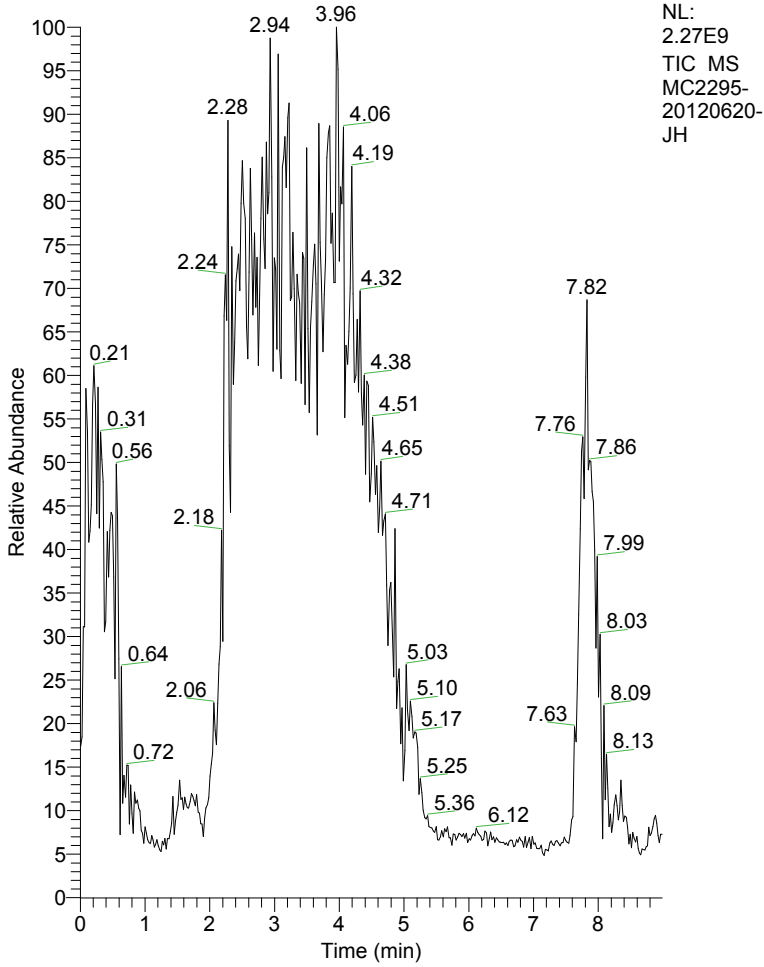
File Name	: L:\intn4281	File Created	: 5/1/2014 3:04:57 PM
Origin	: Acquired, Acquisition started 6/26/2012 12:10:36 PM	Acquired Date	: 6/26/2012 12:50:36 PM
Project	: Work1	By	: Administrator
Method	: Unit_21_40_min_run	By	: Administrator
Description	: UV trace of blank injection		
Created	: 4/17/2008 10:21 AM	Modified	: 5/1/2014 3:24 PM
Column	:	Detection	: UV 205nm
Mobile Phase	:	Temperature	:
Flow Rate	:	Pressure	:
Note	:		



Result Table (Uncal - L:\intn4281 - Unit 21 UV)

Compound Name	Reten. Time [min]	Area [mV.s]	Height [mV]	Area [%]	Height [%]	W05 [min]	Efficiency [th.pl]	Eff/l [t.p./m]	Resolution [-]	Symmetry/Tailing [-]	Response Factor
No peak to report											

RT: 0.00 - 8.99



NL: 2.27E9
TIC MS
MC2295-20120620-JH

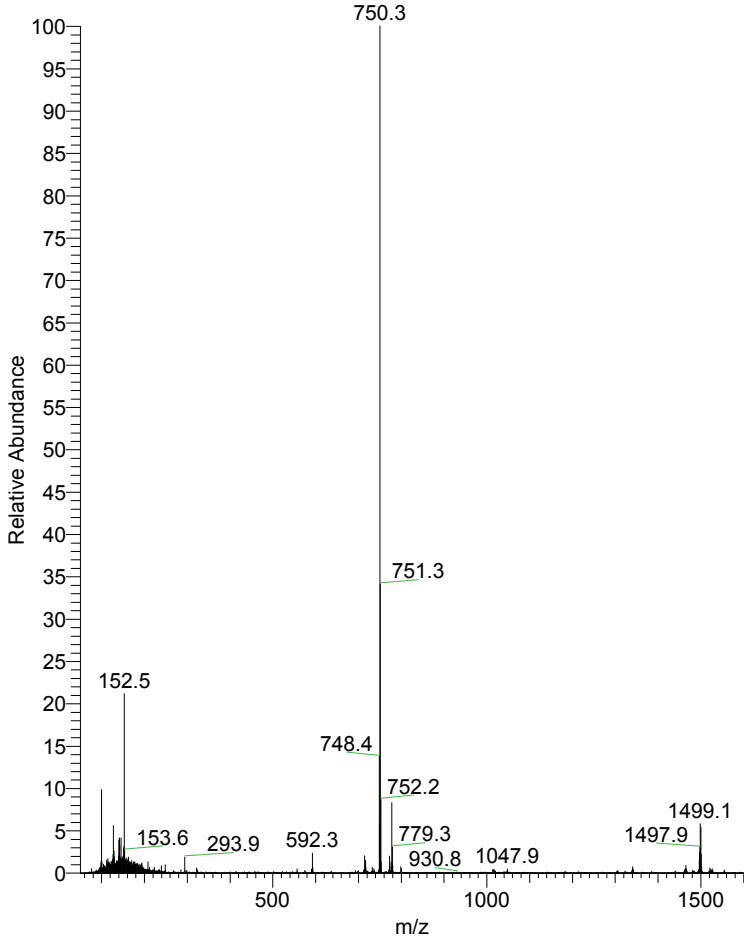
MC2295-20120620-JH#79-288 RT: 1.59-6.01

T: + c ESI Full ms [50.00-1600.00]

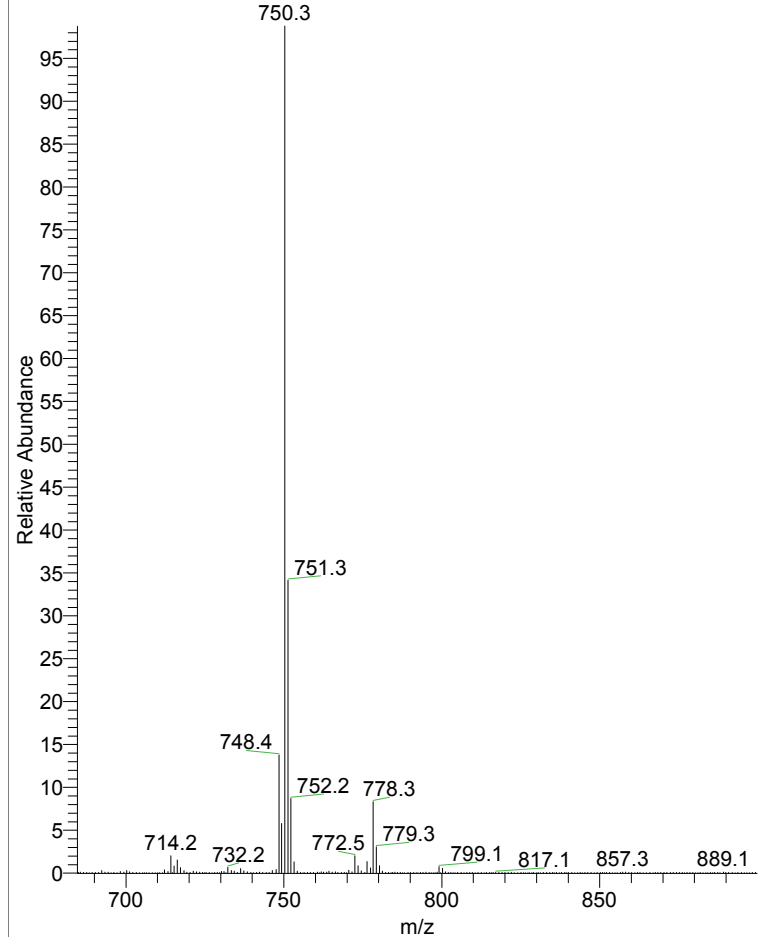
m/z = 740.7-768.1

m/z	Intensity	Relative
744.4	146516.1	0.07
746.3	607678.4	0.30
747.5	803725.3	0.39
748.4	28087570.8	13.75
749.3	11749024.7	5.75
750.3	204272756.2	100.00
751.3	69666150.7	34.10
752.2	17688457.7	8.66
753.2	2608696.8	1.28
754.3	442429.1	0.22
755.2	148737.0	0.07
760.6	203038.4	0.10
761.9	257774.0	0.13
762.5	157657.1	0.08
763.6	165312.2	0.08
764.3	382370.2	0.19
765.3	181376.2	0.09
766.2	248241.2	0.12

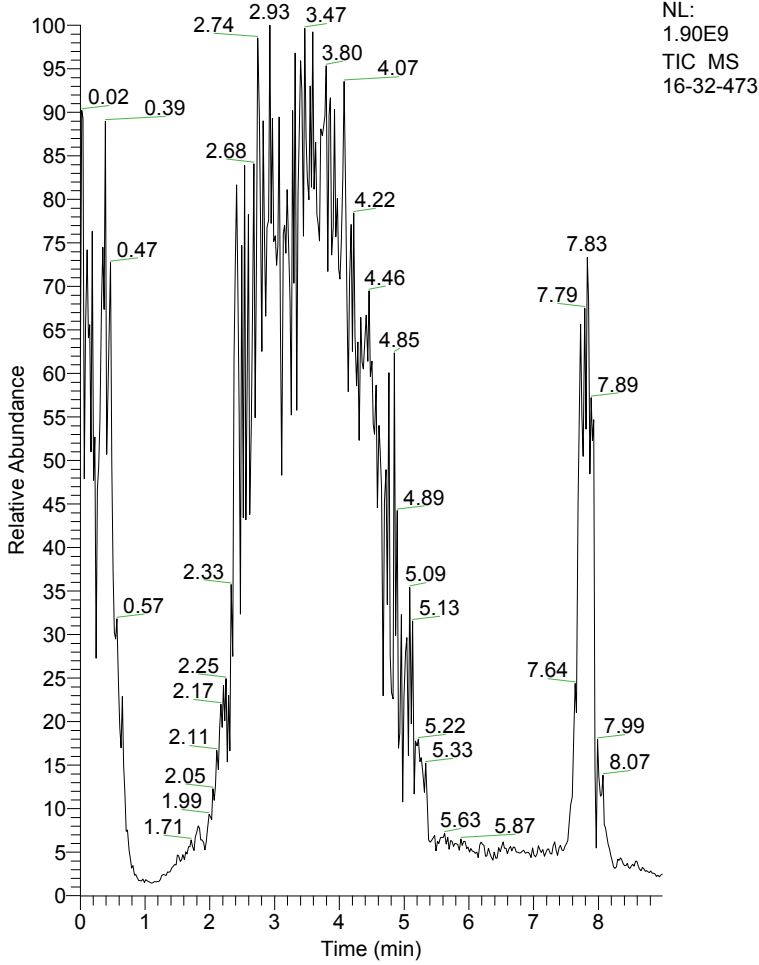
MC2295-20120620-JH #76-288 RT: 1.53-6.01 AV: 213 NL: 2.02E8
T: + c ESI Full ms [50.00-1600.00]



MC2295-20120620-JH #79-288 RT: 1.59-6.01 AV: 210 NL: 2.04E8
T: + c ESI Full ms [50.00-1600.00]



RT: 0.00 - 8.98



NL: 1.90E9
TIC MS 16-32-473

Std MS #76-283 RT: 1.59-5.99 AV: 208

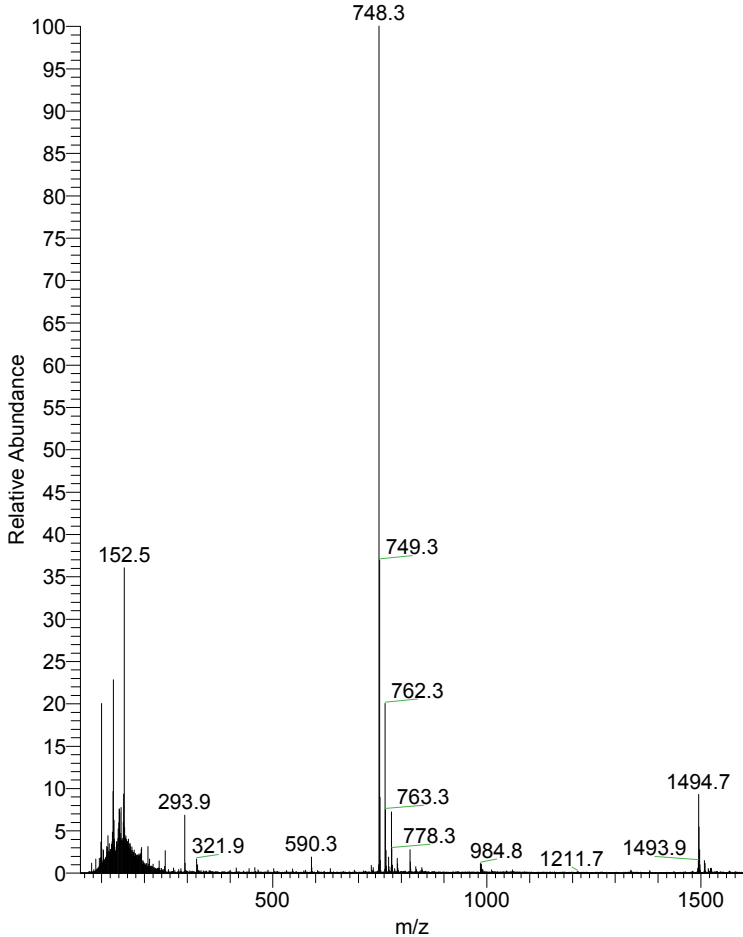
T: + c ESI Full ms [50.00-1600.00]

m/z = 741.1-760.0

m/z	Intensity	Relative
741.5	171219.2	0.17
742.6	104632.7	0.10
743.6	82921.3	0.08
744.4	231360.6	0.23
745.4	137109.5	0.13
746.4	375846.6	0.37
747.5	976773.1	0.95
748.3	102486817.4	100.00
749.3	37838000.4	36.92
750.3	9176259.1	8.95
751.3	1543358.3	1.51
752.3	296779.6	0.29
753.3	85499.4	0.08
754.5	76505.1	0.07
755.3	33547.3	0.03
755.9	110578.0	0.11
756.6	96922.3	0.09
757.4	79130.2	0.08
758.3	60621.0	0.06
759.2	117138.7	0.11

Std MS #77-283 RT: 1.61-5.99 AV: 207 NL: 1.03E8

T: + c ESI Full ms [50.00-1600.00]



Std MS #76-283 RT: 1.59-5.99 AV: 208 NL: 1.02E8

T: + c ESI Full ms [50.00-1600.00]

