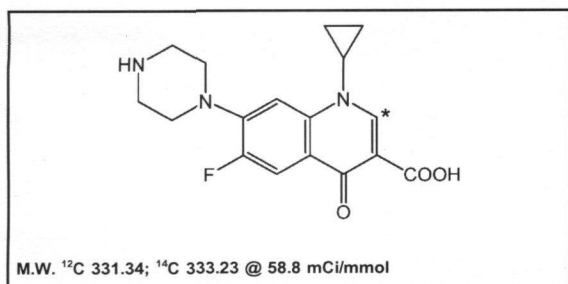




Product Data Sheet

MC-1409

Ciprofloxacin, [2-¹⁴C]-



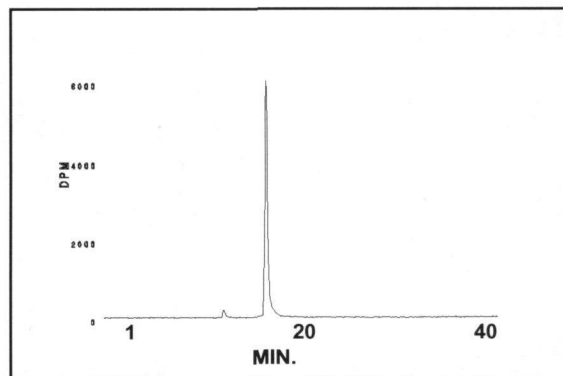
Lot #: 257-118-0588-A-20140217-DJI

Specific Activity: 58.8 mCi/mmol

Packaged as: Solid

Date of Analysis: February 26, 2014

Radiochemical Purity: 97.1%



HPLC ANALYSIS LOT 257-118-0588-A-20140217-DJI
File Name: intk5030 Date and Time: 2/26/2014 11:05:46 A
Unit 20 Radio

| Peak # | Area % | Time | Area |
|--------|--------|----------|-------------|
| 1 | 2.90 | 12.22000 | 364.82537 |
| 2 | 97.10 | 16.53670 | 12228.51193 |

Totals 100.00 12593.33730

Stability and Storage Recommendation: Rate of decomposition is less than 0.02%/month when stored 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-1409

Ciprofloxacin, [2-¹⁴C]-

Lot 257-118-0588-A-20140217-DJI

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.

Ciprofloxacin, [2-¹⁴C]- concentration was 0.1 mCi/ml.

Volume of standard alone injection was 1.0 µl.

Volume of **Ciprofloxacin, [2-¹⁴C]-** alone injection was 1.5 µl.

Co-injection solution consisted of 1.5 µl **Ciprofloxacin, [2-¹⁴C]-** + 1.0 µl standard.

Volume of co-injection was 2.5 µl.

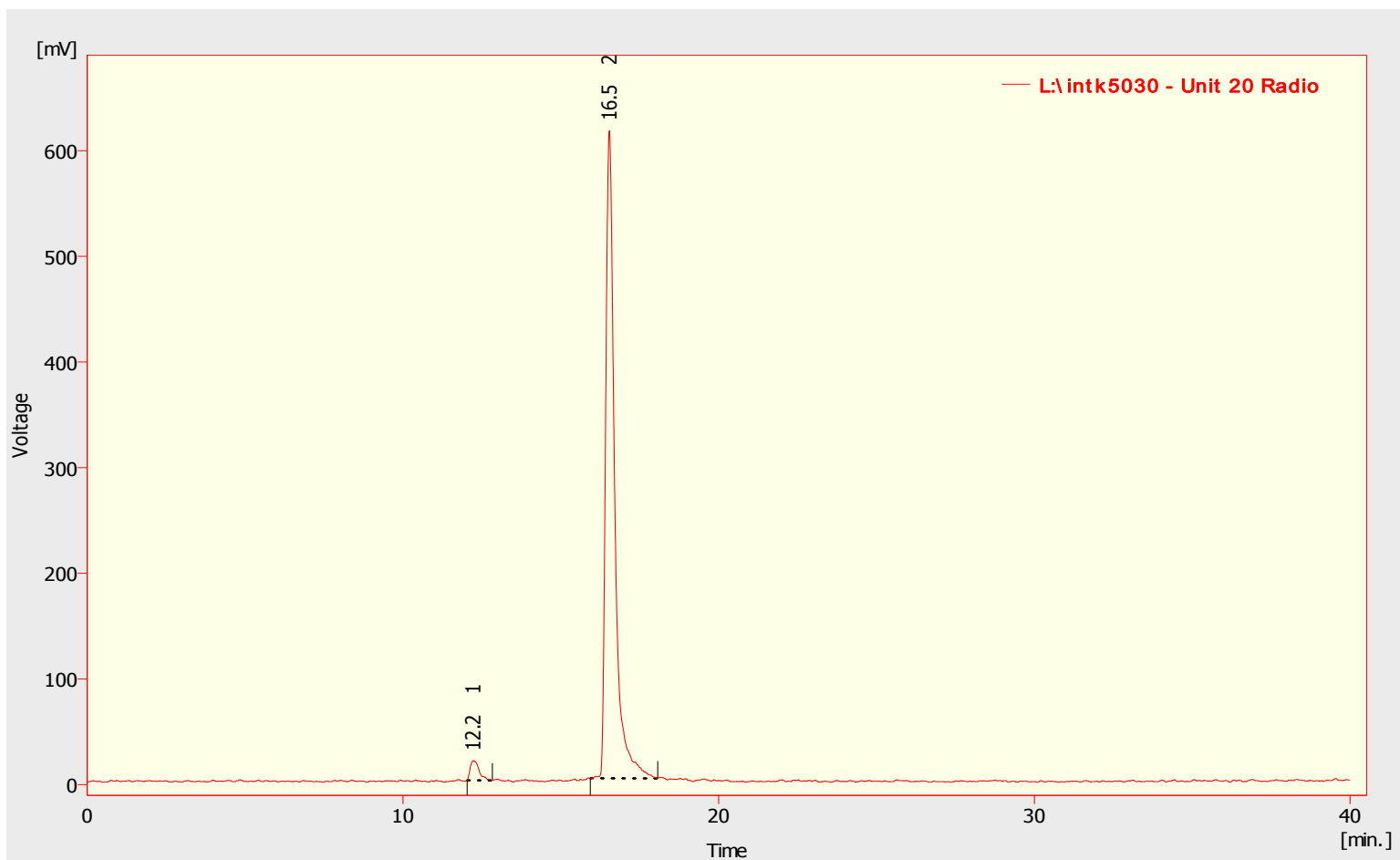
Volume of blank injection was 10.0 µl.

B) Mass spectrometry – Positive mode

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\intk5030 | File Created | : 2/26/2014 11:06:05 AM |
| Origin | : Acquired, Acquisition started 2/26/2014 10:25:47 AM | Acquired Date | : 2/26/2014 11:05:46 AM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : Radiochemical trace of 14C material alone | Modified | : 2/26/2014 1:47 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : Radiochemical |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

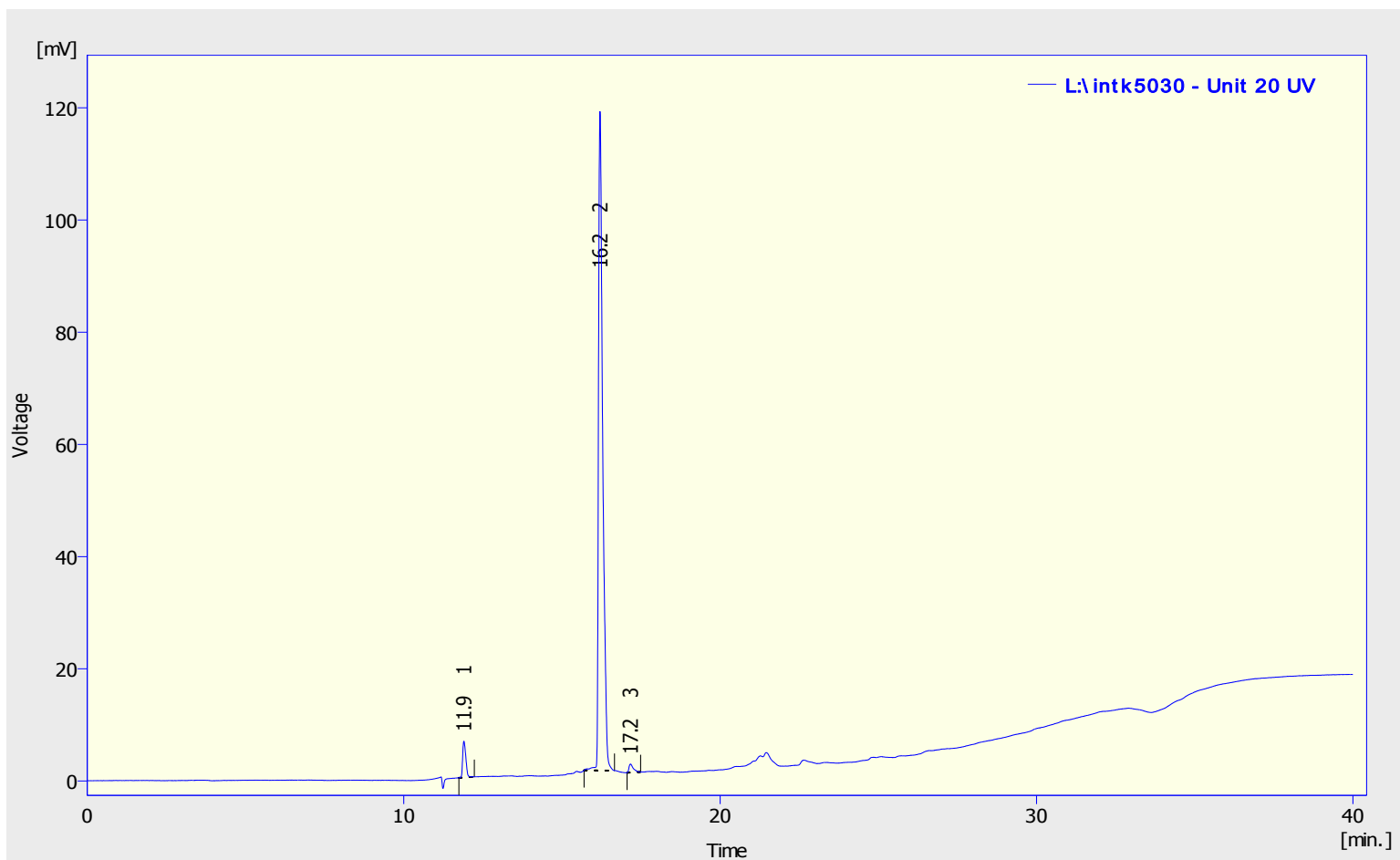
Result Table (Uncal - L:\intk5030 - Unit 20 Radio)

| | Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|---|-------------------------|----------------|----------------|-------------|---------------|--------------|
| 1 | 12.220 | 364.825 | 18.708 | 2.90 | 3.0 | 0.30 |
| 2 | 16.537 | 12228.512 | 613.106 | 97.10 | 97.0 | 0.28 |
| | Total | 12593.337 | 631.814 | 100.00 | 100.0 | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\intk5030 | File Created | : 2/26/2014 11:06:05 AM |
| Origin | : Acquired, Acquisition started 2/26/2014 10:25:47 AM | Acquired Date | : 2/26/2014 11:05:46 AM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : UV trace of 14C material alone | Modified | : 2/26/2014 1:42 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : 254 nm |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

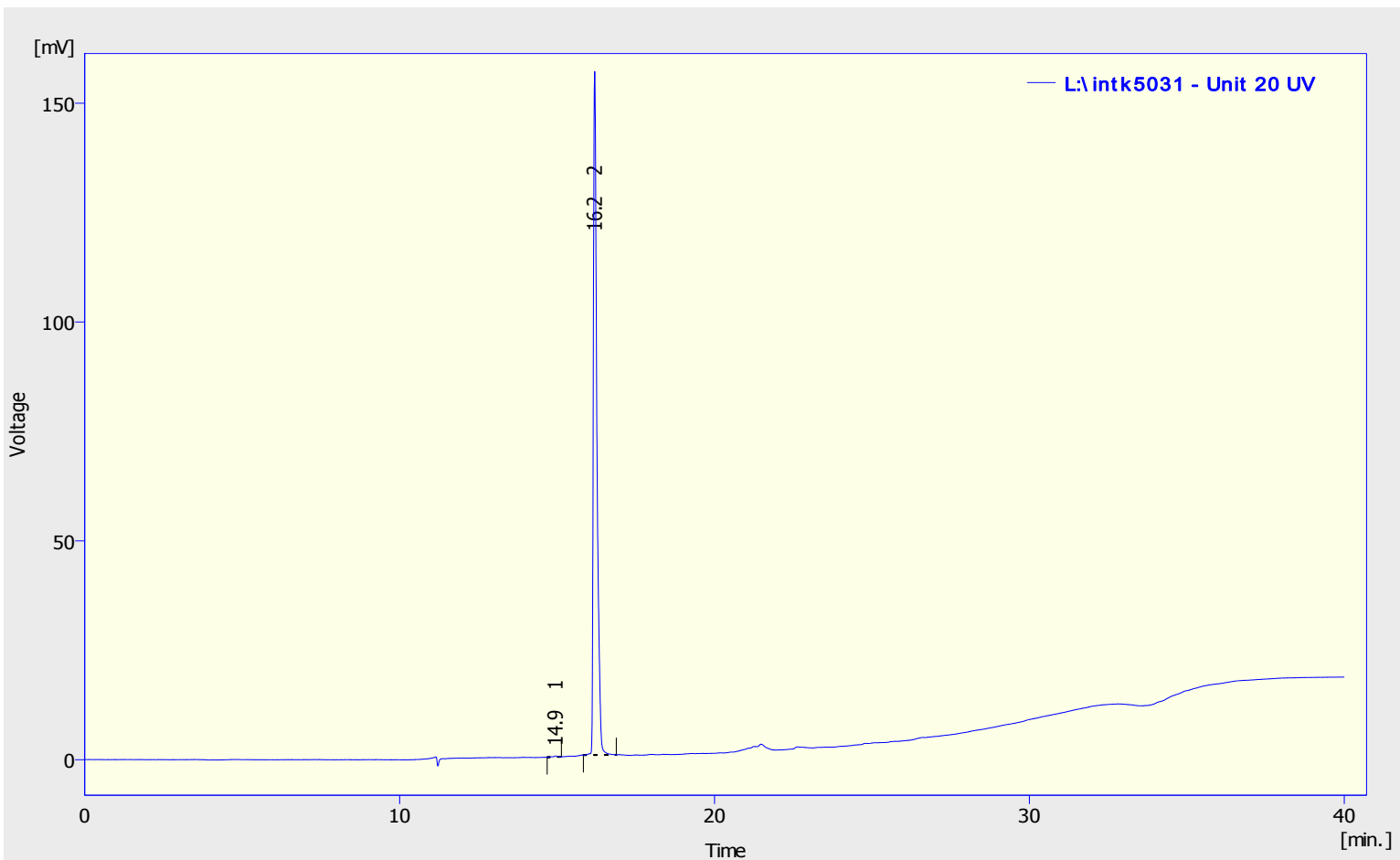
Result Table (Uncal - L:\intk5030 - Unit 20 UV)

| | Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|---|-------------------------|----------------|----------------|-------------|---------------|--------------|
| 1 | 11.900 | 44.757 | 6.472 | 3.90 | 5.2 | 0.11 |
| 2 | 16.203 | 1089.910 | 117.470 | 94.85 | 93.6 | 0.14 |
| 3 | 17.170 | 14.391 | 1.532 | 1.25 | 1.2 | 0.14 |
| | Total | 1149.058 | 125.474 | 100.00 | 100.0 | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\intk5031 | File Created | : 2/26/2014 12:04:45 PM |
| Origin | : Acquired, Acquisition started 2/26/2014 11:24:28 AM | Acquired Date | : 2/26/2014 12:04:27 PM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : UV trace of standard alone | Modified | : 2/26/2014 2:04 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : 254 nm |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

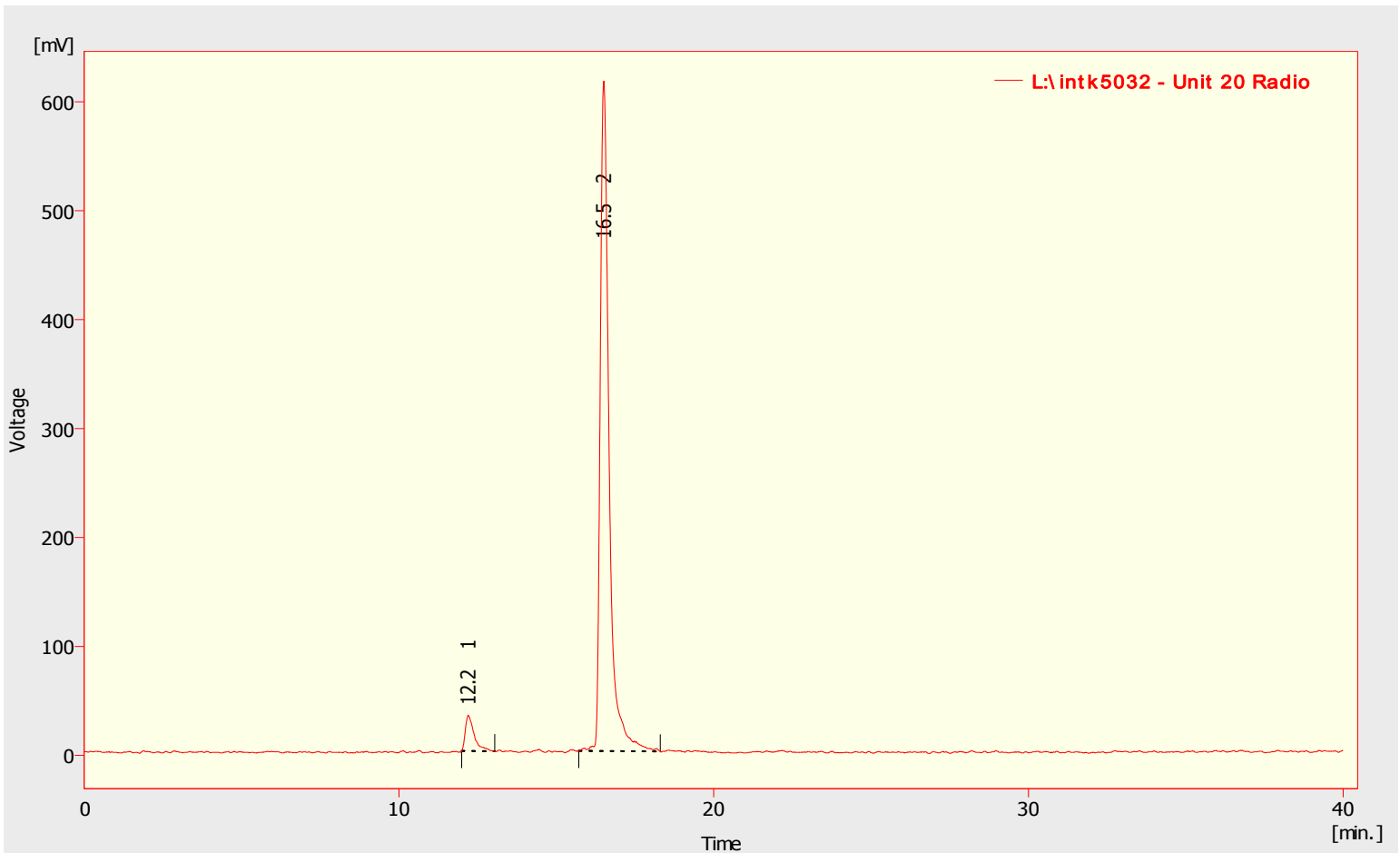
Result Table (Uncal - L:\intk5031 - Unit 20 UV)

| | Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|---|-------------------------|----------------|----------------|-------------|---------------|--------------|
| 1 | 14.947 | 2.381 | 0.235 | 0.19 | 0.2 | 0.12 |
| 2 | 16.193 | 1223.993 | 156.192 | 99.81 | 99.8 | 0.12 |
| | Total | 1226.374 | 156.427 | 100.00 | 100.0 | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\intk5032 | File Created | : 2/26/2014 1:00:06 PM |
| Origin | : Acquired, Acquisition started 2/26/2014 12:19:49 PM | Acquired Date | : 2/26/2014 12:59:48 PM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : Radiochemical trace of 14C material co-injected with standard | Modified | : 2/26/2014 2:09 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : Radiochemical |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

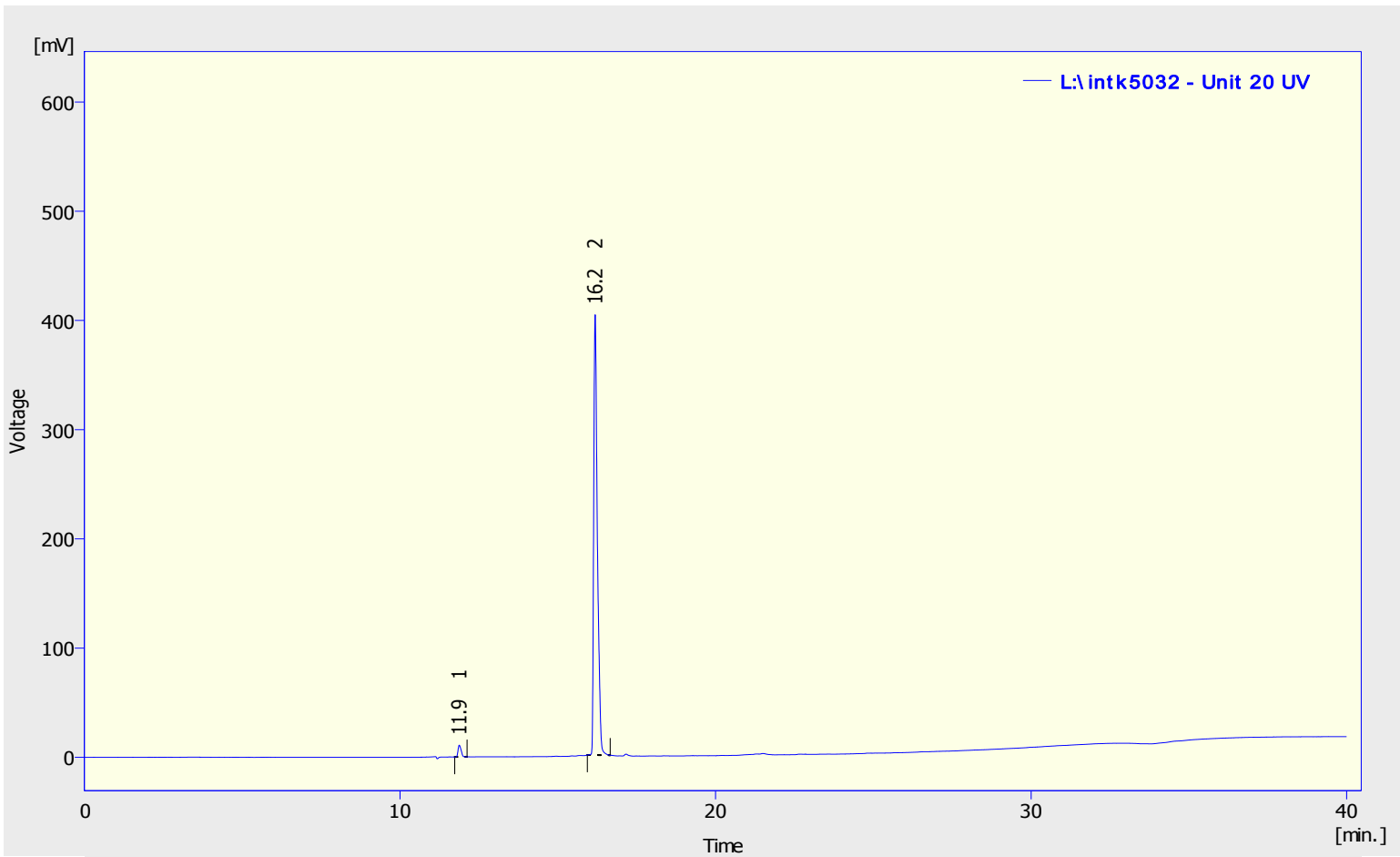
Result Table (Uncal - L:\intk5032 - Unit 20 Radio)

| | Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|---|-------------------------|----------------|----------------|-------------|---------------|--------------|
| 1 | 12.200 | 636.865 | 32.852 | 4.99 | 5.1 | 0.28 |
| 2 | 16.510 | 12131.925 | 615.077 | 95.01 | 94.9 | 0.28 |
| | Total | 12768.790 | 647.929 | 100.00 | 100.0 | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\intk5032 | File Created | : 2/26/2014 1:00:06 PM |
| Origin | : Acquired, Acquisition started 2/26/2014 12:19:49 PM | Acquired Date | : 2/26/2014 12:59:48 PM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : UV trace of 14C material co-injected with standard | Modified | : 2/26/2014 2:14 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : 254 nm |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

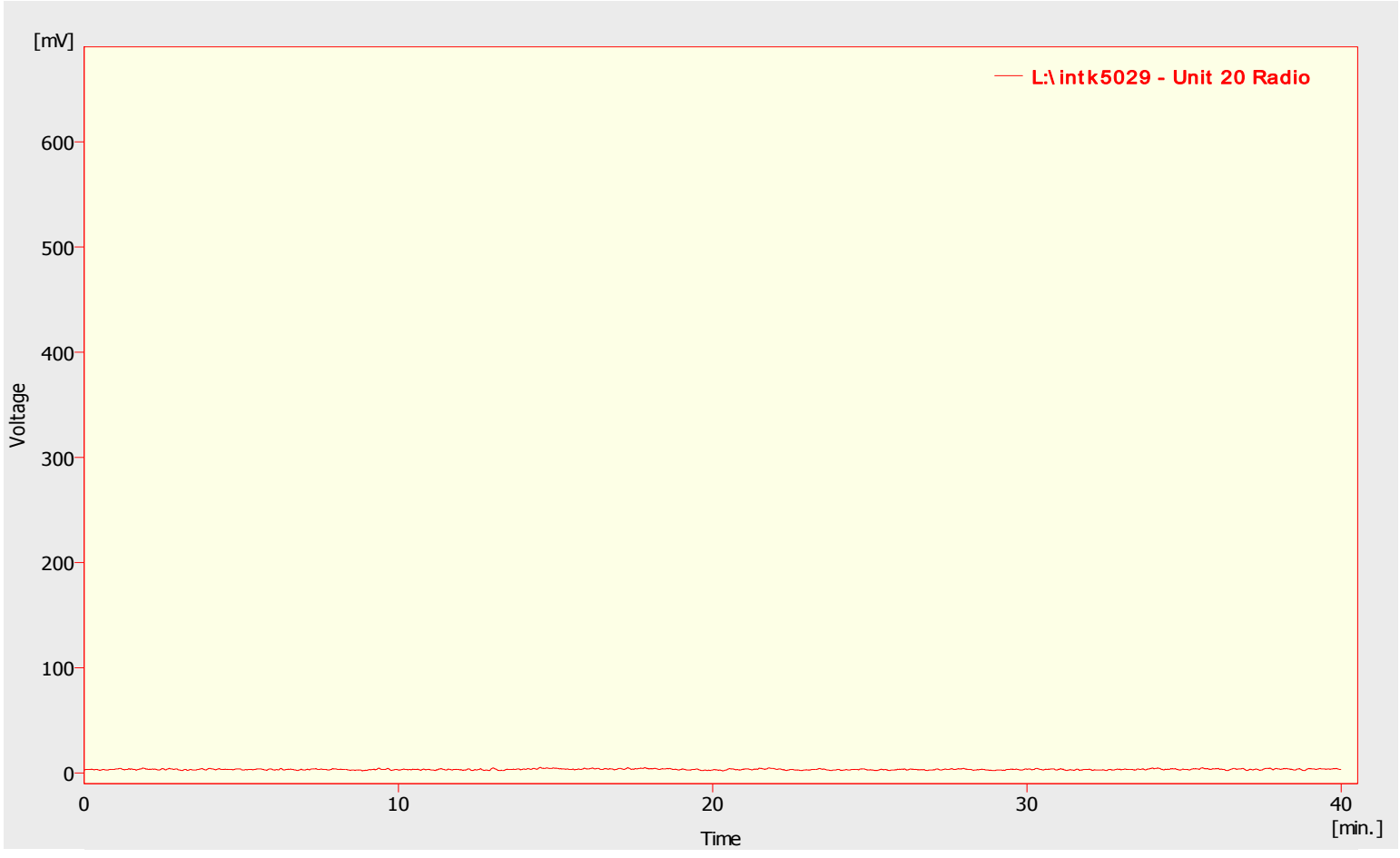
Result Table (Uncal - L:\intk5032 - Unit 20 UV)

| | Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|---|-------------------------|----------------|----------------|-------------|---------------|--------------|
| 1 | 11.877 | 71.690 | 10.750 | 2.14 | 2.6 | 0.11 |
| 2 | 16.183 | 3277.765 | 403.237 | 97.86 | 97.4 | 0.12 |
| | Total | 3349.454 | 413.987 | 100.00 | 100.0 | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|--|---------------|------------------------|
| File Name | : L:\intk5029 | File Created | : 2/26/2014 9:38:21 AM |
| Origin | : Acquired, Acquisition started 2/26/2014 8:58:02 AM | Acquired Date | : 2/26/2014 9:38:01 AM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : Radiochemical trace of blank injection | Modified | : 2/26/2014 1:58 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : Radiochemical |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

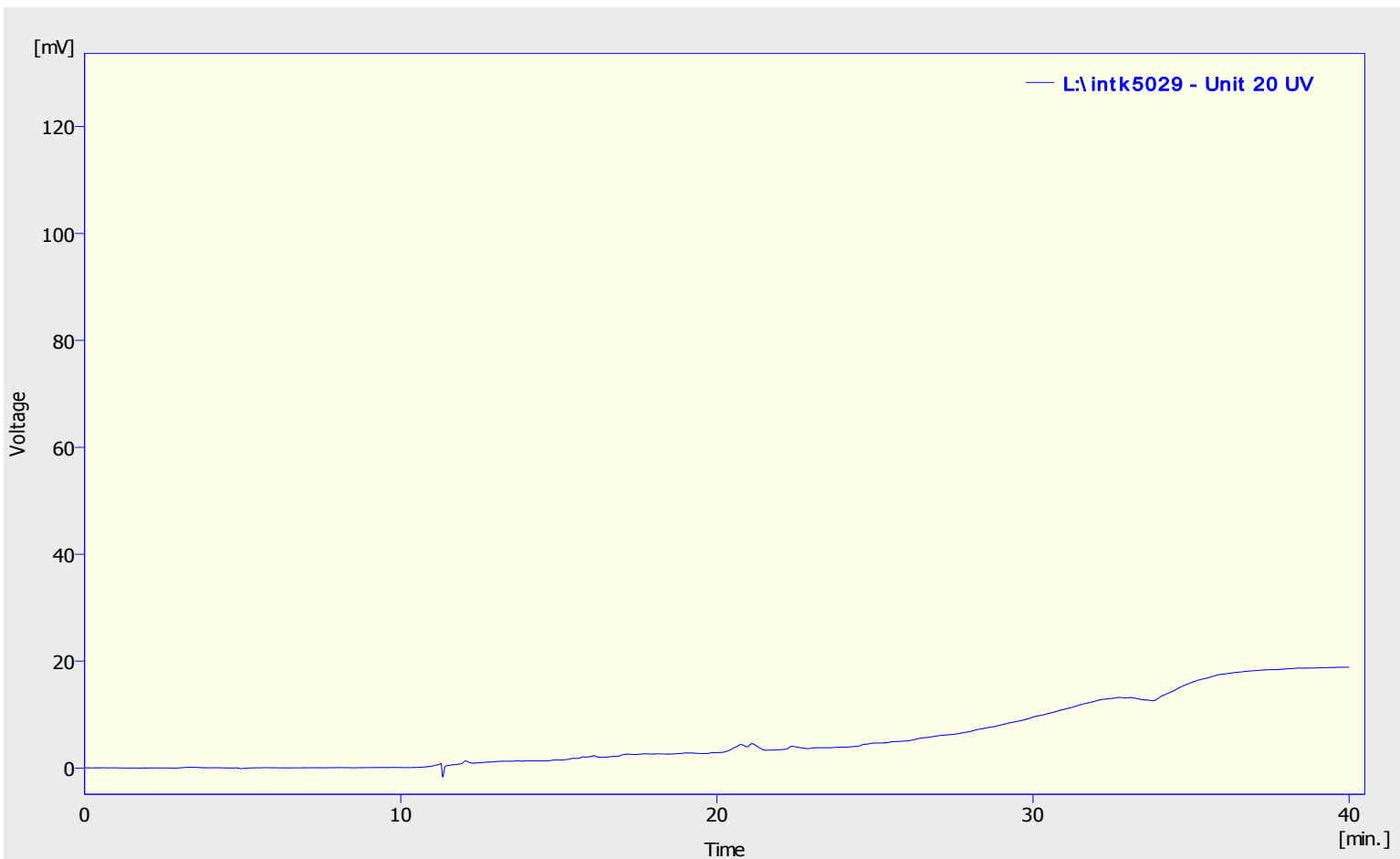
Result Table (Uncal - L:\intk5029 - Unit 20 Radio)

| Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|-------------------------|----------------|----------------|-------------|---------------|--------------|
| No peak to report | | | | | |

MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Chromatogram Info:

| | | | |
|--------------|--|---------------|------------------------|
| File Name | : L:\intk5029 | File Created | : 2/26/2014 9:38:21 AM |
| Origin | : Acquired, Acquisition started 2/26/2014 8:58:02 AM | Acquired Date | : 2/26/2014 9:38:01 AM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit20_40_min_run | By | : Administrator |
| Description | : UV trace of blank injection | Modified | : 2/26/2014 1:59 PM |
| Created | : 7/10/2013 11:04 AM | | |
| Column | : | Detection | : 254 nm |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |

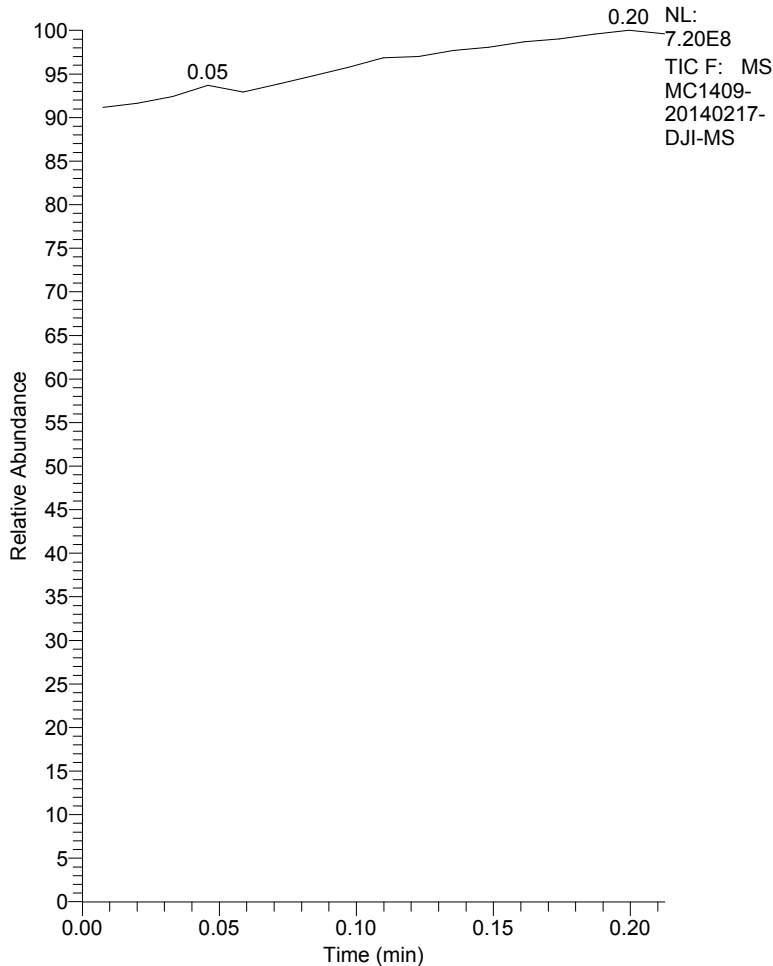


MC-1409
Ciprofloxacin, [2-14C]-
Lot 257-118-0588-A-20140217-DJI

Result Table (Uncal - L:\intk5029 - Unit 20 UV)

| Reten. Time [min] | Area [mV.s] | Height [mV] | Area [%] | Height [%] | W05 [min] |
|-------------------------|----------------|----------------|-------------|---------------|--------------|
| No peak to report | | | | | |

RT: 0.00 - 0.21

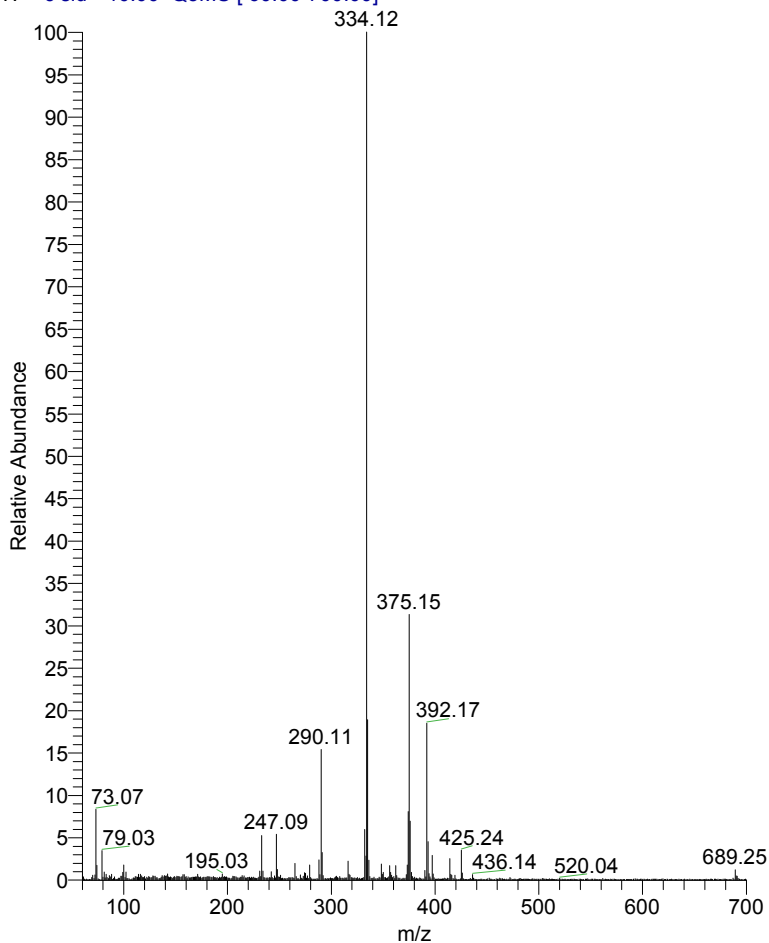


MC1409-20140217-DJI-MS#1 RT: 0.01
T: + c sid=-10.00 Q3MS [60.00-700.00]

m/z = 327.84-346.35

| m/z | Intensity | Relative |
|--------|-------------|----------|
| 329.12 | 276519.6 | 0.17 |
| 330.12 | 324927.2 | 0.19 |
| 331.14 | 477600.3 | 0.29 |
| 332.11 | 9939679.0 | 5.95 |
| 333.30 | 4722861.5 | 2.83 |
| 334.12 | 166926256.0 | 100.00 |
| 335.12 | 31565832.0 | 18.91 |
| 336.13 | 3904547.5 | 2.34 |
| 337.16 | 648981.5 | 0.39 |
| 338.21 | 287871.8 | 0.17 |
| 339.19 | 362929.8 | 0.22 |
| 340.13 | 289553.2 | 0.17 |
| 341.20 | 524177.3 | 0.31 |
| 342.16 | 248677.7 | 0.15 |
| 343.09 | 241704.9 | 0.14 |
| 344.16 | 304965.3 | 0.18 |
| 345.12 | 195494.3 | 0.12 |
| 346.14 | 555896.8 | 0.33 |

MC1409-20140217-DJI-MS #1 RT: 0.01 AV: 1 NL: 1.67E8
T: + c sid=-10.00 Q3MS [60.00-700.00]



MC1409-20140217-DJI-MS #1 RT: 0.01 AV: 1 NL: 1.67E8
T: + c sid=-10.00 Q3MS [60.00-700.00]

