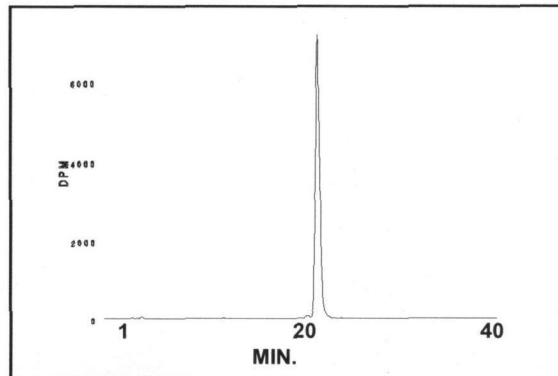
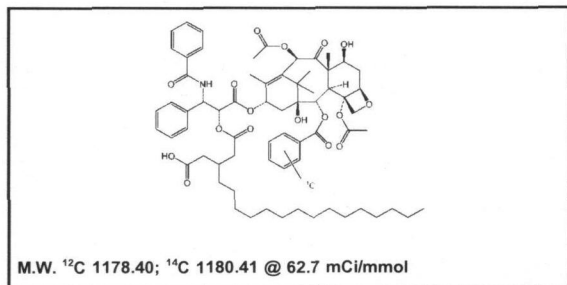




Product Data Sheet

MC-2353

Paclitaxel pentadecylglutarate, [benzoyloxy-ring-¹⁴C(U)]-



HPLC ANALYSIS LOT 642-138-0627-A-20100902-SB
File Name: INTB4436 Date and Time: 9/1/2010 4:30:37 PM
Unit 11 Radio

| Peak # | Area % | Time | Area |
|--------|--------|----------|-------------|
| 1 | 0.12 | 2.93000 | 25.49491 |
| 2 | 0.33 | 3.93000 | 72.99332 |
| 3 | 0.77 | 20.67000 | 171.13191 |
| 4 | 98.78 | 21.82000 | 21839.85098 |
| Totals | 100.00 | | 22109.47112 |

Lot #: 642-138-0627-A-20100902-SB

Specific Activity: 62.7 mCi/mmol

Concentration: 0.025 mCi/ml; 470.66 µg/ml

Packaged in: Ethanol solution under argon

Date of Analysis: September 01, 2010

Radiochemical Purity: 98.7%

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-2353

Paclitaxel pentadecylglutarate, [benzoyloxy-ring-¹⁴C(U)]-

Lot 642-138-0627-A-20100902-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 pentadecylglutarate, [benzoyloxy-ring-¹⁴C(U)]- concentration was 35.0 µCi/ml.

Volume of standard alone injection was 1.0 µl.

Volume of **Paclitaxel pentadecylglutarate, [benzoyloxy-ring-¹⁴C(U)]-** alone injection was 2.5 µl.

Co-injection solution consisted of 2.5 µl **Paclitaxel pentadecylglutarate, [benzoyloxy-ring-¹⁴C(U)]-** + 1.0 µl standard.

Volume of co-injection was 3.5 µl.

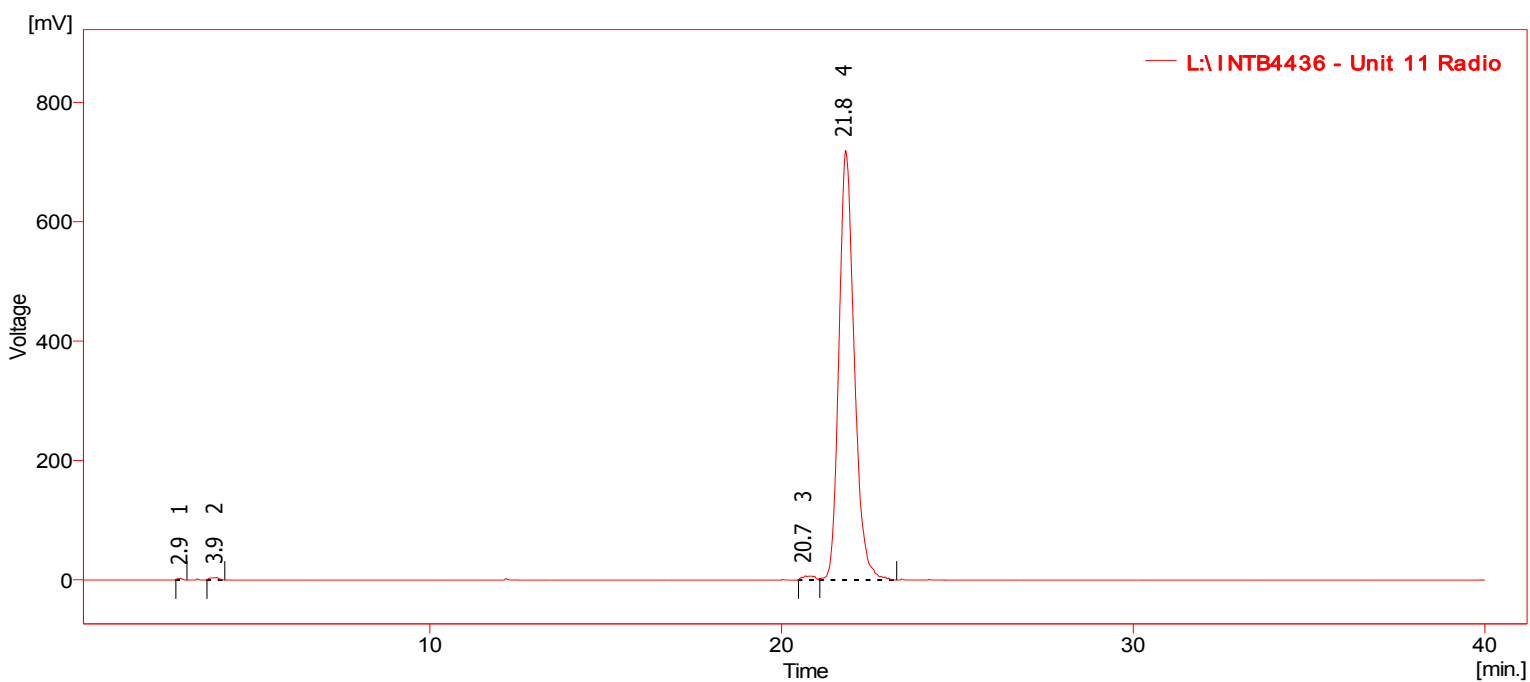
Volume of blank injection was 2.5 µl.

B) Mass spectrometry - Negative mode

MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

File Name : L:\INTB4436 File Created : 5/20/2014 8:59:14 AM
 Origin : Acquired, Acquisition started 9/1/2010 3:50:37 PM Acquired Date : 9/1/2010 4:30:37 PM
 Project : Work1 By : Administrator
 Method : Unit11_40_min_run By : Administrator
 Description : Radiochemical trace of 14C material alone
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:14 AM
 Column : Detection : Radiochemical
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



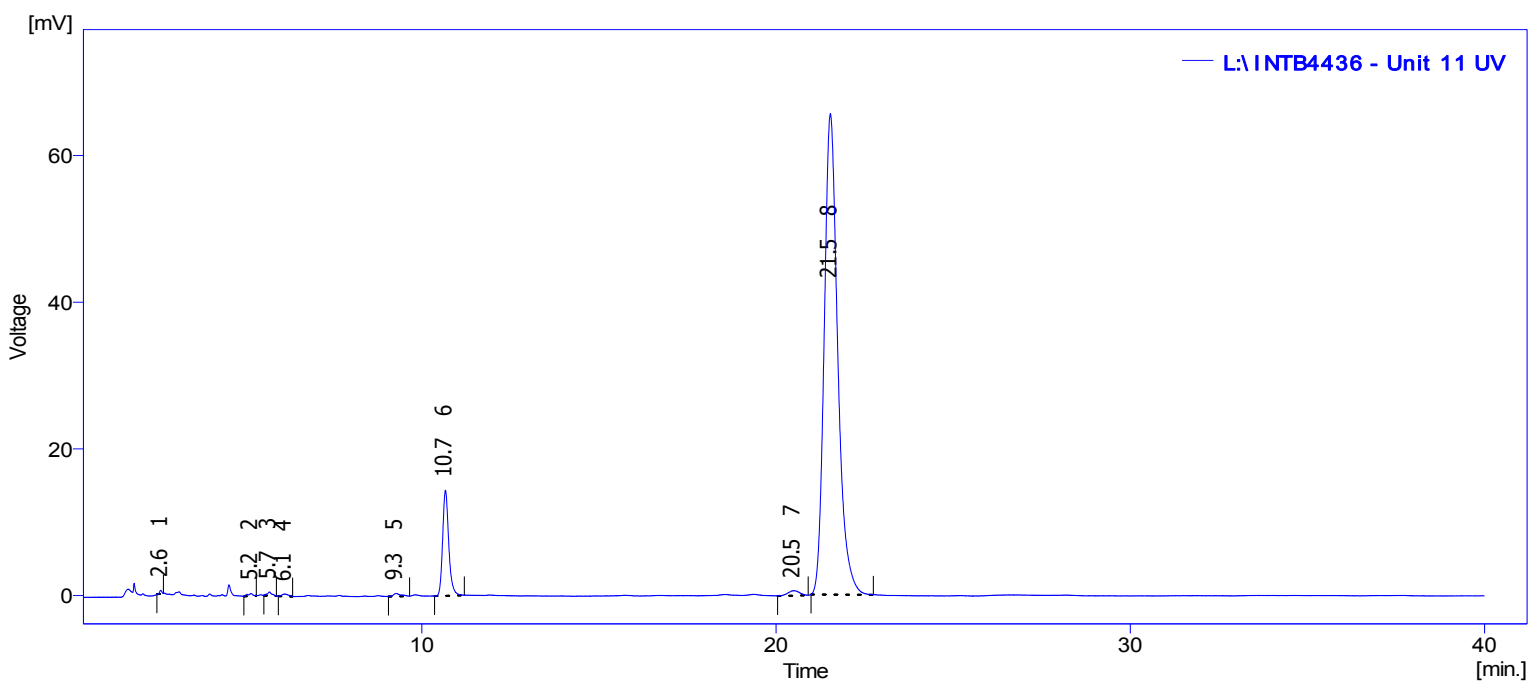
Result Table (Uncal - L:\INTB4436 - Unit 11 Radio)

| | 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 | | 2.93 | 25.495 | 3.01 | 0.12 | 0.4 | 0.16 | 2343 | 46862 | | 0.90 | |
| 2 | | 3.93 | 72.993 | 4.62 | 0.33 | 0.6 | 0.29 | 1427 | 28541 | 2.62 | 0.85 | |
| 3 | | 20.67 | 171.132 | 6.90 | 0.77 | 0.9 | 0.44 | 21996 | 439919 | 27.31 | 1.64 | |
| 4 | | 21.82 | 21839.851 | 720.28 | 98.78 | 98.0 | 0.46 | 8948 | 178959 | 1.51 | 1.23 | |
| | Total | | 22109.471 | 734.81 | 100.00 | 100.0 | | | | | | |

MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

File Name : L:\INTB4436 File Created : 5/20/2014 8:59:14 AM
 Origin : Acquired, Acquisition started 9/1/2010 3:50:37 PM Acquired Date : 9/1/2010 4:30:37 PM
 Project : Work1 By : Administrator
 Method : Unit11_40_min_run By : Administrator
 Description : UV trace of 14C material alone
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:07 AM
 Column : Detection : UV 227nm
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



Result Table (Uncal - L:\INTB4436 - Unit 11 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 | 2.64 | 2.229 | 0.51 | 0.11 | 0.6 | 0.07 | 6385 | 127702 | | 1.00 | |
| 2 | 5.18 | 3.542 | 0.36 | 0.18 | 0.4 | 0.10 | 4859 | 97183 | 17.29 | 0.81 | |
| 3 | 5.69 | 4.892 | 0.54 | 0.25 | 0.7 | 0.10 | 6111 | 122230 | 3.00 | 1.18 | |
| 4 | 6.13 | 4.273 | 0.36 | 0.22 | 0.4 | 0.20 | 5546 | 110923 | 1.70 | 1.26 | |
| 5 | 9.26 | 6.150 | 0.43 | 0.32 | 0.5 | 0.18 | 6047 | 120950 | 9.74 | 1.71 | |
| 6 | 10.67 | 172.065 | 14.41 | 8.83 | 17.4 | 0.18 | 13380 | 267604 | 4.60 | 1.24 | |
| 7 | 20.49 | 15.574 | 0.70 | 0.80 | 0.8 | 0.35 | 18320 | 366403 | 21.87 | 1.03 | |
| 8 | 21.53 | 1739.950 | 65.60 | 89.29 | 79.1 | 0.40 | 11640 | 232799 | 1.65 | 1.26 | |
| Total | | 1948.675 | 82.91 | 100.00 | 100.0 | | | | | | |

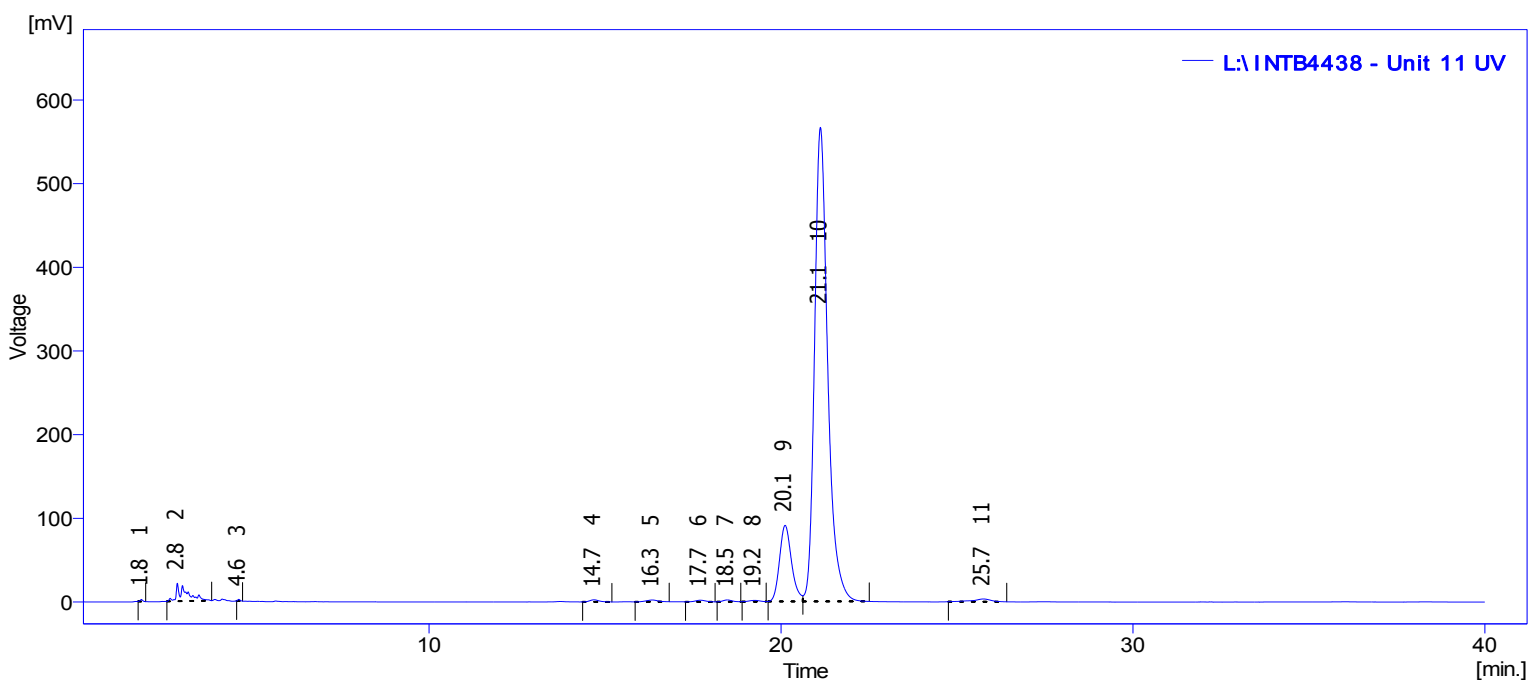
MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

File Name : L:\INTB4438 File Created : 5/20/2014 8:59:13 AM
 Origin : Acquired, Acquisition started 9/2/2010 10:41:32 AM Acquired Date : 9/2/2010 11:21:32 AM
 Project : Work1 By : Administrator

Method : Unit11_40_min_run By : Administrator
 Description : UV trace of standard alone
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:09 AM

Column : Detection : UV 227nm
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



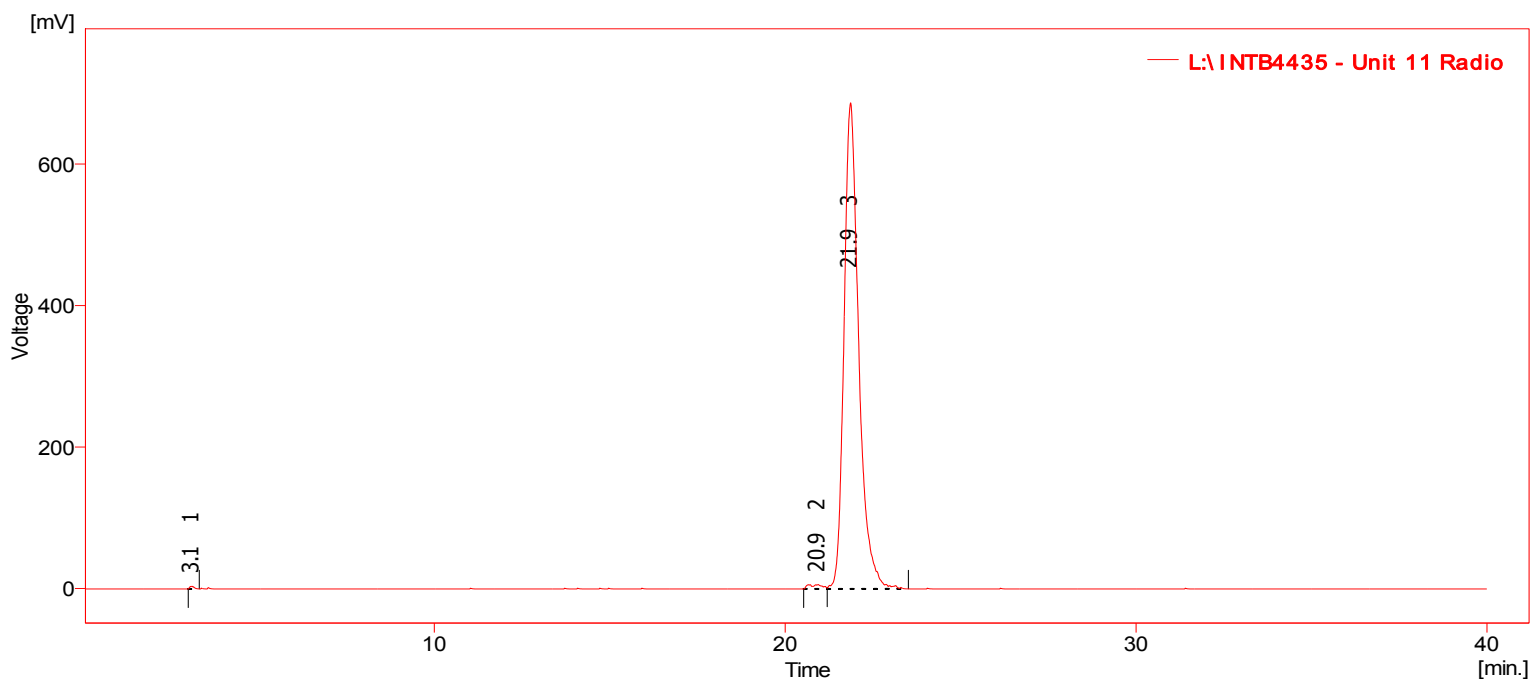
Result Table (Uncal - L:\INTB4438 - Unit 11 UV)

| 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 | 1.83 | 11.888 | 2.47 | 0.07 | 0.4 | 0.08 | 2866 | 57317 | | 1.04 | |
| 2 | 2.85 | 420.971 | 21.41 | 2.39 | 3.1 | 0.07 | 158 | 3154 | 8.02 | 2.19 | |
| 3 | 4.59 | 8.678 | 1.98 | 0.05 | 0.3 | 0.07 | 24184 | 483676 | 14.35 | 1.32 | |
| 4 | 14.69 | 45.486 | 2.52 | 0.26 | 0.4 | 0.28 | 13631 | 272617 | 34.37 | 1.21 | |
| 5 | 16.34 | 48.837 | 2.17 | 0.28 | 0.3 | 0.35 | 11389 | 227788 | 3.12 | 1.01 | |
| 6 | 17.70 | 38.287 | 1.94 | 0.22 | 0.3 | 0.31 | 18433 | 368651 | 2.43 | 1.07 | |
| 7 | 18.47 | 36.731 | 2.19 | 0.21 | 0.3 | 0.27 | 28660 | 573205 | 1.55 | 1.11 | |
| 8 | 19.24 | 30.178 | 1.54 | 0.17 | 0.2 | 0.32 | 24827 | 496543 | 1.55 | 0.99 | |
| 9 | 20.12 | 2161.177 | 90.98 | 12.25 | 13.0 | 0.36 | 15083 | 301658 | 1.51 | 1.23 | |
| 10 | 21.12 | 14714.755 | 566.71 | 83.43 | 81.3 | 0.39 | 11023 | 220458 | 1.58 | 1.31 | |
| 11 | 25.75 | 120.551 | 3.35 | 0.68 | 0.5 | 0.47 | 7859 | 157184 | 6.40 | 0.79 | |
| Total | | 17637.539 | 697.27 | 100.00 | 100.0 | | | | | | |

MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

File Name : L:\INTB4435 File Created : 5/20/2014 8:59:14 AM
 Origin : Acquired, Acquisition started 9/1/2010 2:25:33 PM Acquired Date : 9/1/2010 3:05:32 PM
 Project : Work1 By : Administrator
 Method : Unit11_40_min_run By : Administrator
 Description : Radiochemical trace of 14C material co-injected with standard
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:18 AM
 Column : Detection : Radiochemical
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



Result Table (Uncal - L:\INTB4435 - Unit 11 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 | | 3.11 | 32.067 | 3.66 | 0.16 | 0.5 | 0.14 | 3240 | 64807 | | 1.15 | |
| 2 | | 20.95 | 169.139 | 6.25 | 0.83 | 0.9 | 0.49 | 15584 | 311681 | 33.06 | 0.82 | |
| 3 | | 21.86 | 20061.400 | 687.17 | 99.01 | 98.6 | 0.43 | 8500 | 170004 | 1.17 | 1.32 | |
| | | Total | 20262.606 | 697.08 | 100.00 | 100.0 | | | | | | |

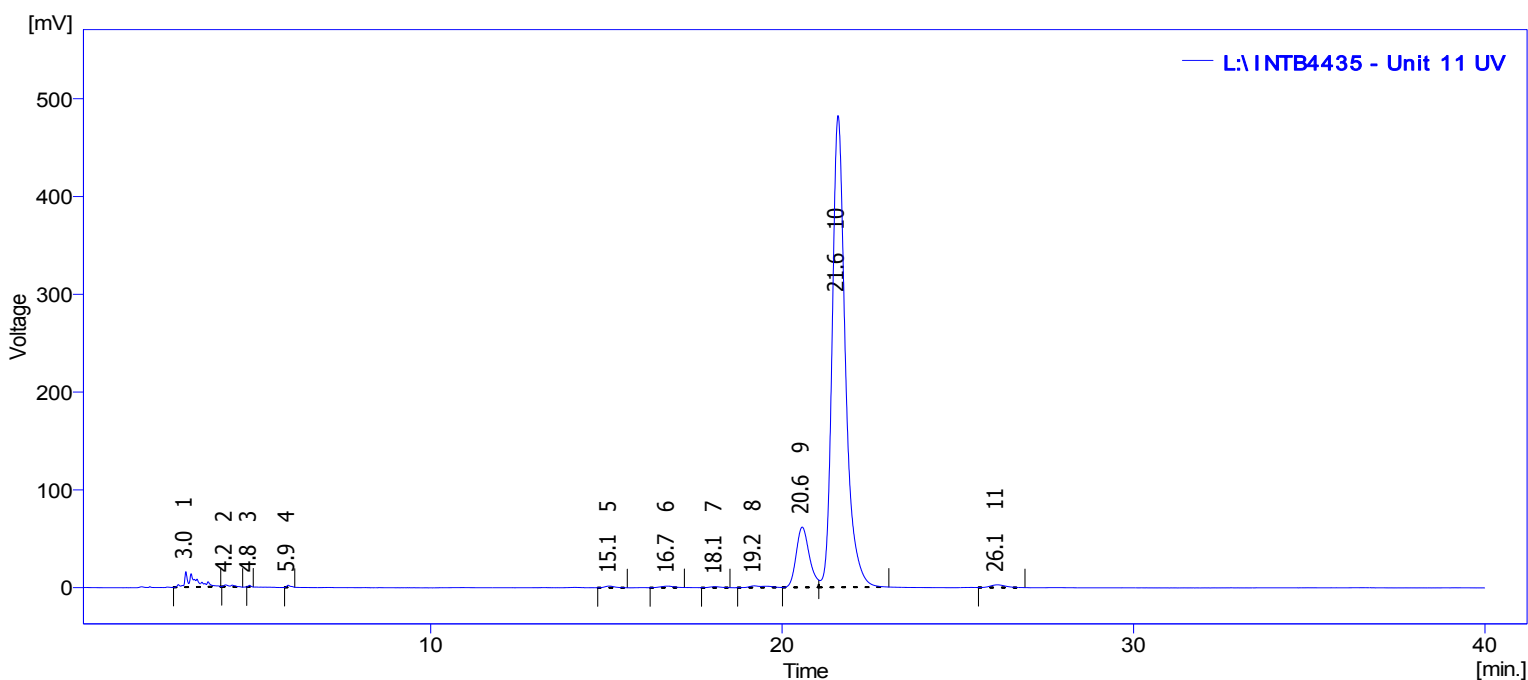
MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

File Name : L:\INTB4435 File Created : 5/20/2014 8:59:14 AM
 Origin : Acquired, Acquisition started 9/1/2010 2:25:33 PM Acquired Date : 9/1/2010 3:05:32 PM
 Project : Work1 By : Administrator

Method : Unit11_40_min_run By : Administrator
 Description : UV trace of 14C material co-injected with standard
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:18 AM

Column : Detection : UV 227nm
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



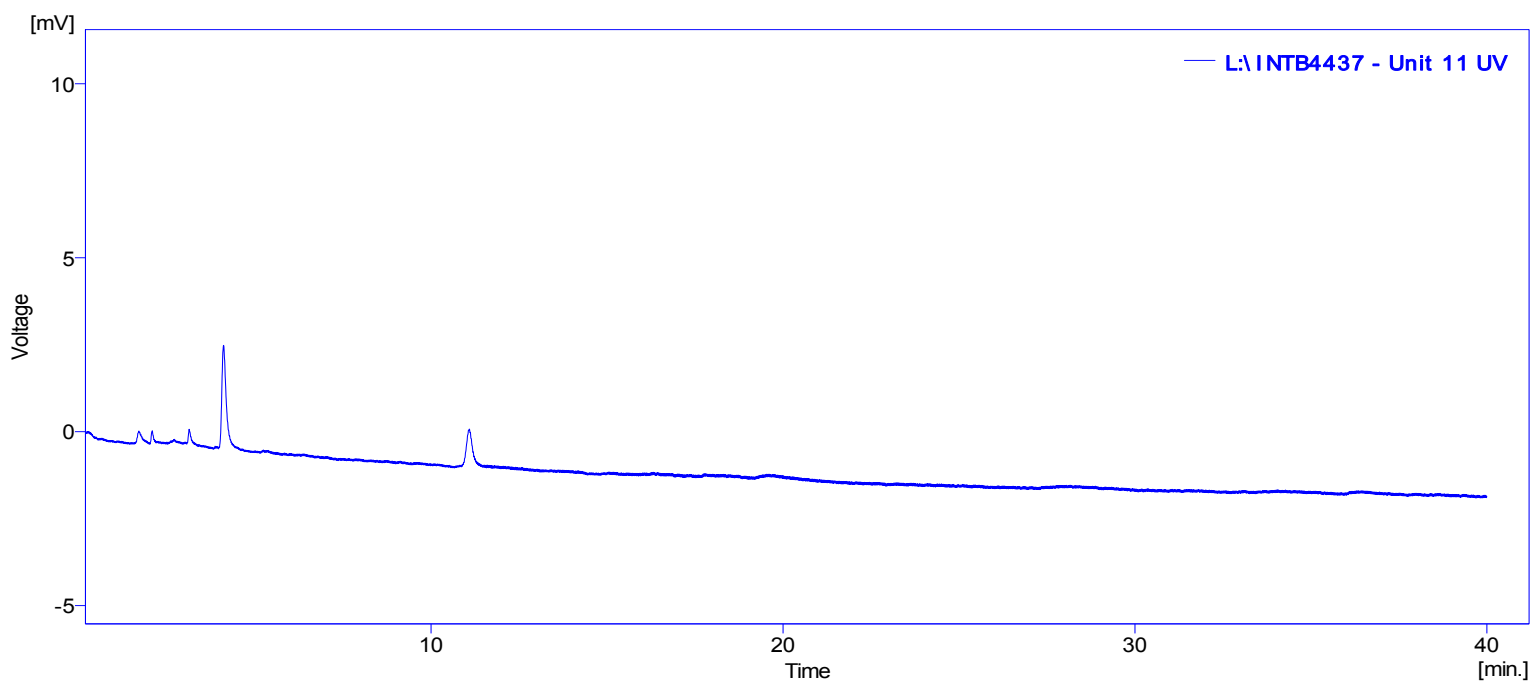
Result Table (Uncal - L:\INTB4435 - Unit 11 UV)

| 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 | 3.03 | 319.981 | 15.89 | 2.16 | 2.8 | 0.07 | 164 | 3285 | | 2.13 | |
| 2 | 4.17 | 32.763 | 1.79 | 0.22 | 0.3 | 0.13 | 1057 | 21145 | 6.49 | 2.61 | |
| 3 | 4.85 | 7.829 | 1.68 | 0.05 | 0.3 | 0.08 | 23171 | 463410 | 3.82 | 1.20 | |
| 4 | 5.94 | 16.772 | 2.21 | 0.11 | 0.4 | 0.11 | 11277 | 225538 | 7.04 | 1.46 | |
| 5 | 15.09 | 33.151 | 1.76 | 0.22 | 0.3 | 0.29 | 12380 | 247606 | 27.45 | 1.21 | |
| 6 | 16.74 | 39.016 | 1.56 | 0.26 | 0.3 | 0.39 | 9873 | 197464 | 2.87 | 1.00 | |
| 7 | 18.10 | 21.940 | 1.04 | 0.15 | 0.2 | 0.34 | 16275 | 325501 | 2.18 | 1.09 | |
| 8 | 19.21 | 63.649 | 1.78 | 0.43 | 0.3 | 0.67 | 6534 | 130681 | 1.30 | 1.62 | |
| 9 | 20.57 | 1596.983 | 61.73 | 10.78 | 10.7 | 0.40 | 14173 | 283468 | 1.50 | 1.12 | |
| 10 | 21.59 | 12600.214 | 482.33 | 85.04 | 83.9 | 0.38 | 10629 | 212571 | 1.52 | 1.34 | |
| 11 | 26.11 | 83.868 | 2.80 | 0.57 | 0.5 | 0.46 | 15615 | 312305 | 6.36 | 1.29 | |
| | Total | 14816.167 | 574.55 | 100.00 | 100.0 | | | | | | |

MC-2353
Paclitaxel pentadecylglutarate, [benzoyloxy-ring-14C(U)]-
Lot 642-138-0627-A-20100902-SB

Chromatogram Info:

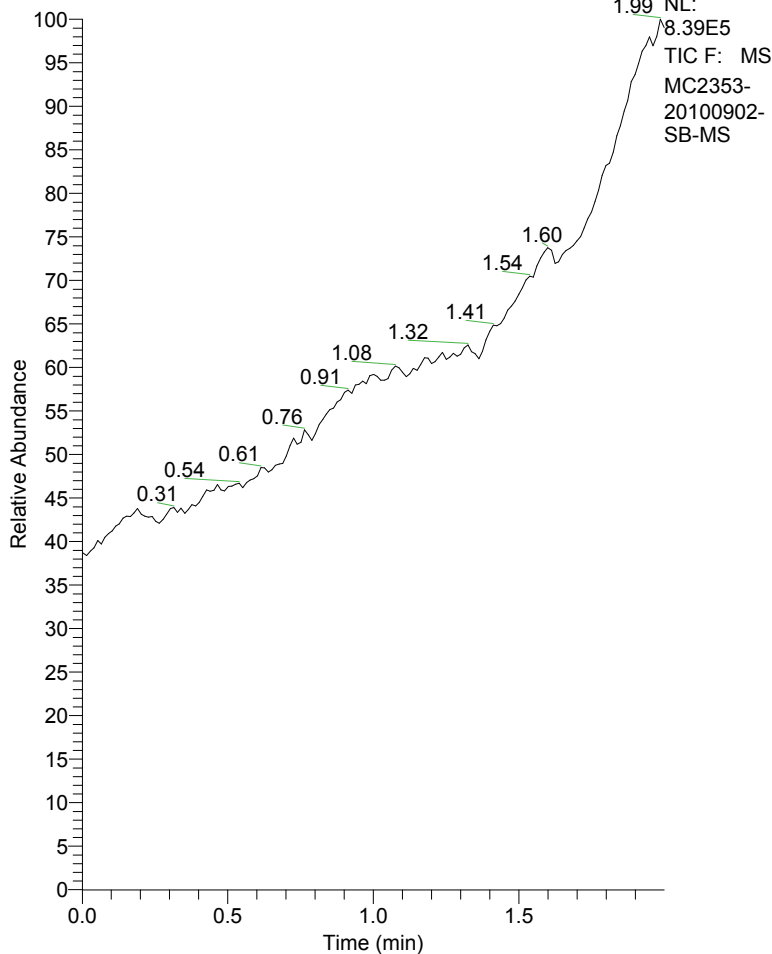
File Name : L:\INTB4437 File Created : 5/20/2014 8:59:14 AM
 Origin : Acquired, Acquisition started 9/2/2010 9:45:20 AM Acquired Date : 9/2/2010 10:25:20 AM
 Project : Work1 By : Administrator
 Method : Unit11_40_min_run By : Administrator
 Description : UV trace of blank injection
 Created : 11/6/2007 2:08 PM Modified : 5/20/2014 9:07 AM
 Column : Detection : UV 227nm
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



Result Table (Uncal - L:\INTB4437 - Unit 11 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 - 2.00



MC2353-20100902-SB-MS#1-161 RT:

T: - c Q3MS [1146.00-1206.00]

m/z = 1175.47-1193.38

| m/z | Intensity | Relative |
|---------|-----------|----------|
| 1175.49 | 732.2 | 0.50 |
| 1176.59 | 146648.5 | 100.00 |
| 1177.61 | 105110.5 | 71.68 |
| 1178.61 | 46567.7 | 31.75 |
| 1179.60 | 16314.8 | 11.13 |
| 1180.60 | 40251.4 | 27.45 |
| 1181.62 | 25855.3 | 17.63 |
| 1182.62 | 18575.5 | 12.67 |
| 1183.60 | 9052.7 | 6.17 |
| 1184.59 | 23763.3 | 16.20 |
| 1185.63 | 14372.1 | 9.80 |
| 1186.63 | 12078.6 | 8.24 |
| 1187.67 | 6555.2 | 4.47 |
| 1188.66 | 6208.8 | 4.23 |
| 1189.70 | 3477.5 | 2.37 |
| 1190.74 | 1711.8 | 1.17 |
| 1192.03 | 1180.9 | 0.81 |
| 1192.75 | 606.2 | 0.41 |

MC2353-20100902-SB-MS #1-161 RT: 0.00-2.00 AV: 161 NL: 1.47E5

T: - c Q3MS [1146.00-1206.00]

