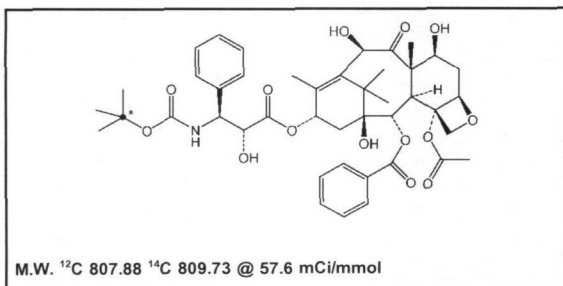




Product Data Sheet

MC-2333

Docetaxel, [tert-butyl-¹⁴C]-



Lot #: 193-007-0576-A-20091116-DR

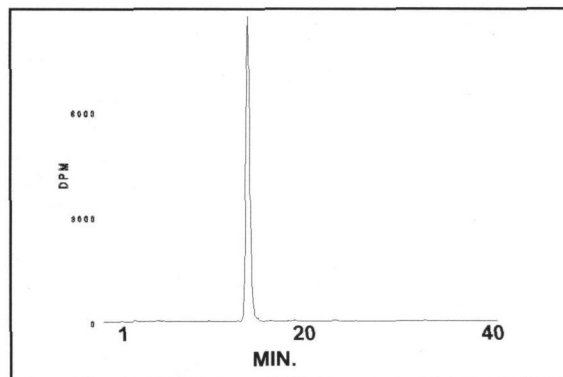
Specific Activity: 57.6 mCi/mmol

Concentration: 0.1 mCi/ml; 1.41 mg/ml

Packaged in: Ethanol solution

Date of Analysis: November 17, 2009

Radiochemical Purity: 99.8%



HPLC ANALYSIS LOT 193-007-0576-A-20091116-DR
File Name: INTB3492 Date and Time: 11/17/2009 12:21:27
Unit 11 Radio

| Peak # | Area % | Time | Area |
|--------|--------|----------|-------------|
| 1 | 99.88 | 14.73670 | 24577.96643 |
| 2 | 0.12 | 15.78330 | 29.54105 |
| Totals | 100.00 | | 24607.50748 |

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-2333

Docetaxel, [tert-butyl-¹⁴C]-

Lot 193-007-0576-A-20091116-DR

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

Concentrations and volumes:

Standard solution concentration was 2.0 mg/mL.

Docetaxel, [tert-butyl-¹⁴C]- concentration was 0.07 mCi/mL.

Volume of standard alone injection was 3.0 µL.

Volume of **Docetaxel, [tert-butyl-¹⁴C]-** alone injection was 1.0 µL.

Co-injection solution consisted of 1.0 µL **Docetaxel, [tert-butyl-¹⁴C]-** + 3.0 µL standard.

Volume of co-injection was 4.0 µL.

Volume of blank injection was 1.0 µL.

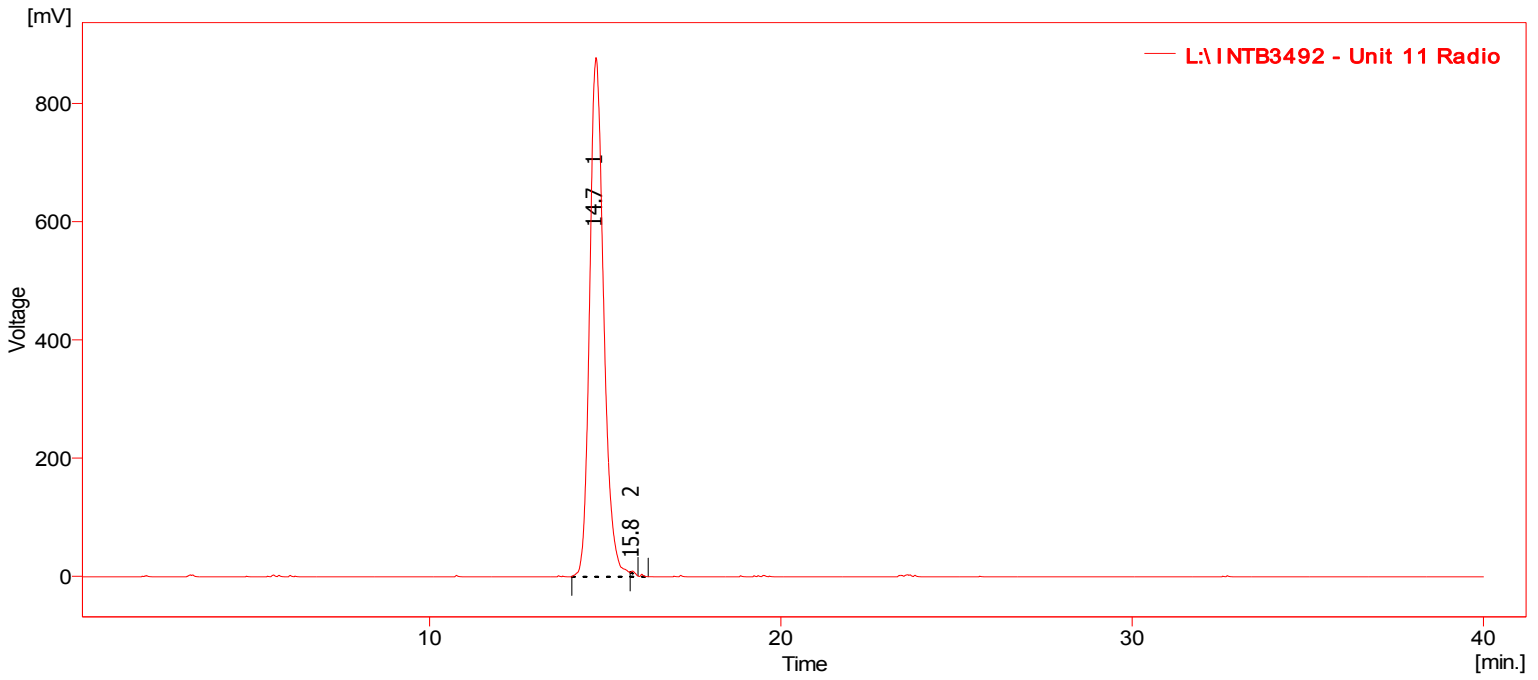
B) Mass spectrometry - Positive mode

C) NMR

MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

| | | | |
|--------------|--|---------------|--------------------------|
| File Name | : L:\INTB3492 | File Created | : 5/7/2014 10:43:00 AM |
| Origin | : Acquired, Acquisition started 11/17/2009 11:41:29 AM | Acquired Date | : 11/17/2009 12:21:27 PM |
| Project | : Work1 | By | : Administrator |
| Method | : Unit11_40_min_run | By | : Administrator |
| Description | : Radiochemical trace of 14C material alone | Modified | : 5/7/2014 11:12 AM |
| Created | : 11/6/2007 2:08 PM | | |
| Column | : | Detection | : Radiochemical |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



Result Table (Uncal - L:\INTB3492 - 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 | 14.74 | 24577.966 | 878.43 | 99.88 | 99.5 | 0.42 | 0 | 0 | | 1.58 | |
| 2 | 15.78 | 29.541 | 4.21 | 0.12 | 0.5 | 0.11 | 138818 | 2776353 | 2.33 | 1.50 | |
| Total | | 24607.507 | 882.64 | 100.00 | 100.0 | | | | | | |

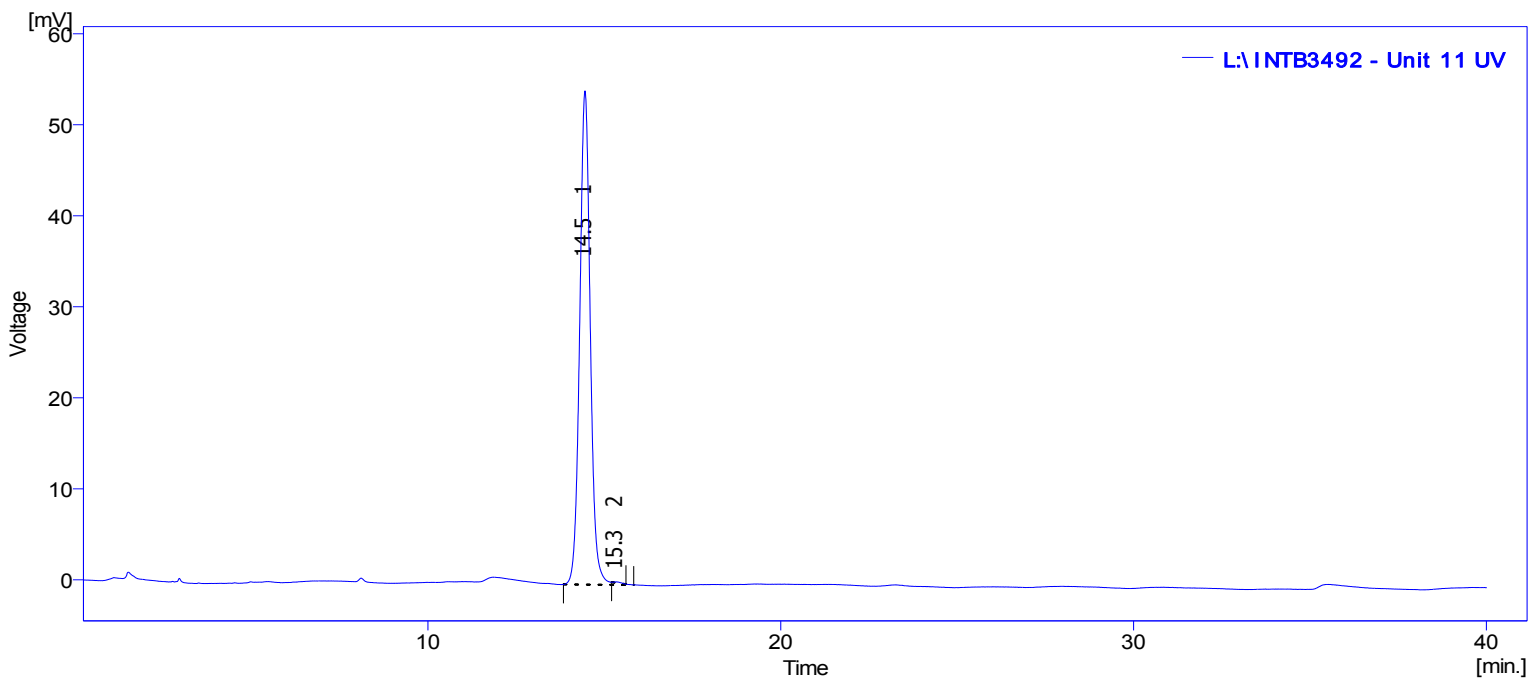
MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

File Name : L:\INTB3492 File Created : 5/7/2014 10:43:00 AM
 Origin : Acquired, Acquisition started 11/17/2009 11:41:29 AM Acquired Date : 11/17/2009 12:21:27 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 : 5/7/2014 11:03 AM

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



Result Table (Uncal - L:\INTB3492 - 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 | | 14.45 | 1129.898 | 54.25 | 99.86 | 99.8 | 0.31 | 0 | 0 | | 1.63 | |
| 2 | | 15.33 | 1.553 | 0.11 | 0.14 | 0.2 | 0.21 | 35837 | 716736 | 1.96 | 1.72 | |
| | Total | | 1131.450 | 54.36 | 100.00 | 100.0 | | | | | | |

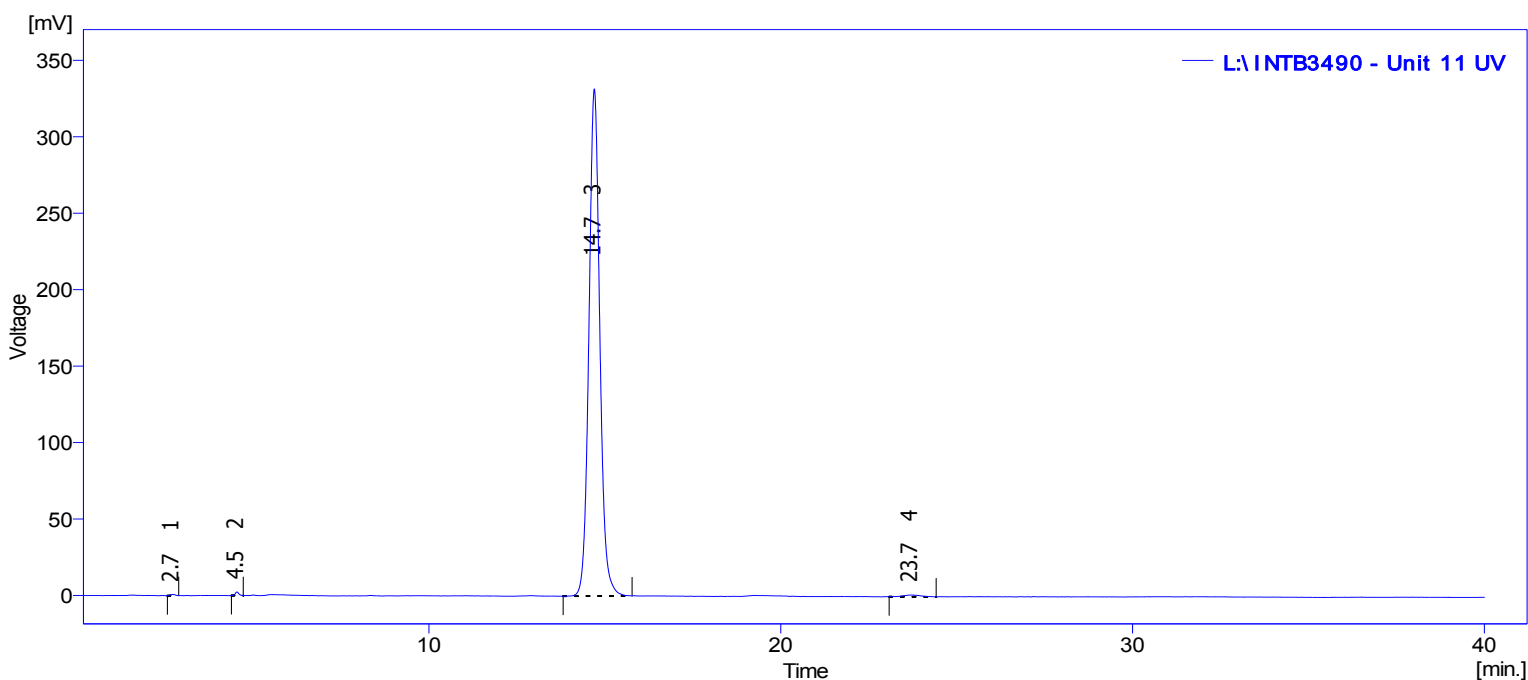
MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

File Name : L:\INTB3490 File Created : 5/7/2014 10:43:00 AM
 Origin : Acquired, Acquisition started 11/17/2009 9:57:54 AM Acquired Date : 11/17/2009 10:37:53 AM
 Project : Work1 By : Administrator

Method : Unit11_40_min_run By : Administrator
 Description : UV trace of standard material alone
 Created : 11/6/2007 2:08 PM Modified : 5/7/2014 11:13 AM

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



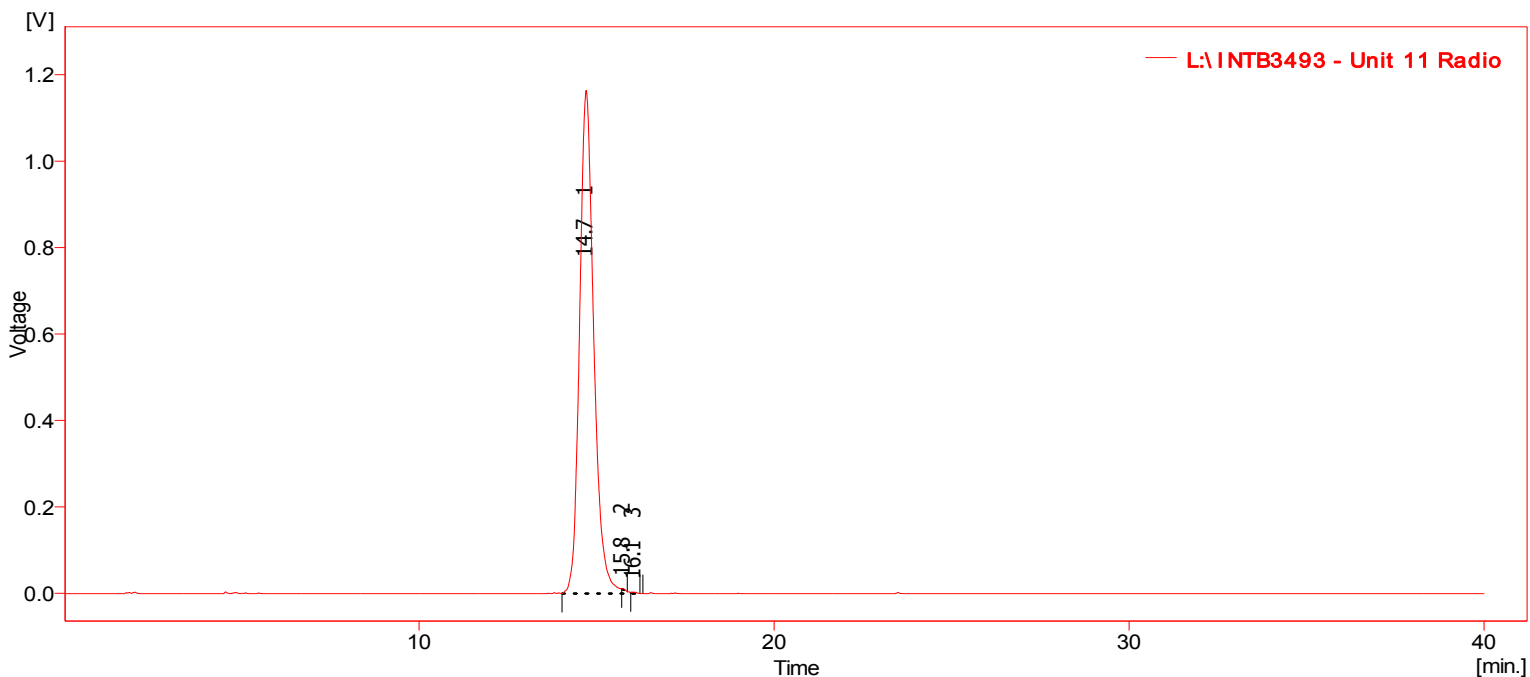
Result Table (Uncal - L:\INTB3490 - Unit 11 UV)

| | 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 | | 2.71 | 7.808 | 0.79 | 0.11 | 0.2 | 0.18 | 2070 | 41397 | | 1.09 | |
| 2 | | 4.54 | 16.634 | 2.37 | 0.23 | 0.7 | 0.11 | 8234 | 164688 | 7.62 | 1.15 | |
| 3 | | 14.70 | 7139.035 | 331.70 | 99.06 | 98.7 | 0.33 | 8313 | 166270 | 27.67 | 1.07 | |
| 4 | | 23.70 | 43.026 | 1.19 | 0.60 | 0.4 | 0.54 | 9295 | 185895 | 12.30 | 1.07 | |
| | Total | | 7206.504 | 336.04 | 100.00 | 100.0 | | | | | | |

MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

| | | | |
|--------------|---|---------------|-------------------------|
| File Name | : L:\INTB3493 | File Created | : 5/7/2014 10:43:00 AM |
| Origin | : Acquired, Acquisition started 11/17/2009 12:22:23 PM | Acquired Date | : 11/17/2009 1:02:22 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 | : 5/7/2014 11:16 AM |
| Column | : | Detection | : Radiochemical |
| Mobile Phase | : | Temperature | : |
| Flow Rate | : | Pressure | : |
| Note | : | | |



Result Table (Uncal - L:\INTB3493 - 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 | 14.71 | 32455.215 | 1164.51 | 99.90 | 99.5 | 0.42 | 0 | 0 | | 1.66 | |
| 2 | 15.76 | 15.983 | 3.04 | 0.05 | 0.3 | 0.07 | 213647 | 4272938 | 2.53 | 1.50 | |
| 3 | 16.06 | 17.815 | 2.29 | 0.05 | 0.2 | 0.15 | 108025 | 2160502 | 1.59 | 1.16 | |
| Total | | 32489.012 | 1169.84 | 100.00 | 100.0 | | | | | | |

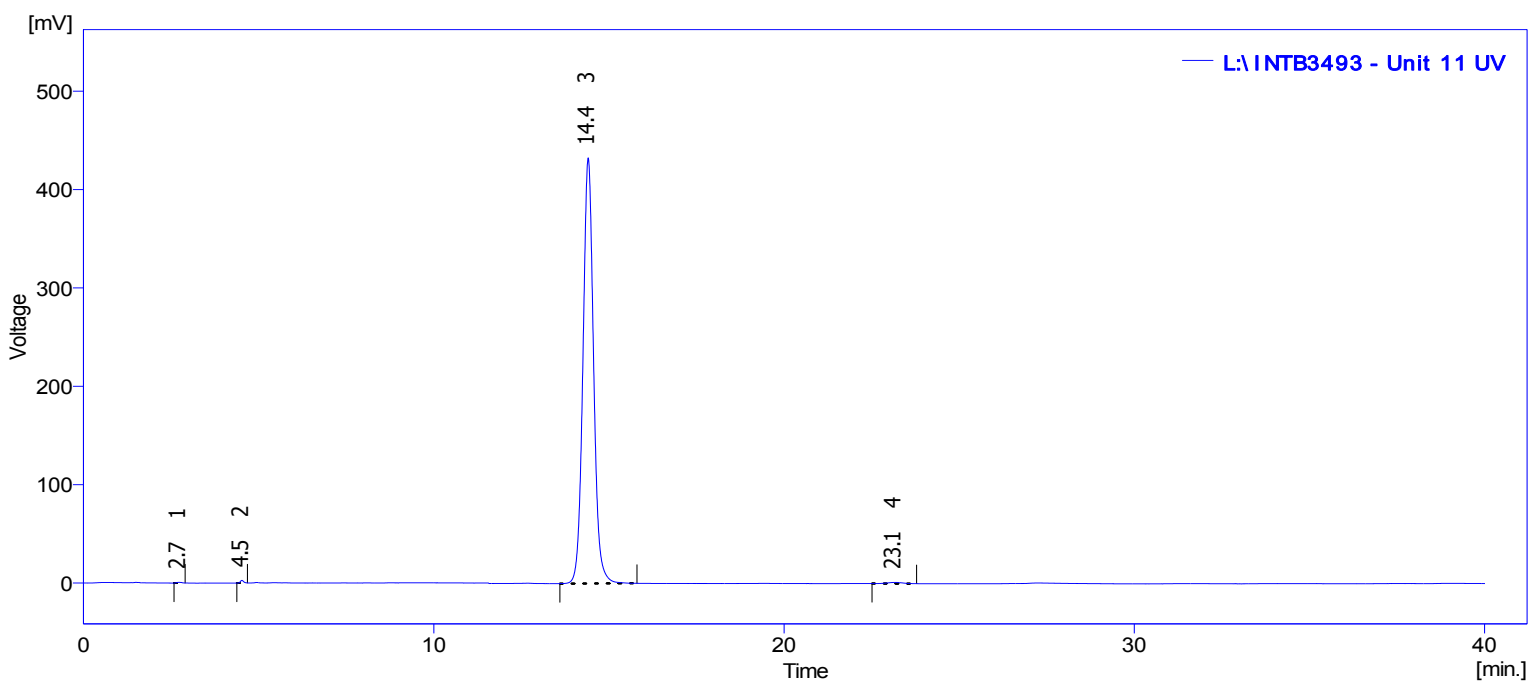
MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

File Name : L:\INTB3493 File Created : 5/7/2014 10:43:00 AM
 Origin : Acquired, Acquisition started 11/17/2009 12:22:23 PM Acquired Date : 11/17/2009 1:02:22 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 : 5/7/2014 11:14 AM

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



Result Table (Uncal - L:\INTB3493 - 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 | | 2.73 | 7.095 | 0.74 | 0.08 | 0.2 | 0.17 | 2170 | 43395 | | 1.06 | |
| 2 | | 4.52 | 16.908 | 2.70 | 0.18 | 0.6 | 0.10 | 10823 | 216469 | 7.94 | 1.14 | |
| 3 | | 14.41 | 9134.807 | 432.77 | 99.33 | 98.9 | 0.32 | 7969 | 159382 | 27.78 | 1.07 | |
| 4 | | 23.15 | 37.888 | 1.23 | 0.41 | 0.3 | 0.48 | 12868 | 257361 | 12.89 | 1.03 | |
| | Total | | 9196.699 | 437.44 | 100.00 | 100.0 | | | | | | |

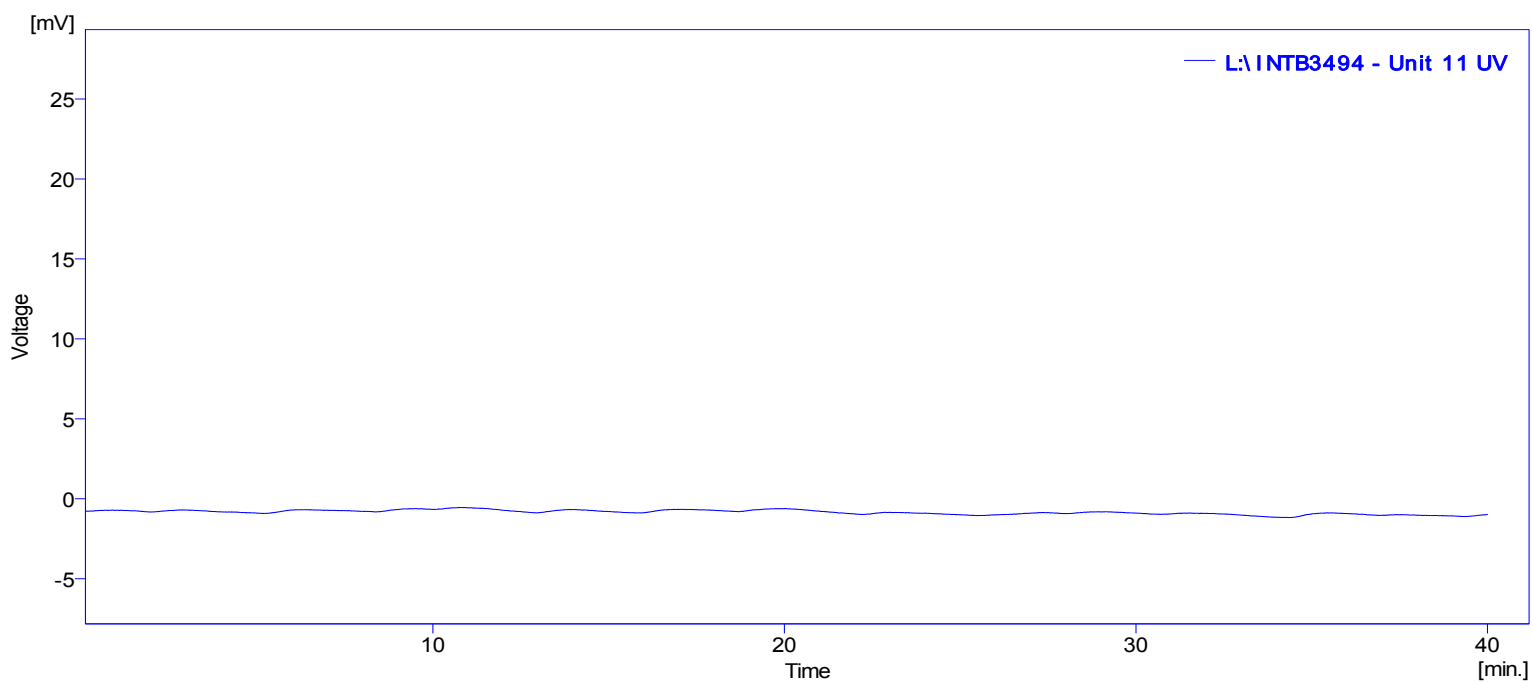
MC-2333
Docetaxel, [tert-butyl-14C]-
Lot 193-007-0576-A-20091116-DR

Chromatogram Info:

File Name : L:\INTB3494 File Created : 5/7/2014 10:42:59 AM
 Origin : Acquired, Acquisition started 11/17/2009 1:04:53 PM Acquired Date : 11/17/2009 1:44:52 PM
 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 : 5/7/2014 10:52 AM

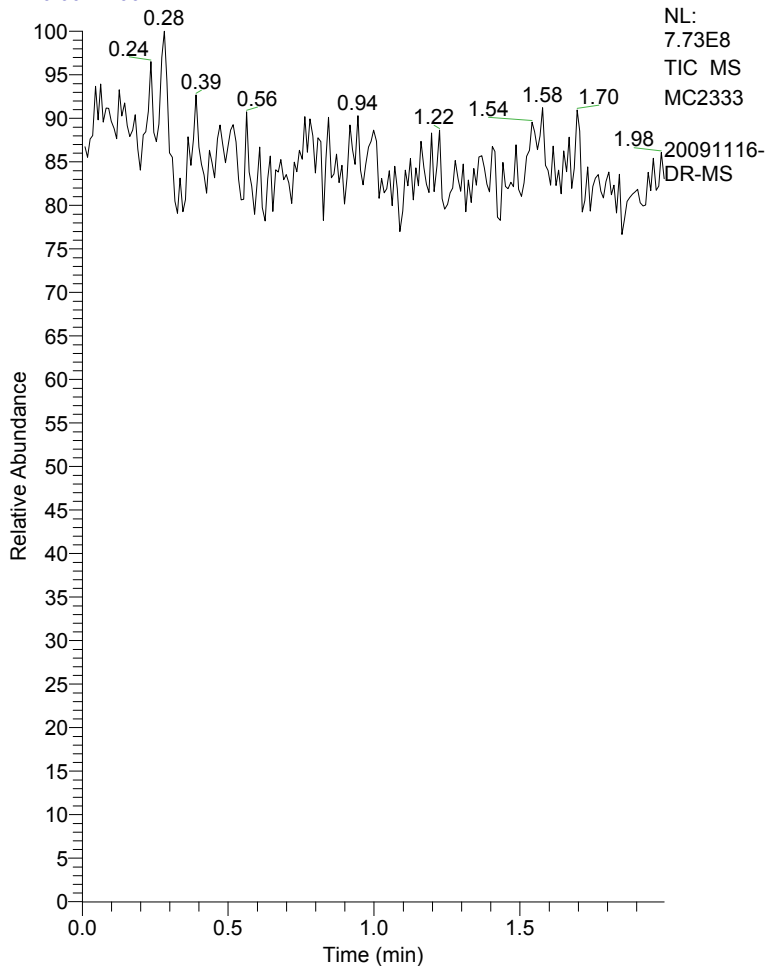
Column : Detection : UV 227nm
 Mobile Phase : Temperature :
 Flow Rate : Pressure :
 Note :



Result Table (Uncal - L:\INTB3494 - 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 - 1.99

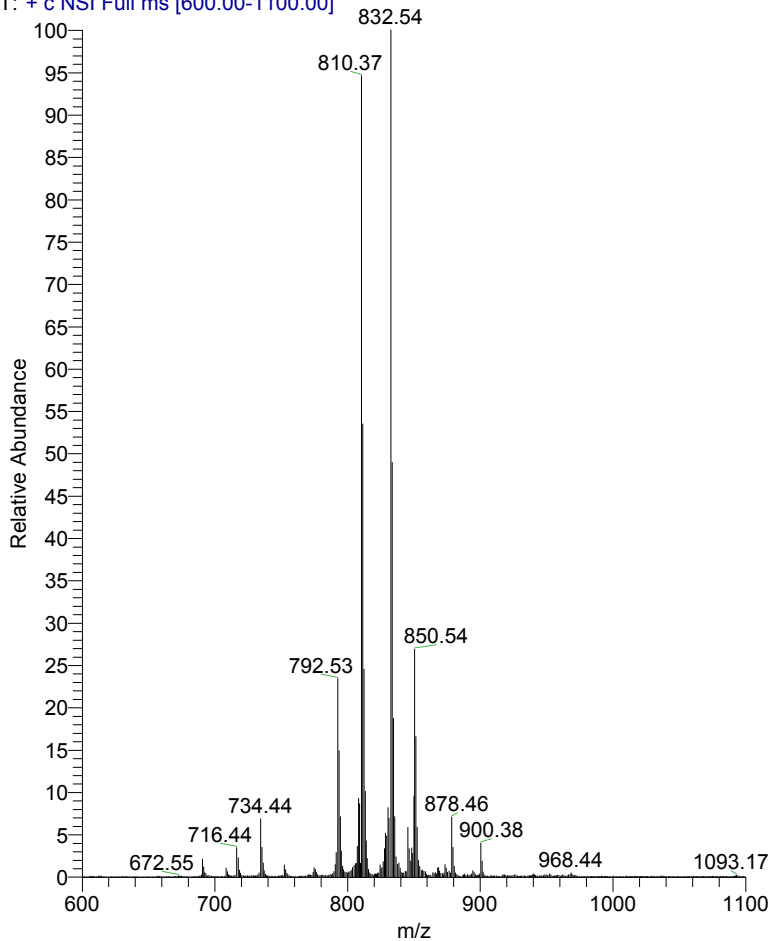


MC2333-20091116-DR-MS#1-220 RT:

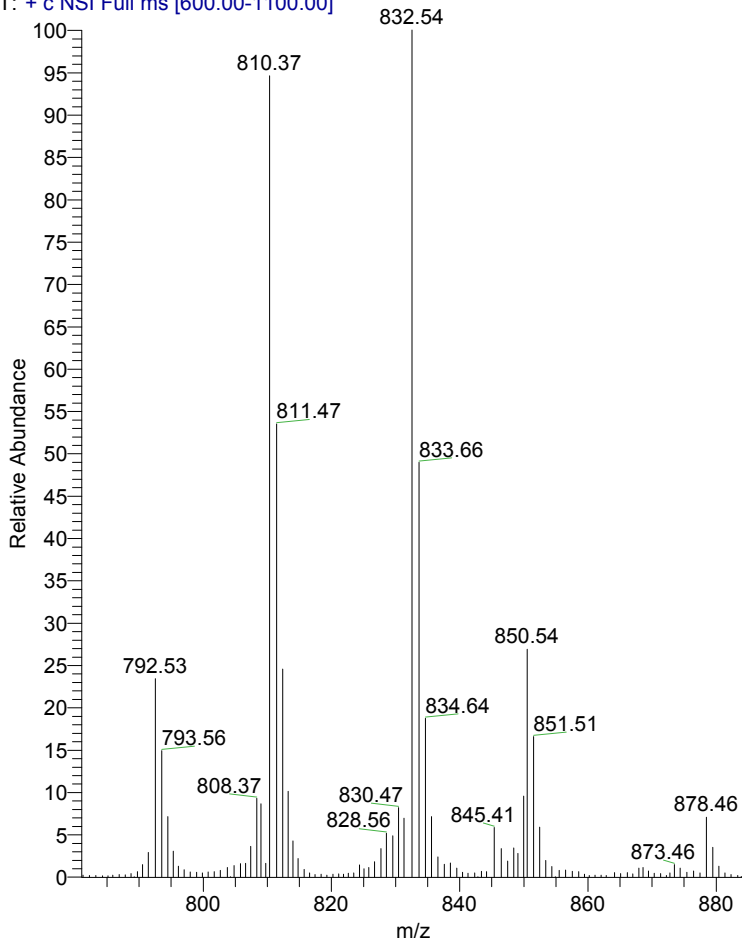
T: + c NSI Full ms [600.00-1100.00]
m/z = 801.72-842.75

| m/z | Intensity | Relative |
|--------|------------|----------|
| 807.41 | 3446532.4 | 3.60 |
| 808.37 | 8903652.1 | 9.30 |
| 809.02 | 8269525.5 | 8.63 |
| 810.37 | 90627221.2 | 94.63 |
| 811.47 | 51225607.6 | 53.49 |
| 812.41 | 23511993.2 | 24.55 |
| 813.26 | 9696377.3 | 10.12 |
| 813.98 | 4080840.9 | 4.26 |
| 814.80 | 2087165.3 | 2.18 |
| 826.74 | 1716460.5 | 1.79 |
| 827.70 | 3217023.8 | 3.36 |
| 828.56 | 4950870.7 | 5.17 |
| 829.58 | 4660578.7 | 4.87 |
| 830.47 | 7837774.2 | 8.18 |
| 831.29 | 6643479.3 | 6.94 |
| 832.54 | 95772703.7 | 100.00 |
| 833.66 | 46895485.0 | 48.97 |
| 834.64 | 17947607.7 | 18.74 |
| 835.58 | 6818273.0 | 7.12 |
| 836.58 | 2263001.9 | 2.36 |

MC2333-20091116-DR-MS #1-220 RT: 0.01-1.99 AV: 220 NL: 9.58E7
T: + c NSI Full ms [600.00-1100.00]



MC2333-20091116-DR-MS #1-220 RT: 0.01-1.99 AV: 220 NL: 9.58E7
T: + c NSI Full ms [600.00-1100.00]



MC2333 1H NMR in CDCl3
 Batch 20091116-DR



8.134
 8.116
 7.656
 7.636
 7.618
 7.539
 7.521
 7.502
 7.439
 7.421
 7.404
 7.359
 7.343
 6.236
 5.709
 5.692
 5.462
 5.437
 5.294
 5.273
 5.227
 4.975
 4.953
 4.639
 4.348
 4.327
 4.264
 4.230
 4.199
 3.944
 3.927
 3.377
 3.365
 2.626
 2.609
 2.592
 2.398
 2.304
 2.284
 1.896
 1.871
 1.833
 1.779
 1.687
 1.616
 1.534
 1.517
 1.363
 1.260
 1.154

MC2333
 EXPNO 1
 PROCNO 1
 Date_ 20091117
 Time 13.24
 INSTRUM spect
 PROBHD 5 mm PABBO BB-
 PULPROG zg30
 TD 65536
 SOLVENT CDCl3
 NS 784
 DS 2
 SWH 8278.146 Hz
 FIDRES 0.126314 Hz
 AQ 3.9584243 sec
 RG 4
 DW 60.400 usec
 DE 6.50 usec
 TE 294.9 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 400.1300000 MHz
 WDW no
 SSB 0
 LB 0.00 Hz
 GB 0
 PC 1.00

