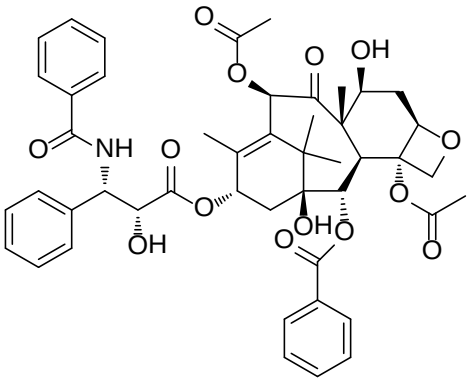
Certificate of Analysis

Issued: September 14th, 2017
Re-Test: September 14th, 2019

Compound Name	Paclitaxel
Potency	991 µg of Paclitaxel per mg
Physical Description	White Solid
Chemtos Lot Number	C3-146-045
Certificate Number	C3-146-045
Chemical Structure	
Empirical Formula	$C_{47}H_{51}NO_{14}$
Molecular Weight	853.91
Exact Mass	853.33
Mass Spectrometry	Electrospray MS(ES+): m/z 854.3 $(M+H)^+$ Data consistent to that of the title compound

HPLC Purity

The product was examined by analytical HPLC using a diode array detector. Column: Chromolith Performance C_{18} 4.6 mm X 100 mm; Flow Rate: 1 ml/min; Solvents: Water (0.1% TFA) and acetonitrile; Gradient: 5% to 100% acetonitrile over 20 min, return to 95% water over 10 minutes.
The chromatogram used for purity and homogeneity assessment was the summed absorbance between 210 nm and 254 nm. Purity was determined as the area percent of the major peak after integration of any impurities judged to be authentic by the analyst. Using this method the purity was determined at **99.9%**.

^{1}H NMR

Proton magnetic resonance spectra were run in DMSO-d_6 at 300 MHz. The NMR data is consistent with the structure.

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Karl Fischer Water Analysis

Water content was determined via Coulometric titration in accordance with USP<921>. The analysis was performed in duplicate. Prior to performing analysis on the above sample the operation of the apparatus was verified using a potassium citrate monohydrate water standard containing 5.55 ±0.05% water.

Method	Sample	Result	Sample Amount	Date
1c USP<921>	Solid Standard	5.664% Pass	5.50 mg	09/14/2017
1c USP<921>	C3-146-045	0.786%	2.43 mg	09/14/2017
1c USP<921>	C3-146-045 Duplicate	0.765%	4.34 mg	09/14/2017

The water content of the above sample was determined as the summed average of the total number of Karl Fischer titrations. Using this method the water content is determined at **0.776%.** The potency is corrected for this presence of water.

Storage Conditions

Individual variation in chemical stability profiles, do occur and for this reason we recommend adherence to the minimum recommended storage conditions. Because most compounds are custom made and shipped upon completion, long-term stability data is not available in most cases. If data is available, a specific recommendation will be provided below. Chemtos cannot provide a guarantee of the long-term chemical stability of any compound.

Minimum Recommended Storage Conditions:

- Samples should be stored in an air tight vial
- Samples should be stored at ≤ 0˚ Celsius when not in use for a prolonged period of time.
- Samples should be stored in the dark or in an amber vial.

Caution

This information is provided as an indication of the quality of the underlying material when examined by a specific technique. The reported values are subject to normal experimental error and should be treated as estimates. The absence of undetected impurities cannot be guaranteed by this or any other general approach and this certificate does not certify the absence of such substances in the sample.

Intended Use

This product is intended for investigational use only and should not be used in humans. It is pharmaceutically unrefined, may contain uncharacterized toxic impurities, and is not intended for use in humans. Responsibility for its use and compliance with all federal laws rests solely with the purchaser.

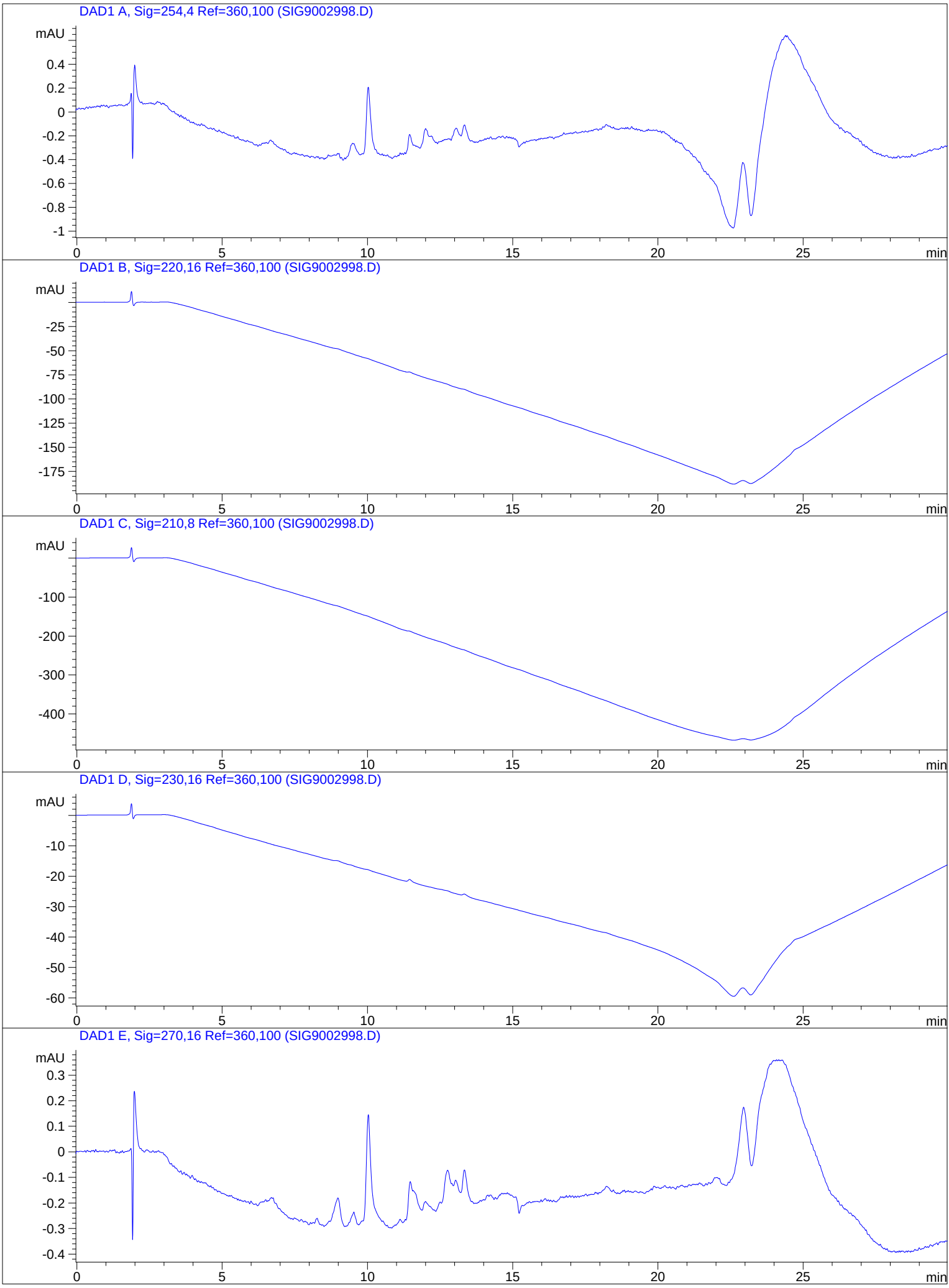
Preparer	Digitally signed by Manpinder Kaur Date: 2017.09.14 12:16:53 -05'00'	
Analytical Review and Approval	Digitally signed by Hui Huang Date: 2017.09.14 14:23:12 -05'00'	
QA Review	Digitally signed by Khalid Thakur DN: cn=Khalid Thakur, o=Chemtos, ou=Business, email=khalid.thakur@chemtos.com, c=US Date: 2017.09.14 14:27:54 -05'00'	

Data File C:\HPCHEM\1\DATA\SIG9002998.D
Sample Name: C3-146-045 Blank

==========

Acq. Operator : mk
Acq. Instrument : 1100 Location : Vial 1
Injection Date : 9/14/2017 10:43:17 AM
Inj Volume : 5 µl
Acq. Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
Last changed : 9/14/2017 10:41:04 AM by mk
(modified after loading)
Analysis Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
Last changed : 9/14/2017 11:51:36 AM by mk
(modified after loading)

Data File C:\HPCHEM\1\DATA\SIG9002998.D
Sample Name: C3-146-045 Blank



Data File C:\HPCHEM\1\DATA\SIG9002998.D
Sample Name: C3-146-045 Blank

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Area Percent Report

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Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

No peaks found

==========

*** End of Report ***

Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample

==========

Acq. Operator : mk
Acq. Instrument : 1100 Location : Vial 1
Injection Date : 9/14/2017 11:18:32 AM
Inj Volume : 5 µl
Acq. Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
Last changed : 9/14/2017 11:13:37 AM by mk
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Analysis Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
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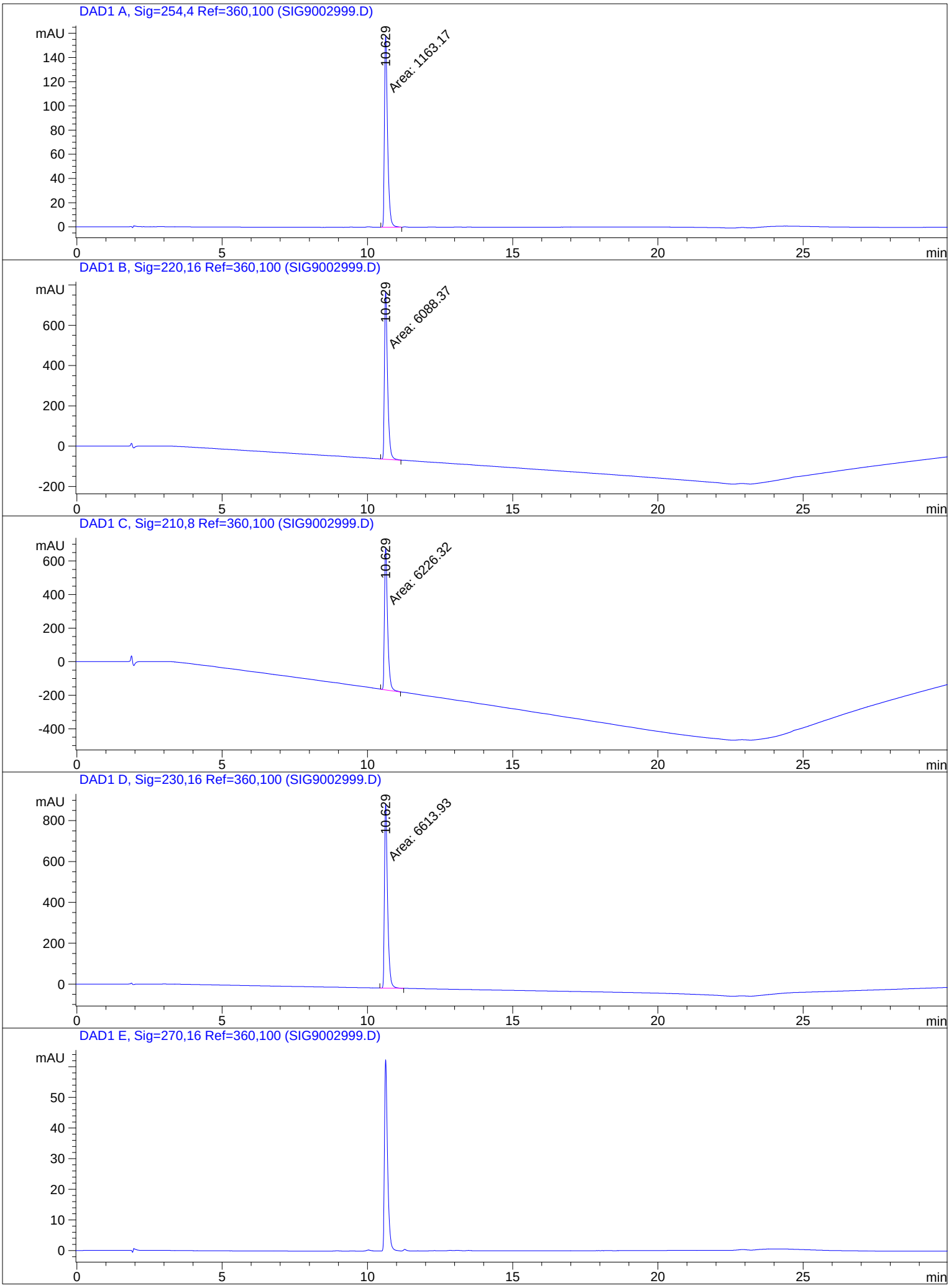
Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample



Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample

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Area Percent Report

==========

Sorted By : Signal
Multiplier : 1.0000
Dilution : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=254,4 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	10.629	MM	0.1220	1163.16968	158.93175	100.0000
Totals :				1163.16968	158.93175	

Signal 2: DAD1 B, Sig=220,16 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	10.629	MM	0.1216	6088.36572	834.47644	100.0000
Totals :				6088.36572	834.47644	

Signal 3: DAD1 C, Sig=210,8 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	10.629	MM	0.1221	6226.32080	849.75421	100.0000
Totals :				6226.32080	849.75421	

Signal 4: DAD1 D, Sig=230,16 Ref=360,100

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	10.629	MM	0.1218	6613.93164	905.25470	100.0000
Totals :				6613.93164	905.25470	

Signal 5: DAD1 E, Sig=270,16 Ref=360,100

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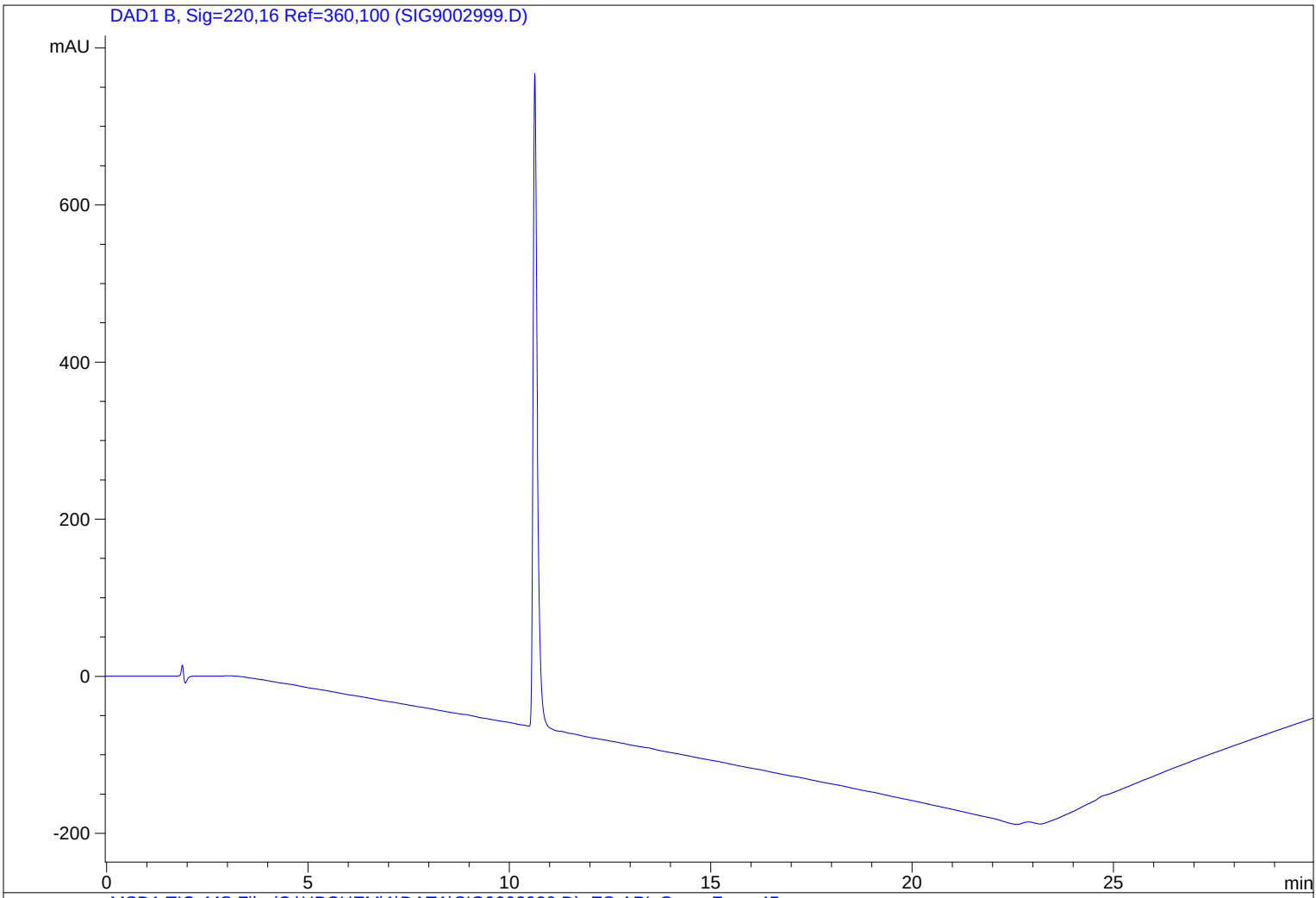
*** End of Report ***

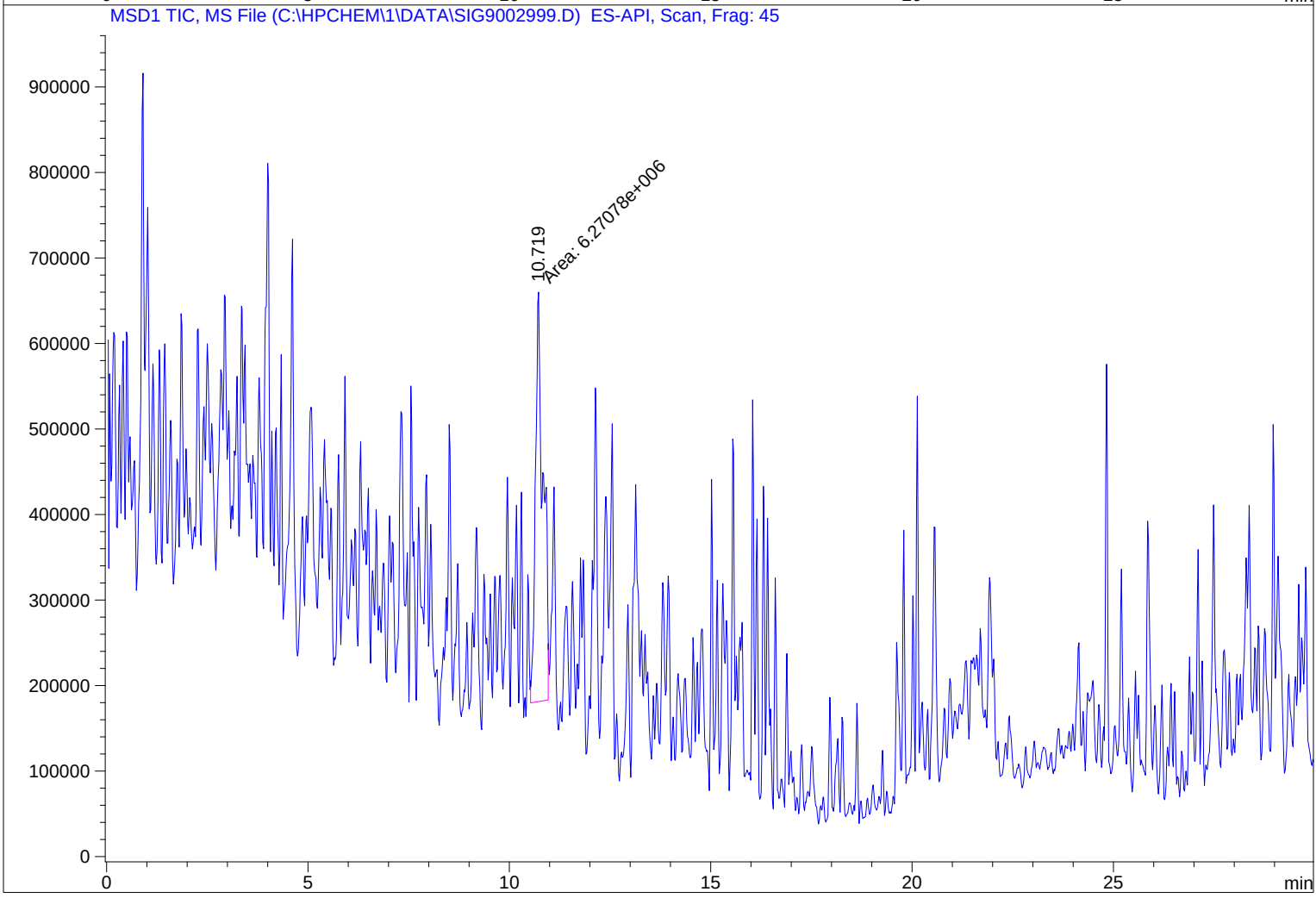
Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample

==========

Acq. Operator : mk
Acq. Instrument : 1100 Location : Vial 1
Injection Date : 9/14/2017 11:18:32 AM Inj : 1
Inj Volume : 5 µl
Acq. Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
Last changed : 9/14/2017 11:13:37 AM by mk
(modified after loading)
Analysis Method : C:\HPCHEM\1\METHODS\CHEMDAG1.M
Last changed : 9/14/2017 11:54:44 AM by mk
(modified after loading)

Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample



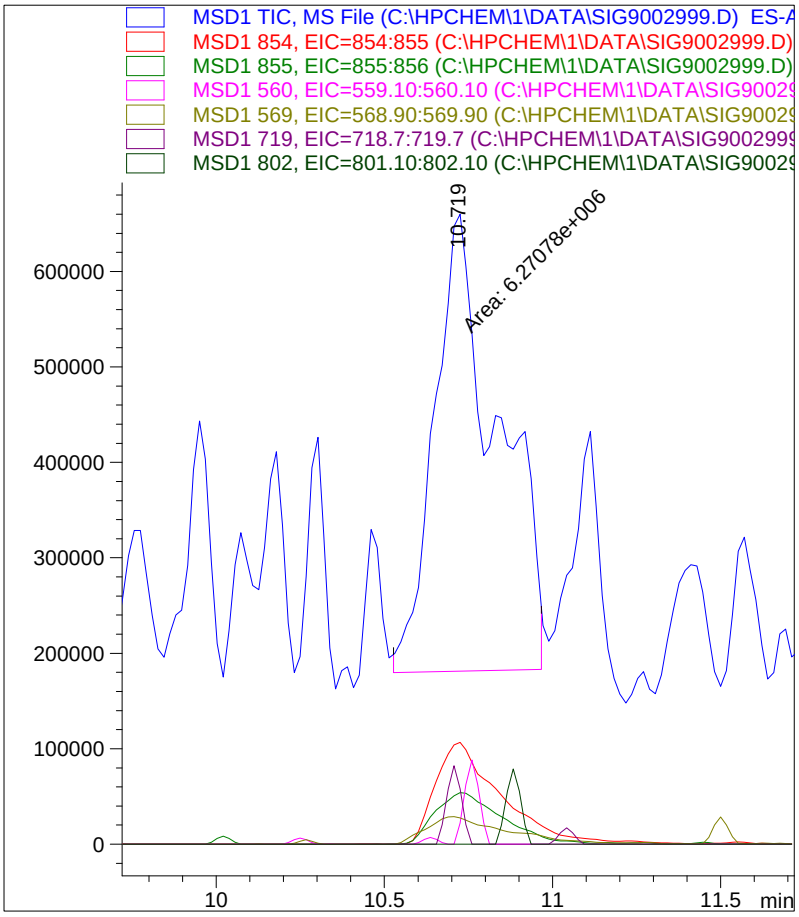


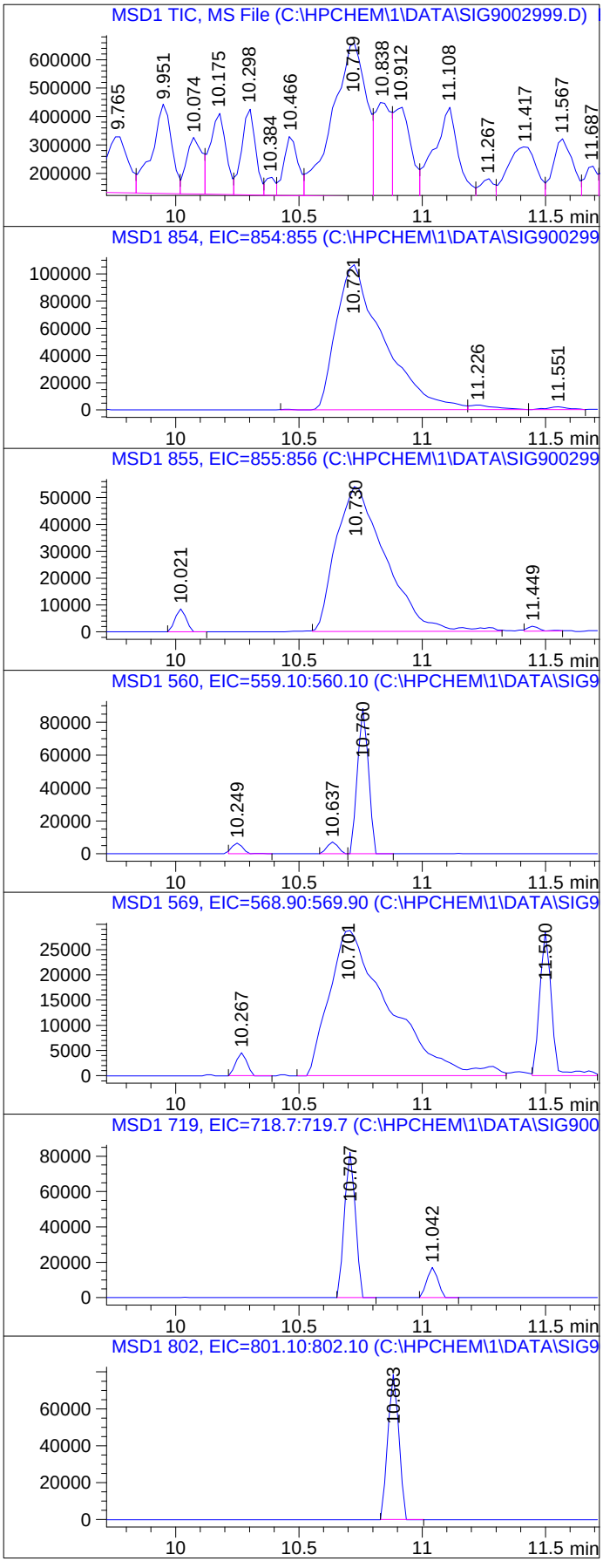
Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample

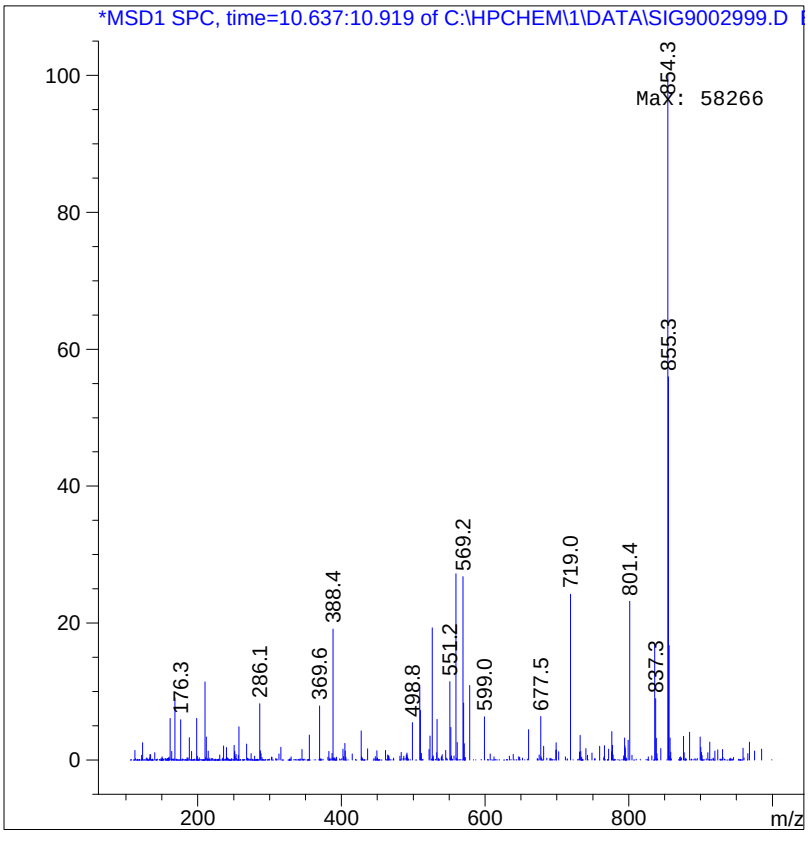
Spectra averaged over upper half of peaks.
Number of ions per peak: 6
Display Time Range(+- mins): 1.0

Data File C:\HPCHEM\1\DATA\SIG9002999.D
Sample Name: C3-146-045 Sample

DataPath : C:\HPCHEM\1\DATA\SIG9002999.D
DateTime: 14 Sep 17 11:18 am -0600
Operator : mk Vial : 1
Sample : C3-146-045 Sample
Retention : 10.719 minutes

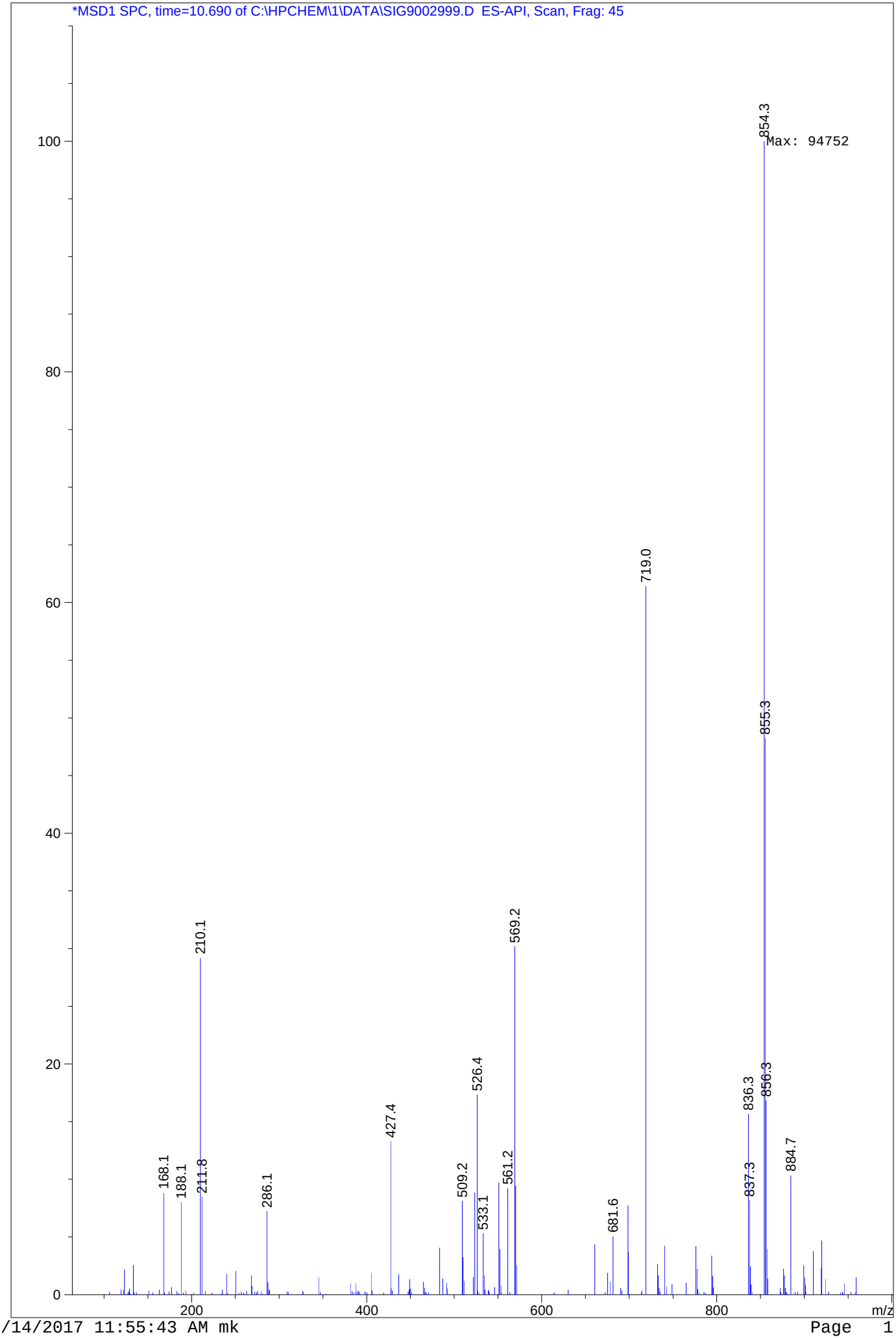






*** End of Report ***

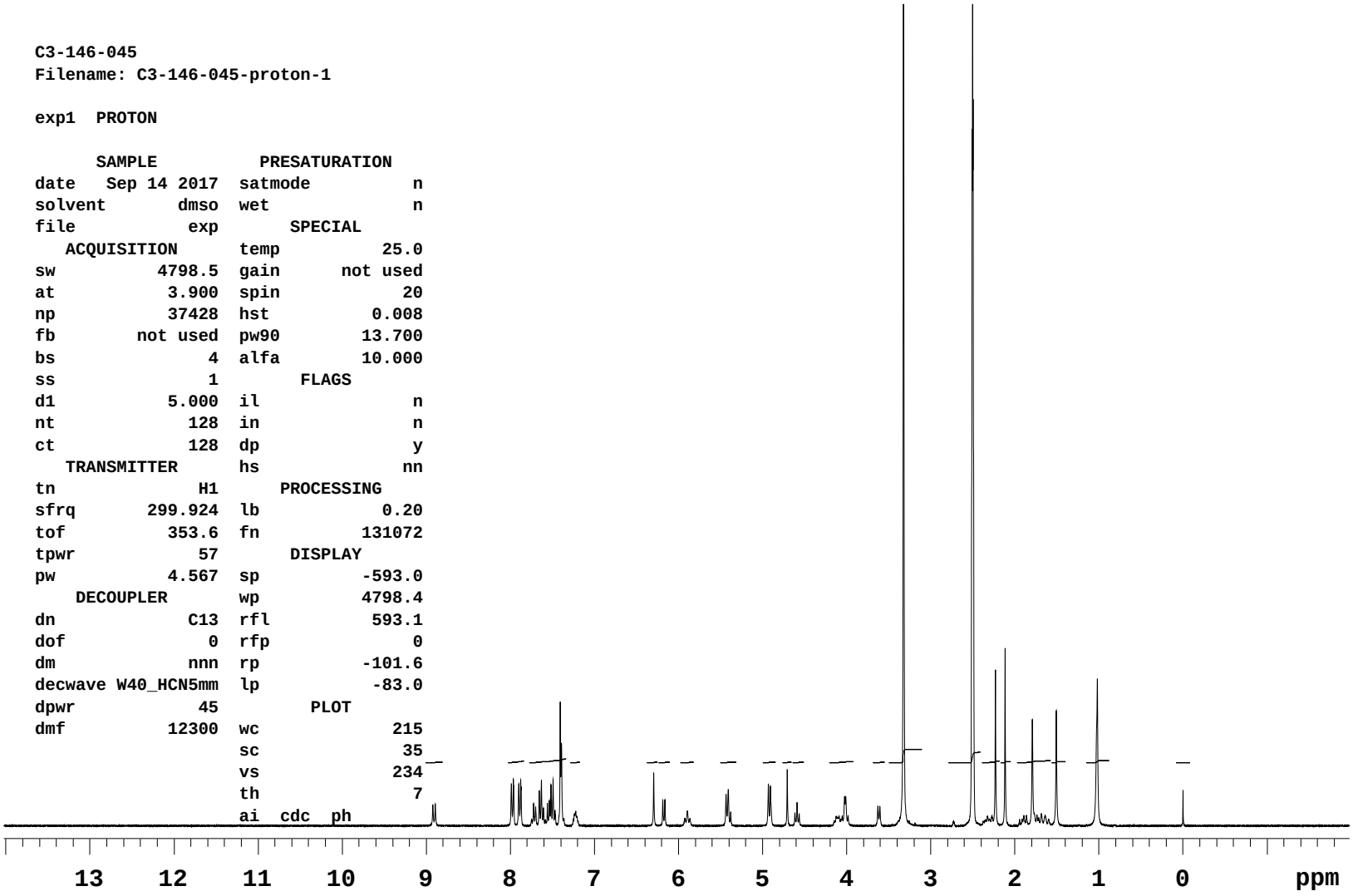
MS Spectrum


*MSD1 SPC, time=10.690 of C:\HPCHEM\1\DATA\SIG9002999.D ES-API, Scan, Frag: 45
Max: 94752
854.3
855.3
719.0
569.2
210.1
526.4
427.4
836.3
856.3
884.7
168.1
188.1
211.8
286.1
509.2
533.1
561.2
681.6
837.3
100
80
60
40
20
0
200
400
600
800
m/z

C3-146-045
Filename: C3-146-045-proton-1

exp1 PROTON

SAMPLE		PRESATURATION	
date	Sep 14 2017	satmode	n
solvent	dmso	wet	n
file	exp	SPECIAL	
ACQUISITION		temp	25.0
sw	4798.5	gain	not used
at	3.900	spin	20
np	37428	hst	0.008
fb	not used	pw90	13.700
bs	4	alfa	10.000
ss	1	FLAGS	
d1	5.000	il	n
nt	128	in	n
ct	128	dp	y
TRANSMITTER		hs	nn
tn	H1	PROCESSING	
sfrq	299.924	lb	0.20
tof	353.6	fn	131072
tpwr	57	DISPLAY	
pw	4.567	sp	-593.0
DECOUPLER		wp	4798.4
dn	C13	rfl	593.1
dof	0	rfp	0
dm	nnn	rp	-101.6
decwave	W40_HCN5mm	lp	-83.0
dpwr	45	PLOT	
dmf	12300	wc	215
		sc	35
		vs	234
		th	7
		ai cdc ph	



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C3-146-045
Filename: C3-146-045-proton-1

Sample Name:

Data Collected on:
vnmrj42.chemtocs.lan-mercury300
Archive directory:

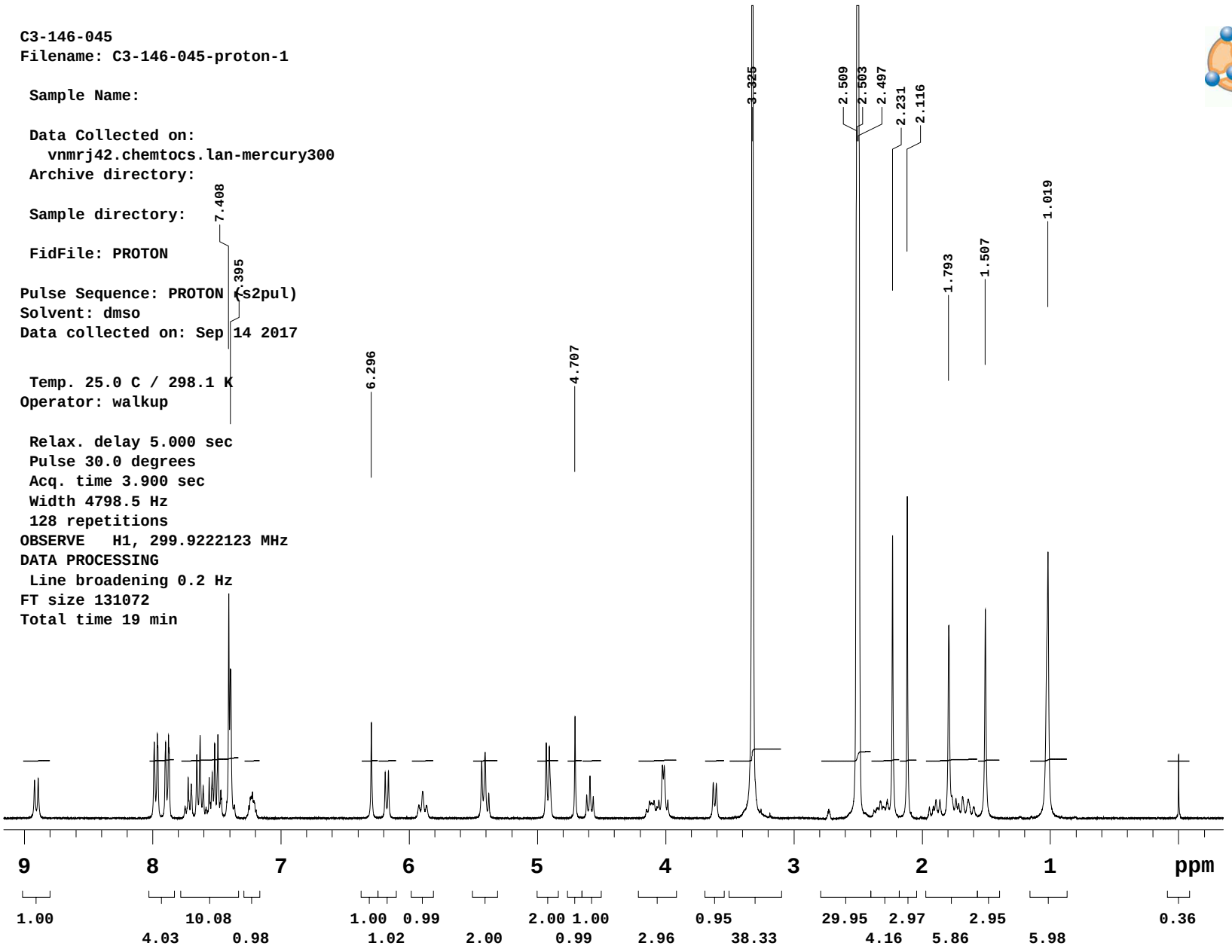
Sample directory:

FidFile: PROTON

Pulse Sequence: PROTON (s2pul)
Solvent: dmso
Data collected on: Sep 14 2017

Temp. 25.0 C / 298.1 K
Operator: walkup

Relax. delay 5.000 sec
Pulse 30.0 degrees
Acq. time 3.900 sec
Width 4798.5 Hz
128 repetitions
OBSERVE H1, 299.9222123 MHz
DATA PROCESSING
Line broadening 0.2 Hz
FT size 131072
Total time 19 min



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File:01 ID No:131
SMPL:01 -01

<RESULT>
Conc: 5.66364 %
M: 311.5 µg

B.G.:0.05 µg/sec

Time: 04:26
2017/09/14 10:23

<SAMPLE>
M/(W-w)
W:0.00550 g
w:0.00000 g
W-w: 0.00550 g

<PARAMETER>
File Name:001
Delay:.3 min
Min Titr:.5 min
Titr Stop:6.5 min
End Sense:.4 µg/s
Print Form:3
Calc Form:1
Calc Unit:1
VA Select:0

File:01 ID No:132
SMPL:01 -02

<RESULT>
Conc: 0.78601 %
M: 19.1 µg

B.G.:0.05 µg/sec

Time: 00:30
2017/09/14 10:38

<SAMPLE>
M/(W-w)
W:0.00303 g
w:0.00060 g
W-w: 0.00243 g

<PARAMETER>
File Name:001
Delay:.3 min
Min Titr:.5 min
Titr Stop:6.5 min
End Sense:.4 µg/s
Print Form:3
Calc Form:1
Calc Unit:1
VA Select:0

0.00000 g
0.00550 g
0.00000 g
01
Std

TA

0.00000 g
0.00303 g
0.00060 g
02

0.00550 g
0.00116 g
03

File:01 ID No:133
SMPL:01 -03

<RESULT>
Conc: 0.76498 %
M: 33.2 µg

B.G.:0.07 µg/sec

Time: 00:36
2017/09/14 10:49

<SAMPLE>
M/(W-w)
W:0.00550 g
w:0.00116 g
W-w: 0.00434 g

<PARAMETER>
File Name:001
Delay:.3 min
Min Titr:.5 min
Titr Stop:6.5 min
End Sense:.4 µg/s
Print Form:3
Calc Form:1
Calc Unit:1
VA Select:0