CERTIFICATE OF ANALYSIS

(Certificate No. SZ-E041071-1026)

Analysis Date: 10/02/2023 **Re-test Date:** 07/02/2025

Edoxaban Tosylate Hydrate

Identification

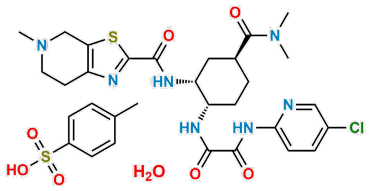
Chemical Name : N1-(5-Chloropyridin-2-yl)-N2-((1S,2R,4S)-4-(dimethylcarbamoyl)-2-(5-methyl-4,5,6,7-tetrahydrothiazolo[5,4-c]pyridine-2-carboxamido)cyclohexyl)oxalamide 4-methylbenzenesulfonate hydrate

CAT No. : SZ-E041071

CAS No. : 1229194-11-9

Molecular Formula : C24H30ClN7O4S · C7H8O3S · H2O

Molecular Weight : 548.1 · 172.2 · 18.0



Analytical Information

Batch Code	:	SRL-1188-026	**HPLC Purity**	:	99.70 %
Solubility	:	ACN:H2O(8:2)	**Mass**	:	Confirm
Appearance of product	:	White Hygroscopic Solid	**IR Analysis**	:	Confirm
Long Term Storage	:	2-8 °C for long term storage	**1H NMR**	:	Confirm
Weight Loss By TGA	:	1.03 %	**13C NMR**	:	Confirm
			DEPT Analysis	:	Confirm

Additional Information

% Potency = [100 - 1.03 (Wt loss by TGA)] X [99.70 (HPLC Purity)] / 100 = 98.67 %

Recommendation : Released

	Department	Signature	Date
Prepared and Reviewed by	Analytical		
Approved By	Quality Control		

Attachments : HPLC, Mass, 1H NMR, IR, TGA, 13C NMR, DEPT

Shipping Condition : All Products are stable to be shipped at room temperature, unless otherwise specified.

=== SynZeal HPLC Report ===

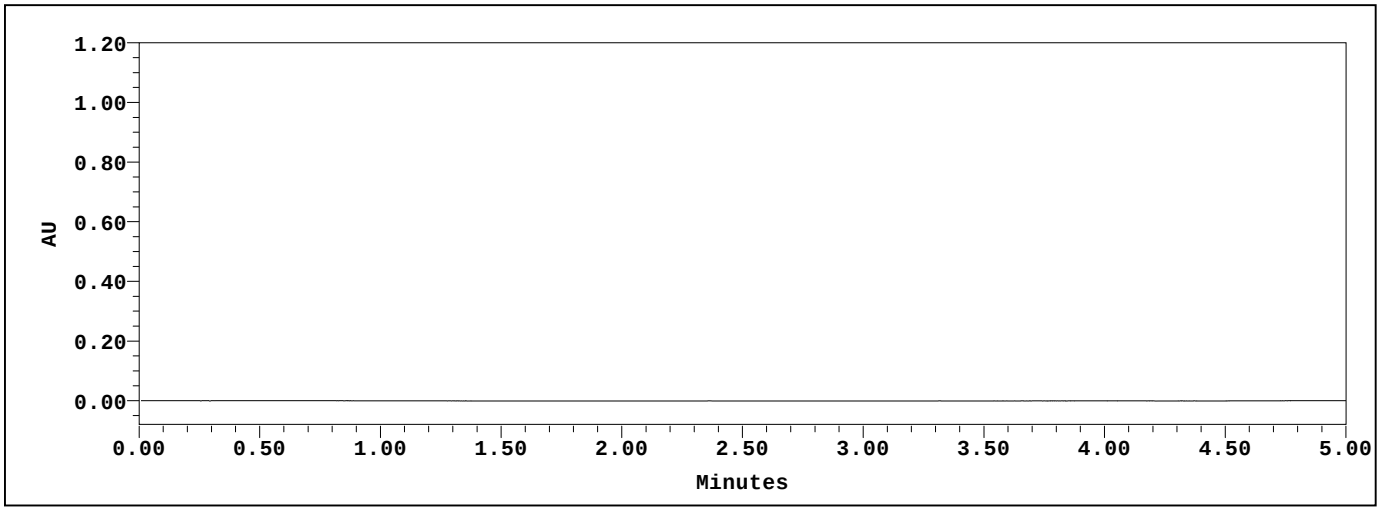
Sample Name	:	Blank	Program	:	Gradient
Sample ID	:	Diluent	Column Temp	:	40 °C
Column Name	:	Acquity UPLC BEH	Vial	:	1:A,1
Column ID	:	SRL/C18/2023/285	Injection Volume	:	0.20 ul
Column Desc.	:	50 mm * 2.1 mm; 1.7µ	Sample Conc.	:	-
Diluent	:	ACN:H2O (8:2)	Flow Rate	:	0.5 mL/min
Mobile Phase_A	:	0.1 % TFA in water			
Mobile Phase_B	:	ACN:H2O (90:10)			
Method Name	:	SZ_UPLC_RA_AKIRA_01			

Gradient :
=> T(min)/%B 0.01-2.5/10-100 -> 2.5-3.5/100 -> 3.5-3.6/100-10 -> 3.6-5.0/10

Sample Set Name : 2023_02_08_UPLC_02
Date Acquired : 08-02-2023 13:54:44 IST
Date Processed : 08-02-2023 15:27:50 IST
Acquired By : Preeti_Pal

Chromatogram

Blank



Channel Name 290.0nm

Results

	Retention Time (min)	Area (µV*sec)	Height (µV)	% Area
1				
Sum				

=== SynZeal HPLC Report ===

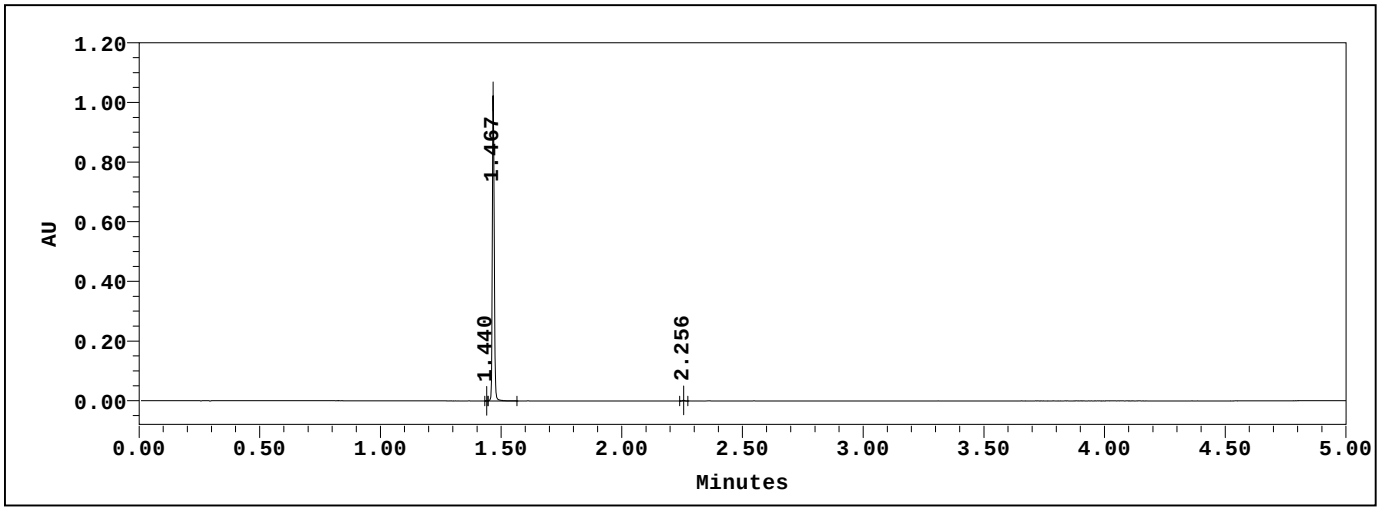
Sample Name	:	SRL-1188-026	Program	:	Gradient
Sample ID	:	Edoxaban	Column Temp	:	40 °C
Column Name	:	Acquity UPLC BEH	Vial	:	1:F,2
Column ID	:	SRL/C18/2023/285	Injection Volume	:	0.20 ul
Column Desc.	:	50 mm * 2.1 mm; 1.7µ	Sample Conc.	:	500 ppm
Diluent	:	ACN:H2O (8:2)	Flow Rate	:	0.5 mL/min
Mobile Phase_A	:	0.1 % TFA in water			
Mobile Phase_B	:	ACN:H2O (90:10)			
Method Name	:	SZ_UPLC_RA_AKIRA_01			

Gradient :
=> T(min)/%B 0.01-2.5/10-100 -> 2.5-3.5/100 -> 3.5-3.6/100-10 -> 3.6-5.0/10

Sample Set Name : 2023_02_08_UPLC_02
Date Acquired : 08-02-2023 14:00:17 IST
Date Processed : 08-02-2023 15:28:20 IST
Acquired By : Preeti_Pal

Chromatogram

SRL-1188-026



Channel Name 290.0nm

Results

	Retention Time (min)	Area (µV*sec)	Height (µV)	% Area
1	1.440	273	589	0.05
2	1.467	554831	1026376	99.70
3	2.256	1370	2097	0.25

	Retention Time (min)	Area (µV*sec)	Height (µV)	% Area
Sum				100.0

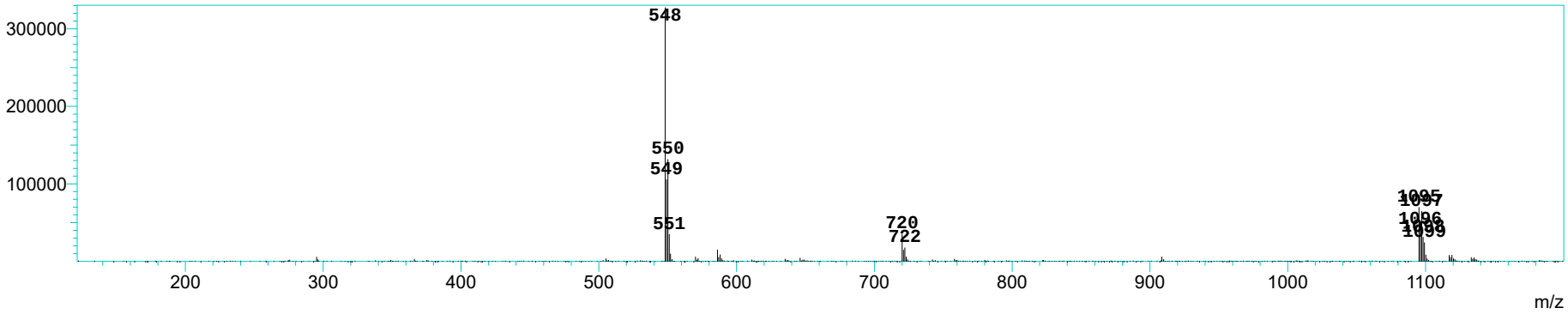
SynZeal Research Pvt. Ltd.

Sample Information

Sample Name : SRL-1188-026
Date Acquired : 09-02-2023 16:22:41

Mass Analysis

ESI
+



ESI
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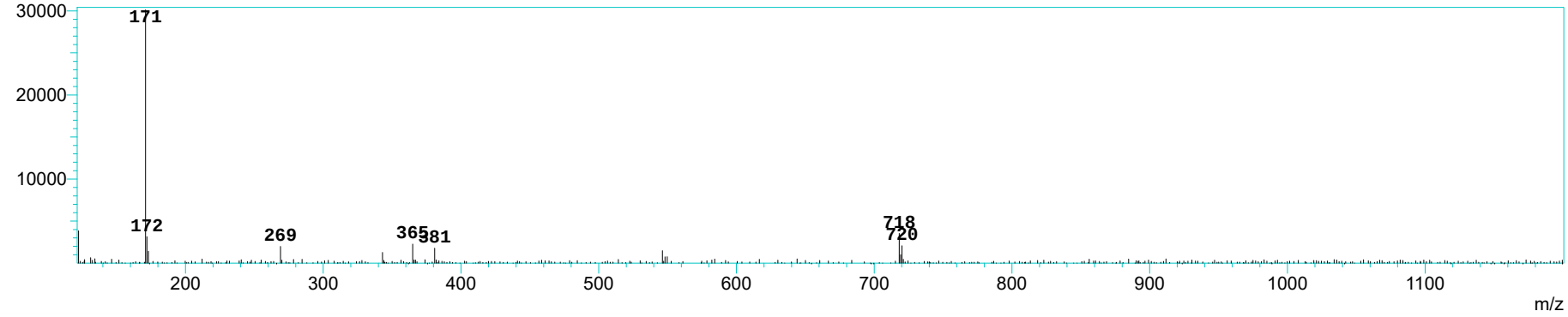
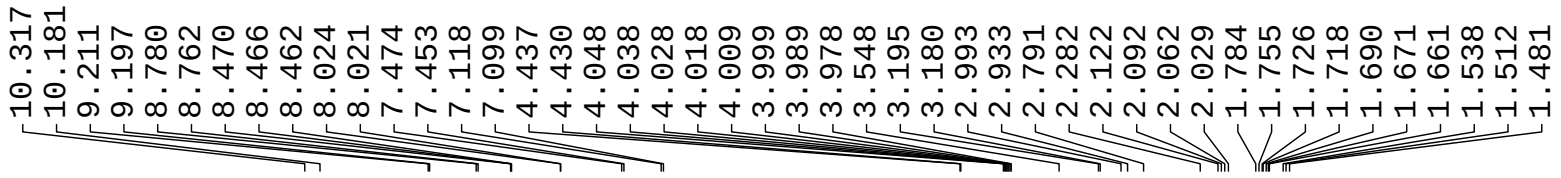
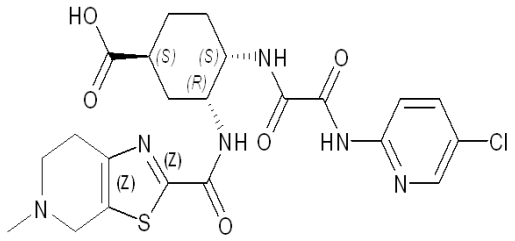


SynZeal Research Pvt.Ltd.
1H SRL-1188-026 /DMSO-D6





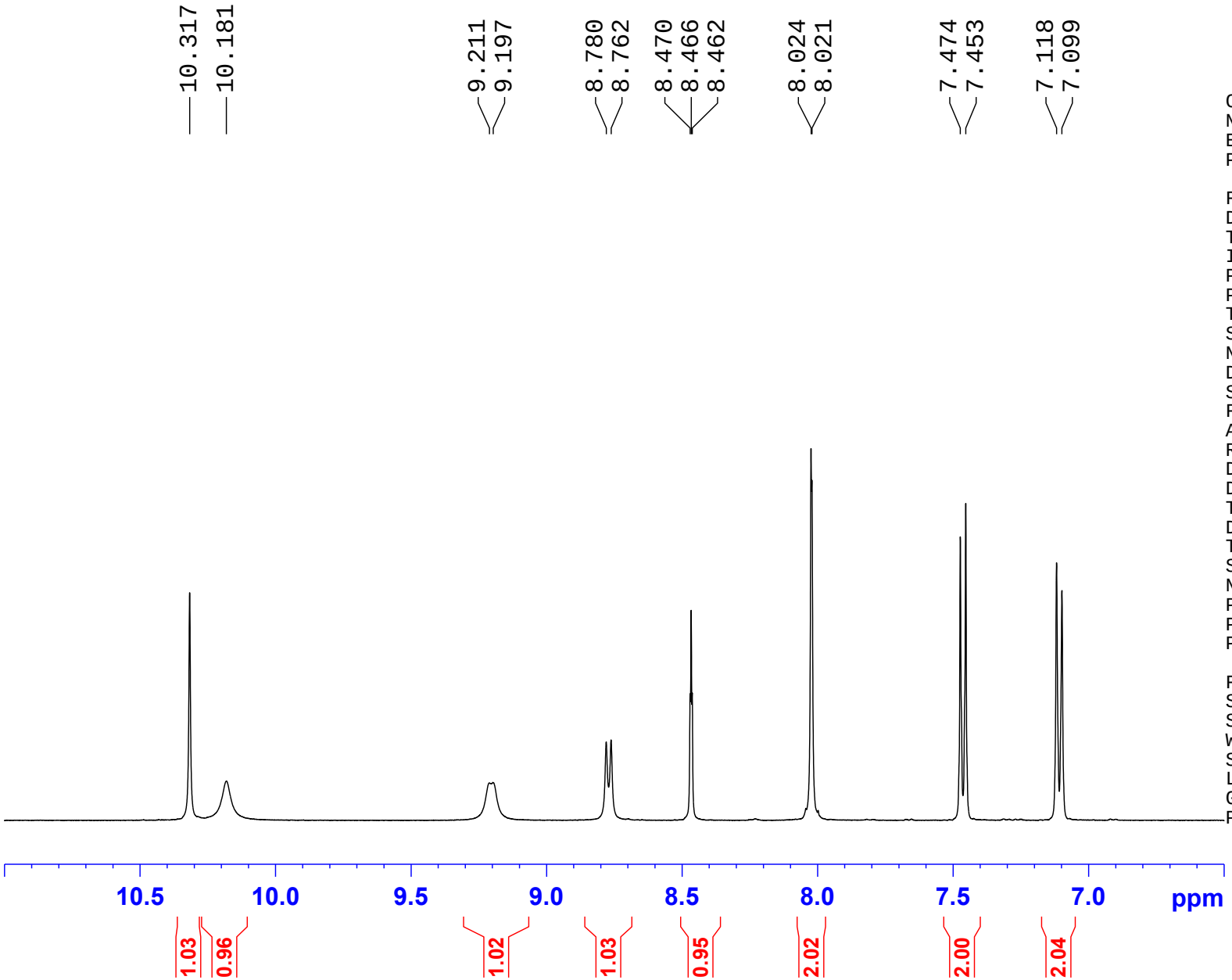
Exact Mass: 692.15
Molecular Weight: 693.19

Current Data Parameters
NAME SRL-1188-026
EXPNO 1
PROCNO 1

F2 - Acquisition Parameters
Date_ 20230211
Time 10.20 h
INSTRUM Avance NEO 400
PROBHD Z163739_0060 (
PULPROG zg30
TD 65536
SOLVENT DMSO
NS 24
DS 2
SWH 8196.722 Hz
FIDRES 0.250144 Hz
AQ 3.9976959 sec
RG 101
DW 61.000 usec
DE 13.54 usec
TE 293.9 K
D1 1.00000000 sec
TD0 1
SFO1 400.1324708 MHz
NUC1 1H
P0 3.33 usec
P1 10.00 usec
PLW1 14.61900043 W

F2 - Processing parameters
SI 65536
SF 400.1300000 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00

SynZeal Research Pvt.Ltd.
1H SRL-1188-026 /DMSO-D6



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NAME SRL-1188-026
EXPNO 1
PROCNO 1

F2 - Acquisition Parameters
Date_ 20230211
Time 10.20 h
INSTRUM Avance NEO 400
PROBHD Z163739_0060 (
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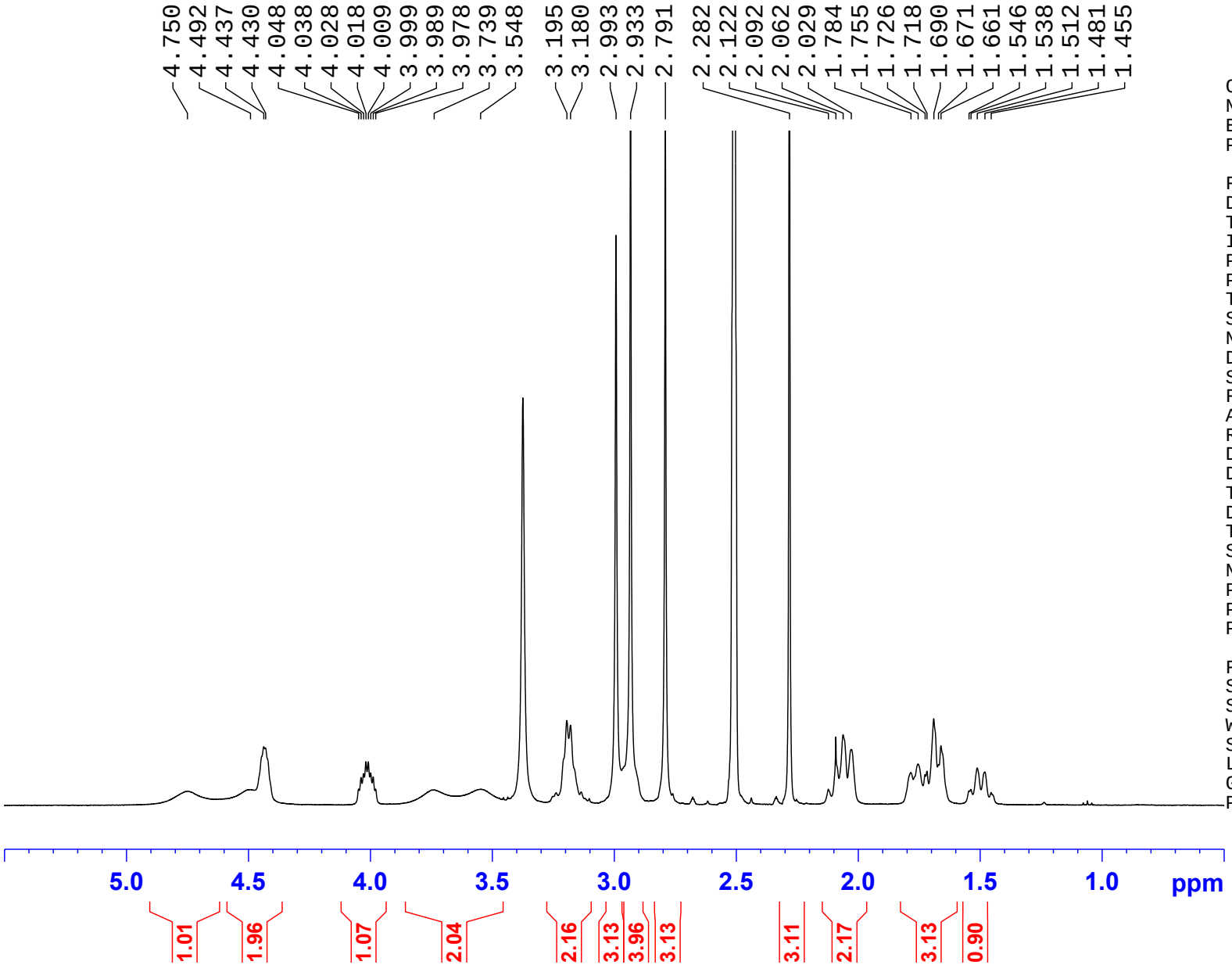
TD 65536
SOLVENT DMSO
NS 24
DS 2
SWH 8196.722 Hz
FIDRES 0.250144 Hz
AQ 3.9976959 sec
RG 101
DW 61.000 usec
DE 13.54 usec
TE 293.9 K
D1 1.00000000 sec
TD0 1
SFO1 400.1324708 MHz
NUC1 1H
P0 3.33 usec
P1 10.00 usec
PLW1 14.61900043 W

F2 - Processing parameters
SI 65536
SF 400.1300000 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00

SynZeal Research Pvt.Ltd.
1H SRL-1188-026 /DMSO-D6



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NAME SRL-1188-026
EXPNO 1
PROCNO 1

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Date_ 20230211
Time 10.20 h
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PROBHD Z163739_0060 (
PULPROG zg30
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SOLVENT DMSO
NS 24
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DE 13.54 usec
TE 293.9 K
D1 1.00000000 sec
TD0 1
SFO1 400.1324708 MHz
NUC1 1H
P0 3.33 usec
P1 10.00 usec
PLW1 14.61900043 W

F2 - Processing parameters
SI 65536
SF 400.1300000 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00

SRL-1188-026

SZ-TGA-SA-ROI-40-950-ISO
SynZeal Research Pvt Ltd
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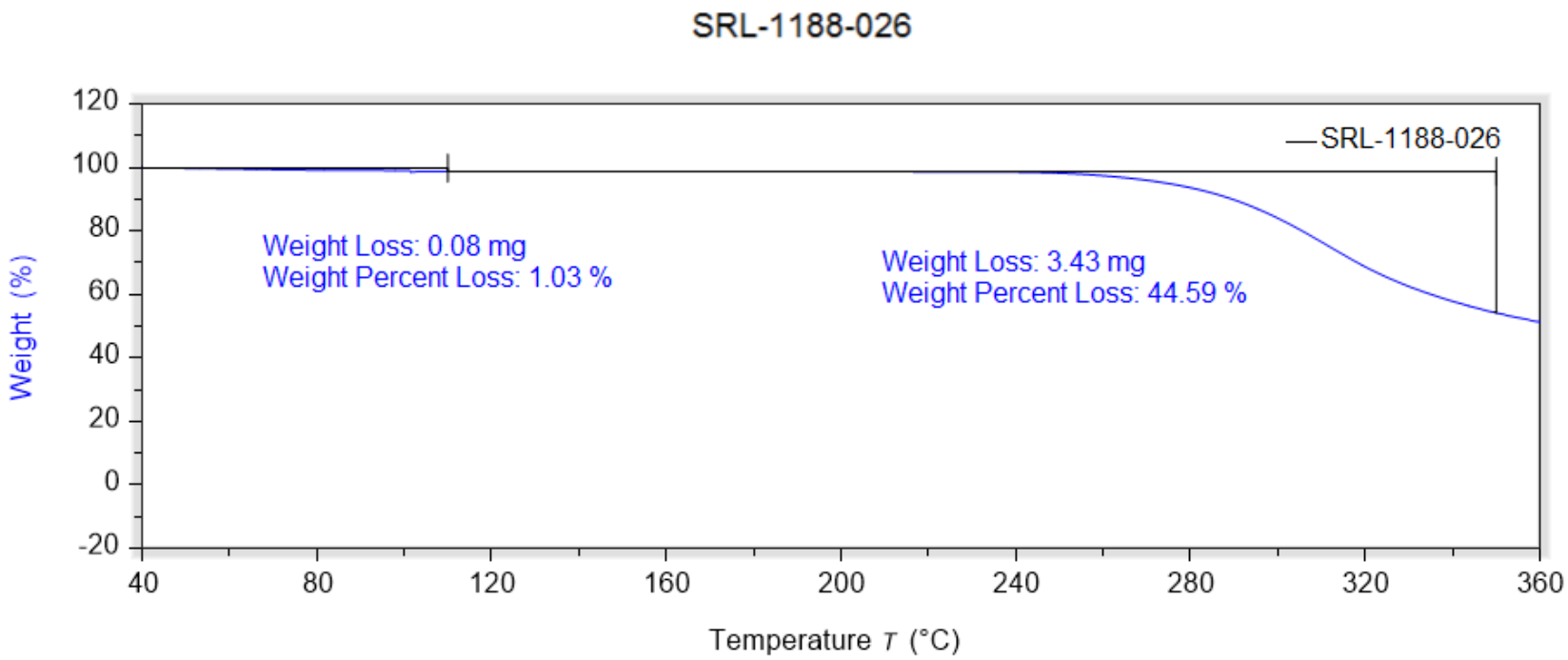
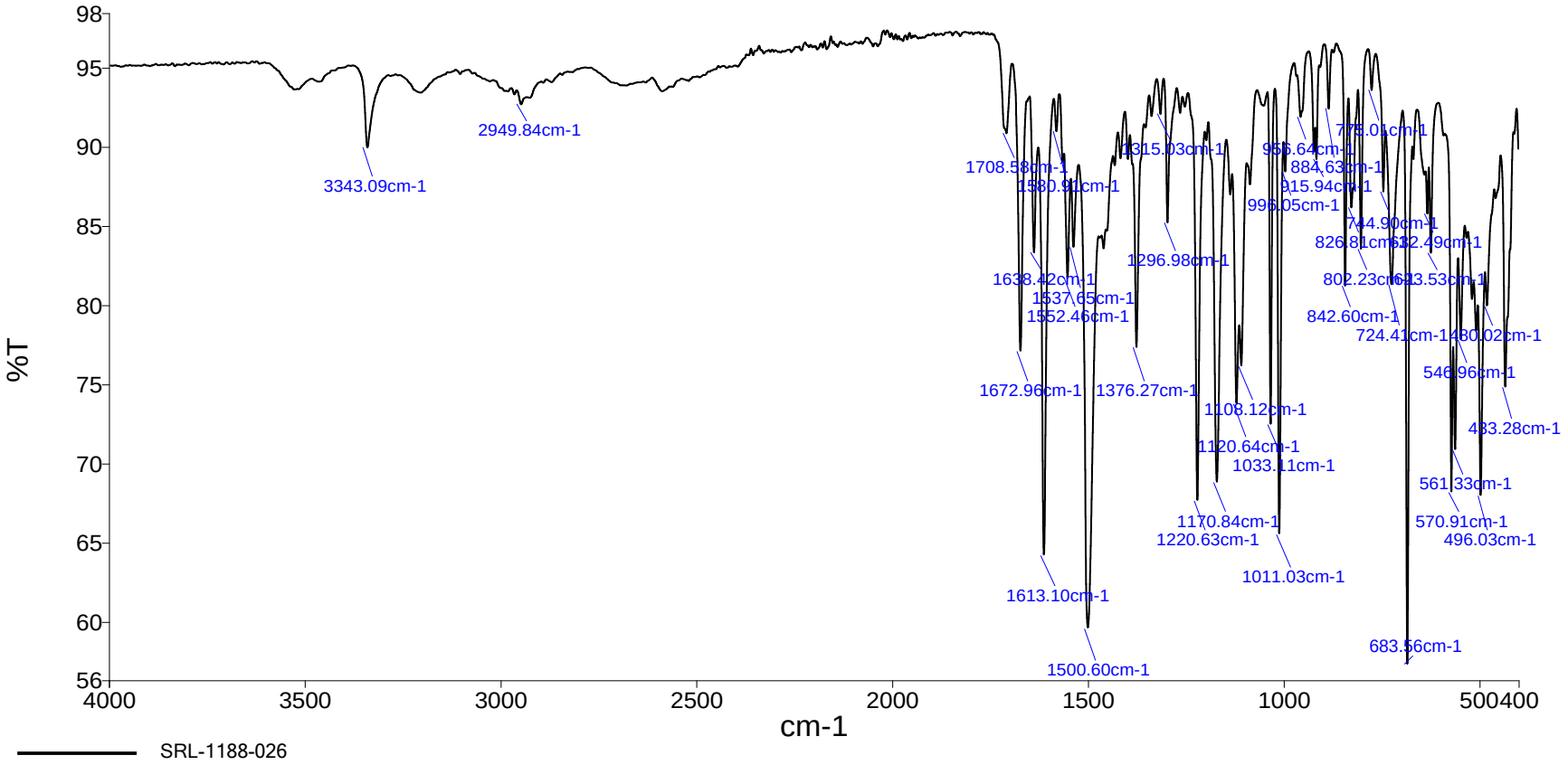
TGA55,09-02-23 16:22:30
7.689 mg
Platinum HT
-



Analyst Synzeal Research Private Limited
Date 10 February 2023 13:29



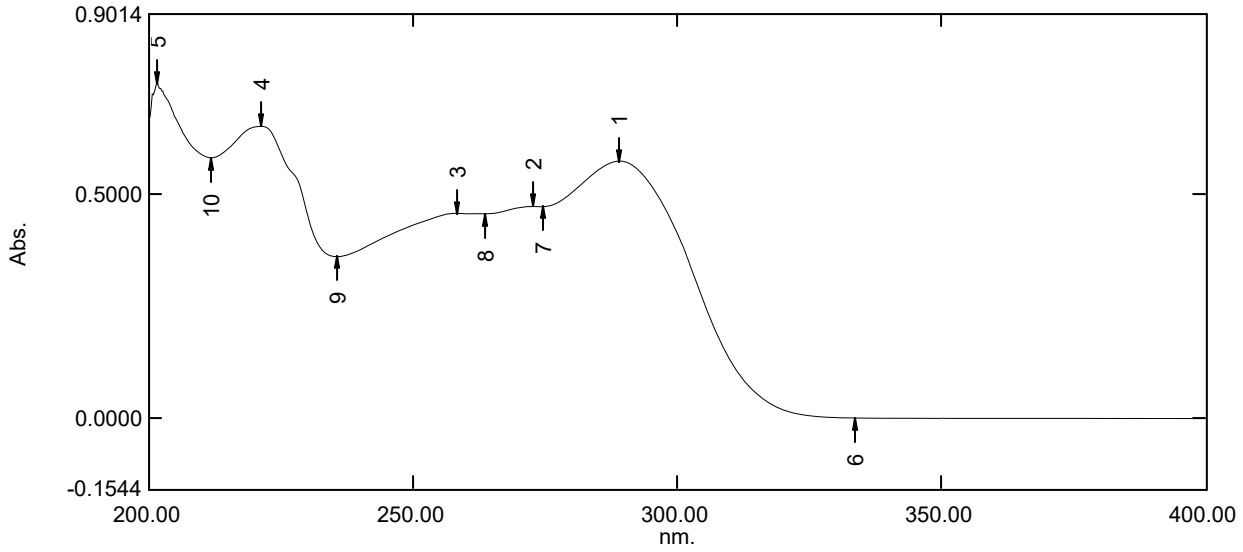
Source Spectra Results	
Spectrum Name	Number Of Peaks
SRL-1188-026	38

List of Peak Area/Height		
Peak Number	X (cm-1)	Y (%T)
1	3343.09	90.04
2	2949.84	92.77
3	1708.58	90.94
4	1672.96	77.16
5	1638.42	83.39
6	1613.10	64.26
7	1580.91	91.06
8	1552.46	81.79
9	1537.65	83.73
10	1500.60	59.63
11	1376.27	77.40
12	1315.03	92.16
13	1296.98	85.28
14	1220.63	67.71
15	1170.84	68.87
16	1120.64	73.83
17	1108.12	76.23
18	1033.11	72.53
19	1011.03	65.58
20	996.05	88.51
21	956.64	91.97
22	915.94	89.29
23	884.63	92.49
24	842.60	81.29
25	826.81	86.24
26	802.23	83.62
27	775.01	93.67
28	744.90	87.23
29	724.41	81.37
30	683.56	57.33
31	632.49	85.84

List of Peak Area/Height		
Peak Number	X (cm-1)	Y (%T)
32	623.53	83.37
33	570.91	68.24
34	561.33	70.92
35	546.96	77.89
36	496.03	68.02
37	480.02	80.03
38	433.28	74.89

09-02-2023
15:56:58

SRL-1188-026 - RawData



[Measurement Properties]

Wavelength Range (nm.):	200.00 to 400.00
Scan Speed:	Fast
Sampling Interval:	0.2
Auto Sampling Interval:	Enabled
Scan Mode:	Single

[Instrument Properties]

Instrument Type:	UV-1900 Series
Measuring Mode:	Absorbance
Slit Width:	1.0 nm
Light Source Change Wavelength:	340.8 nm
S/R Exchange:	Normal

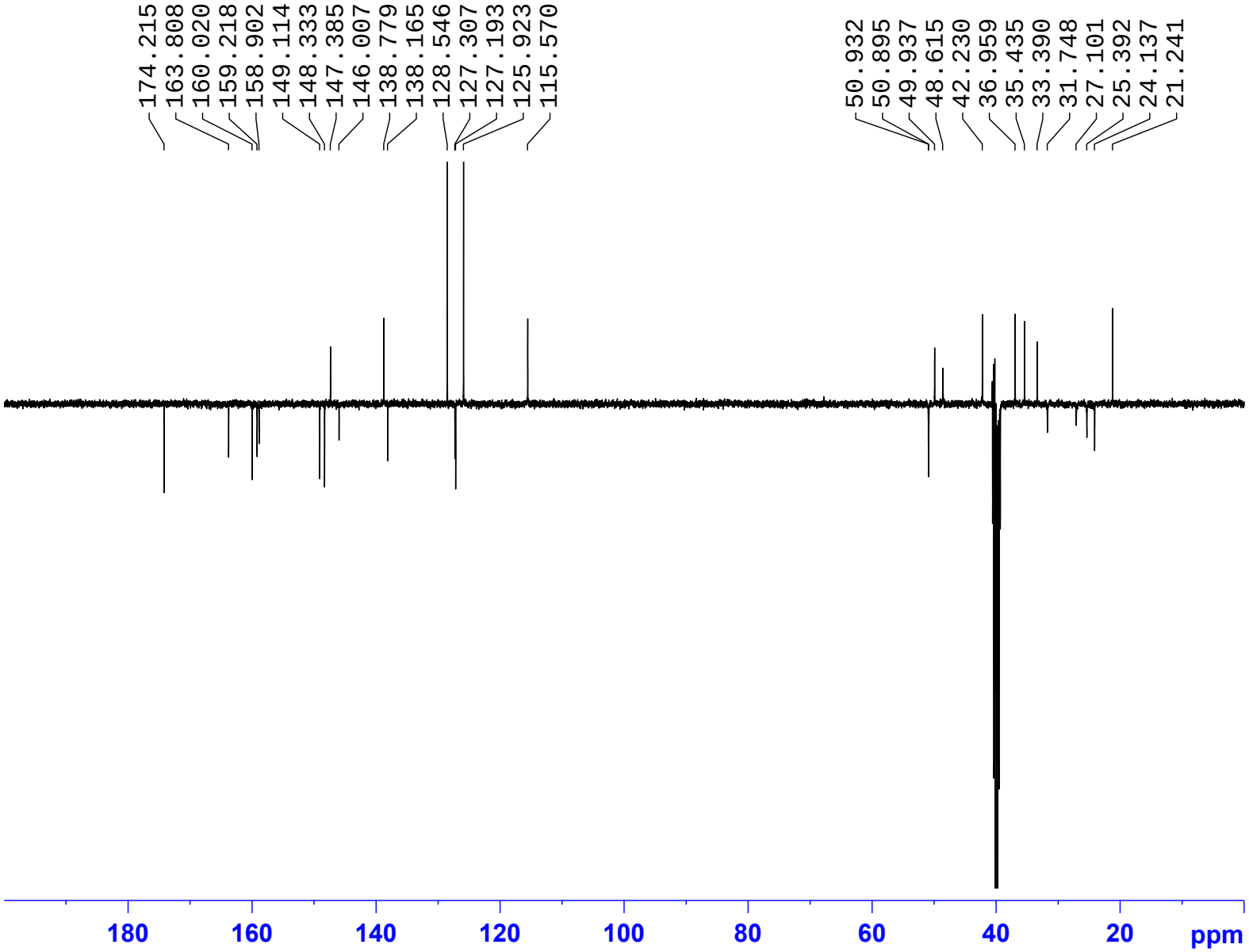
.....

Peak Pick Table

No.	P/V	Wavelength	Abs.	Descriptio
1	↑	289.00	0.5739	
2	↑	272.60	0.4727	
3	↑	258.20	0.4574	
4	↑	221.40	0.6513	
5	↑	201.60	0.7468	
6	↓	333.80	0.0012	
7	↓	274.60	0.4722	
8	↓	263.80	0.4564	
9	↓	235.60	0.3609	
10	↓	211.60	0.5811	

Note - This data is for the reference purpose only. It does not have any correlation with HPLC wavelength. Selection of wavelength of HPLC report is based on the IN-HOUSE protocol.

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



Current Data Parameters

NAME	SRL-1188-026
EXPNO	3
PROCNO	1

F2 - Acquisition Parameters

Date_	20230211
Time	12.23 h
INSTRUM	Avance NEO 400
PROBHD	Z163739_0060 (
PULPROG	jmod
TD	65536
SOLVENT	DMSO
NS	2048
DS	4
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
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LB	1.00 Hz
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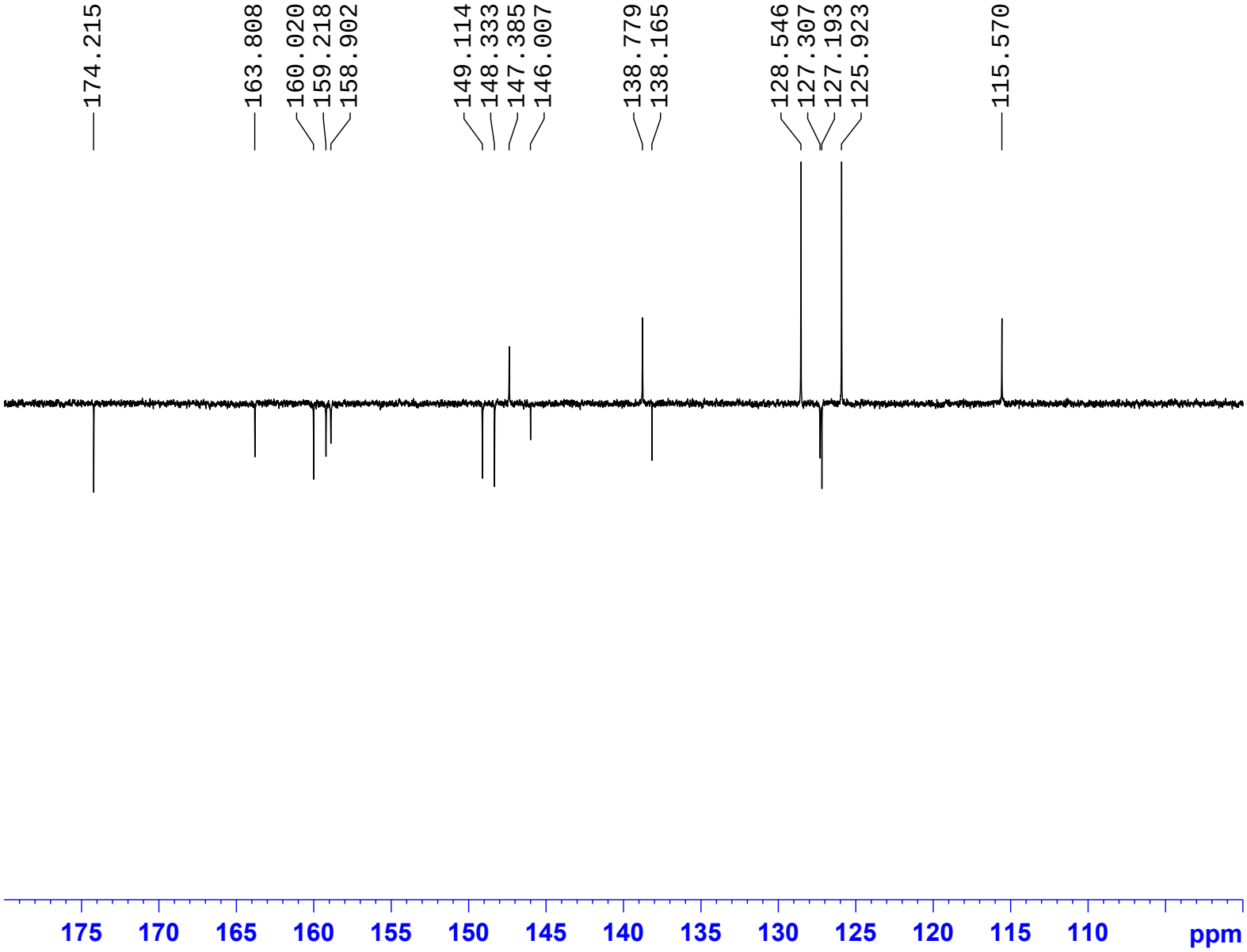
PC	1.40

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



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SOLVENT	DMSO
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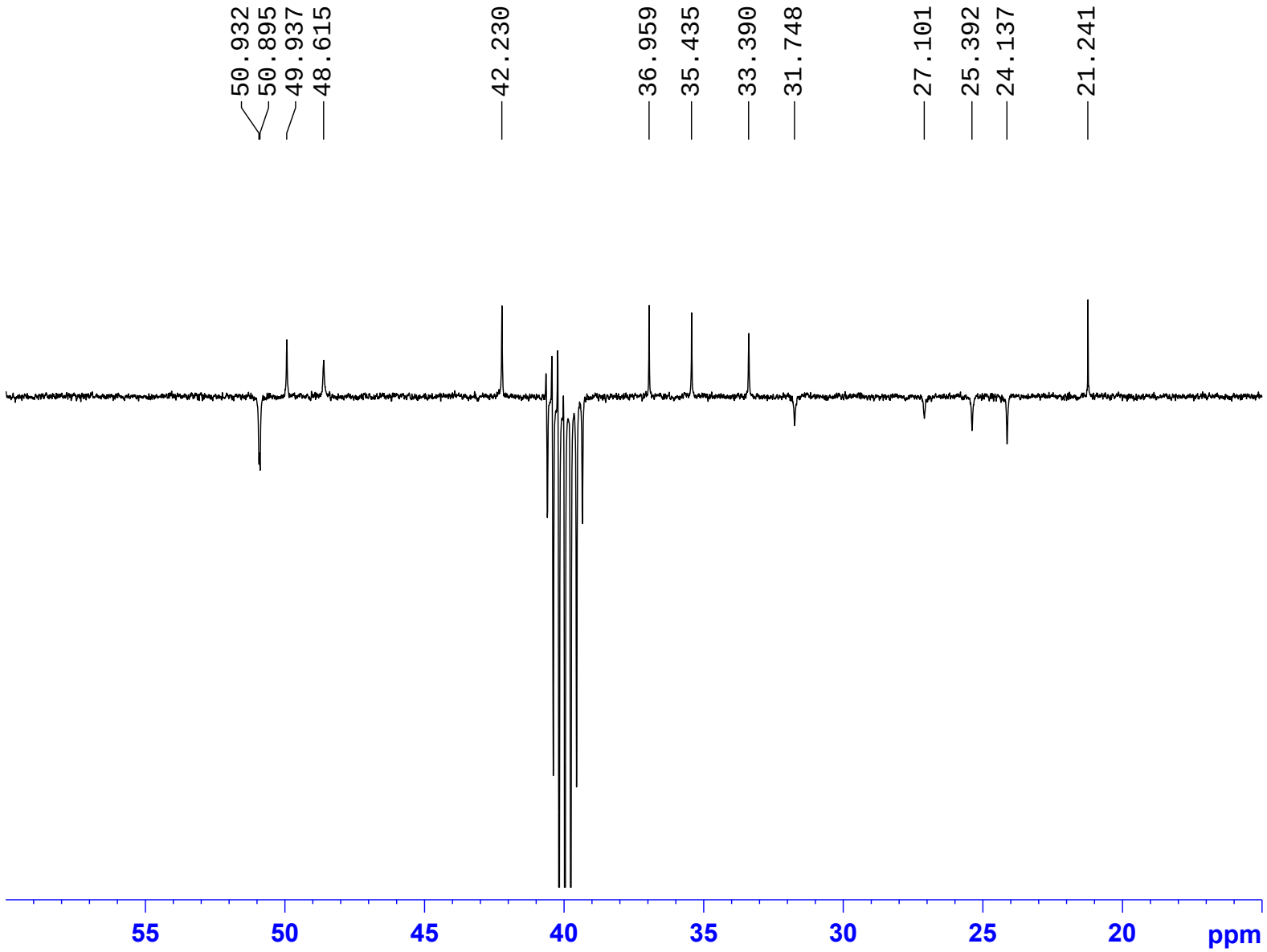
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
SSB	0
LB	1.00 Hz
GB	0
PC	1.40

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



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Date_	20230211
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INSTRUM	Avance NEO 400
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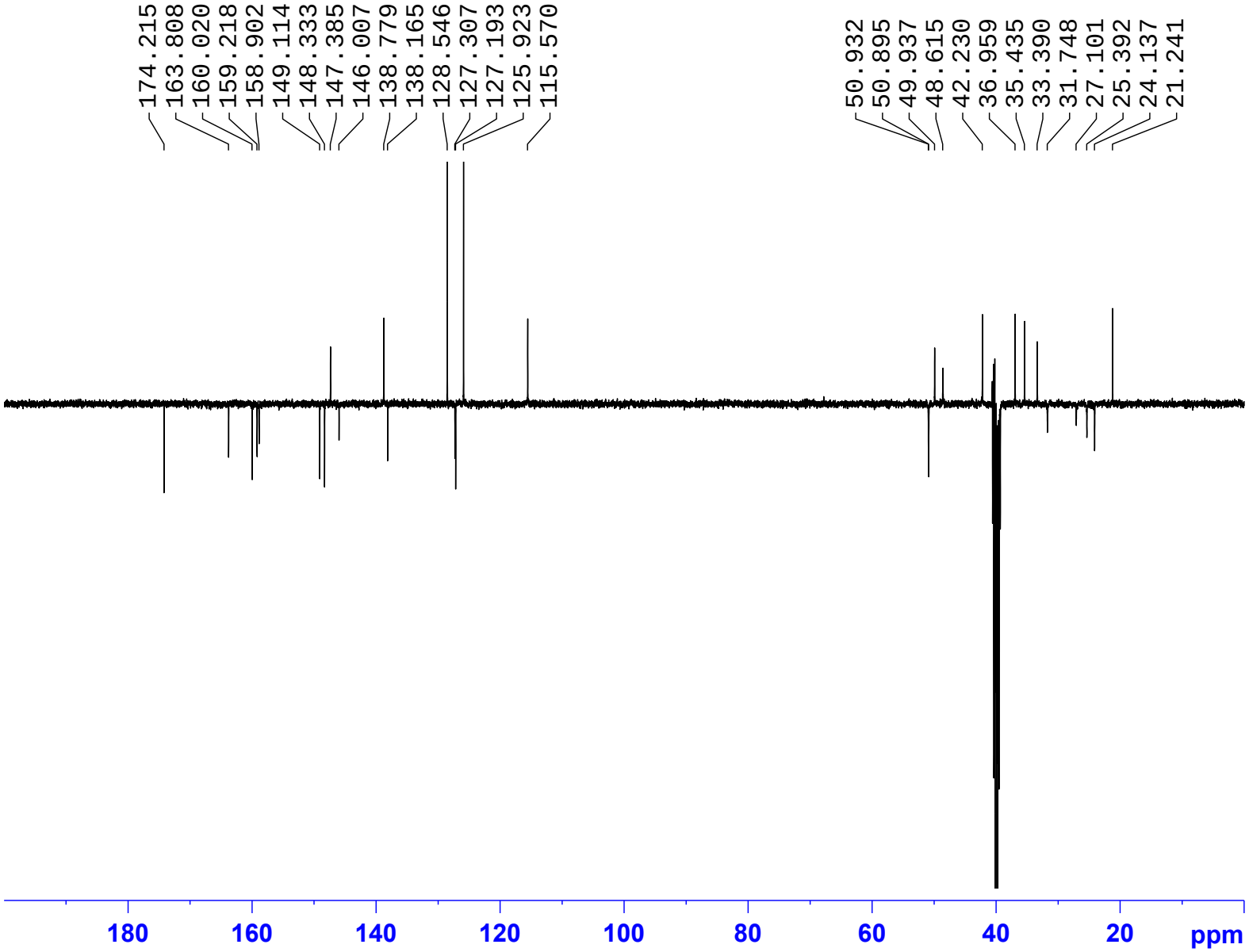
PULPROG	jmod
TD	65536
SOLVENT	DMSO
NS	2048
DS	4
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
SSB	0
LB	1.00 Hz
GB	0
PC	1.40

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



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Date_	20230211
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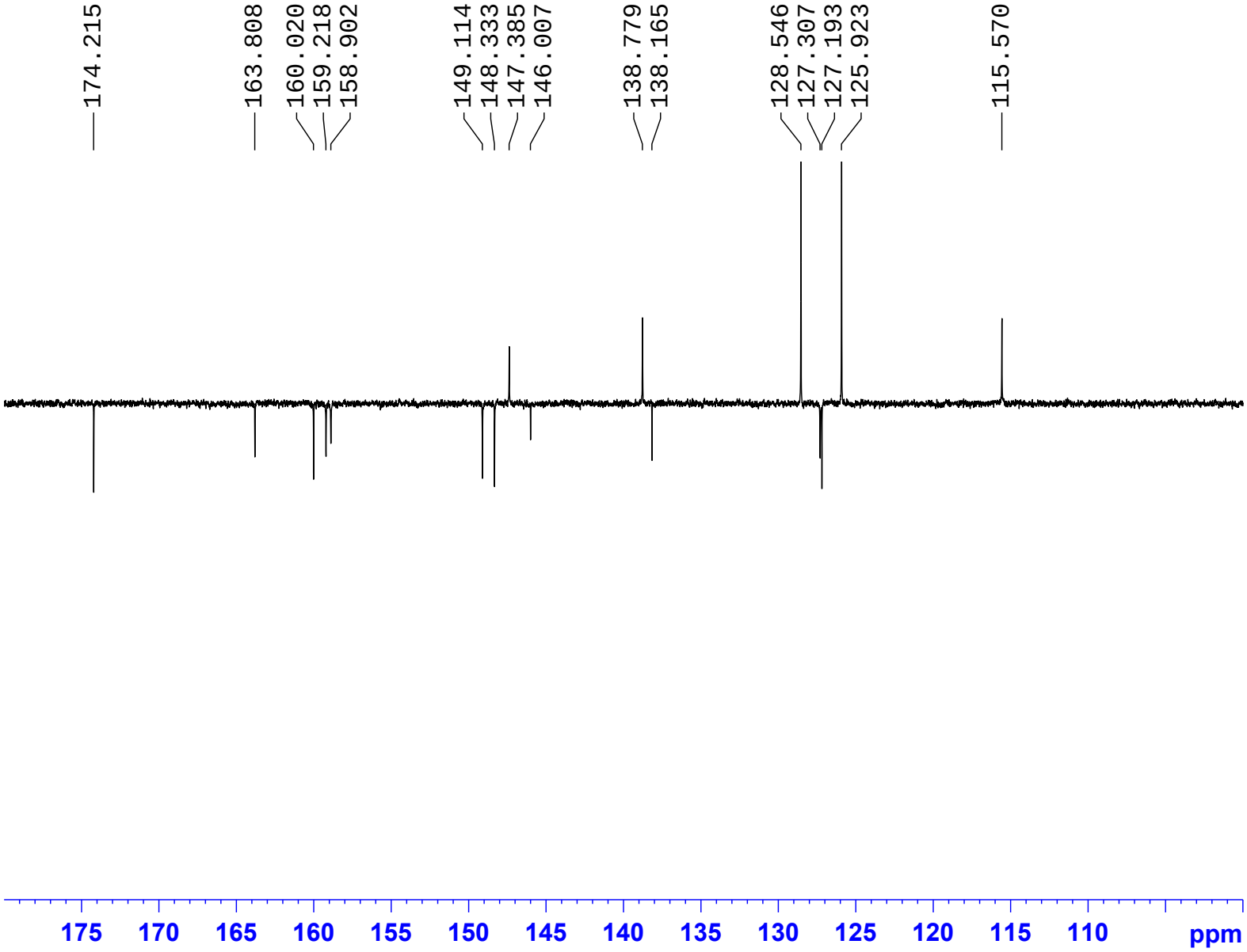
PULPROG	jmod
TD	65536
SOLVENT	DMSO
NS	2048
DS	4
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
SSB	0
LB	1.00 Hz
GB	0
PC	1.40

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



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PROCNO	1

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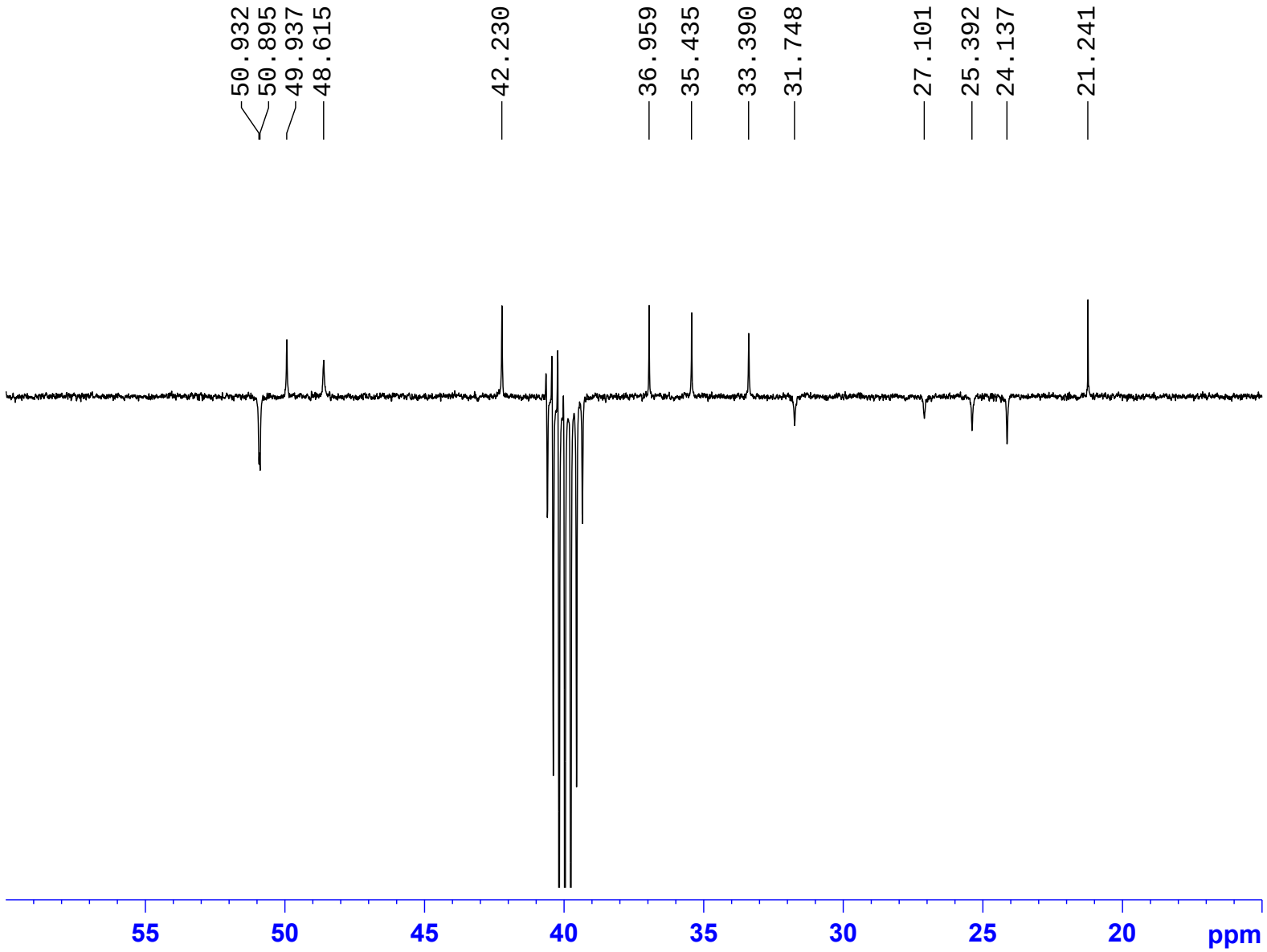
DS	4
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
SSB	0
LB	1.00 Hz
GB	0
PC	1.40

SynZeal Research Pvt.Ltd.
APT SRL-1188-026 /DMSO-D6



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PROCNO	1

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PULPROG	jmod
TD	65536
SOLVENT	DMSO
NS	2048
DS	4
SWH	23809.523 Hz
FIDRES	0.726609 Hz
AQ	1.3762560 sec
RG	101
DW	21.000 usec
DE	6.50 usec
TE	294.9 K
CNST2	145.0000000
CNST11	1.0000000
D1	2.00000000 sec
D20	0.00689655 sec
TD0	1
SFO1	100.6228298 MHz
NUC1	13C
P1	10.00 usec
P2	20.00 usec
PLW1	62.16799927 W
SFO2	400.1316005 MHz
NUC2	1H
CPDPRG[2	waltz65
PCPD2	90.00 usec
PLW2	14.61900043 W
PLW12	0.18048000 W

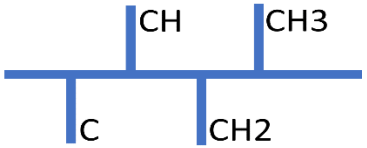
F2 - Processing parameters

SI	32768
SF	100.6127685 MHz
WDW	EM
SSB	0
LB	1.00 Hz
GB	0
PC	1.40

APT NMR Assignment

Instrument: BRUKER

Condition: 400 MHz



Carbon Assignment	Chemical Shift δ	No. of Carbon	Type of Carbon

Carbon Assignment	Chemical Shift δ	No. of Carbon	Type of Carbon

Chemical Formula:		Total Number of Carbon:	

Remarks:	

Conclusion:	The structure is confirmed by the signals of the spectrum and their interpretation.

Instrument -

Method -

Sr. No.	M/Z	Fragments

Conclusion -

Instrument -

Condition -

Proton Assignment	Chemical Shift δ	Multipli-city	No. of Proton

Proton Assignment	Chemical Shift (δ)	Multipli-city	No. of Proton

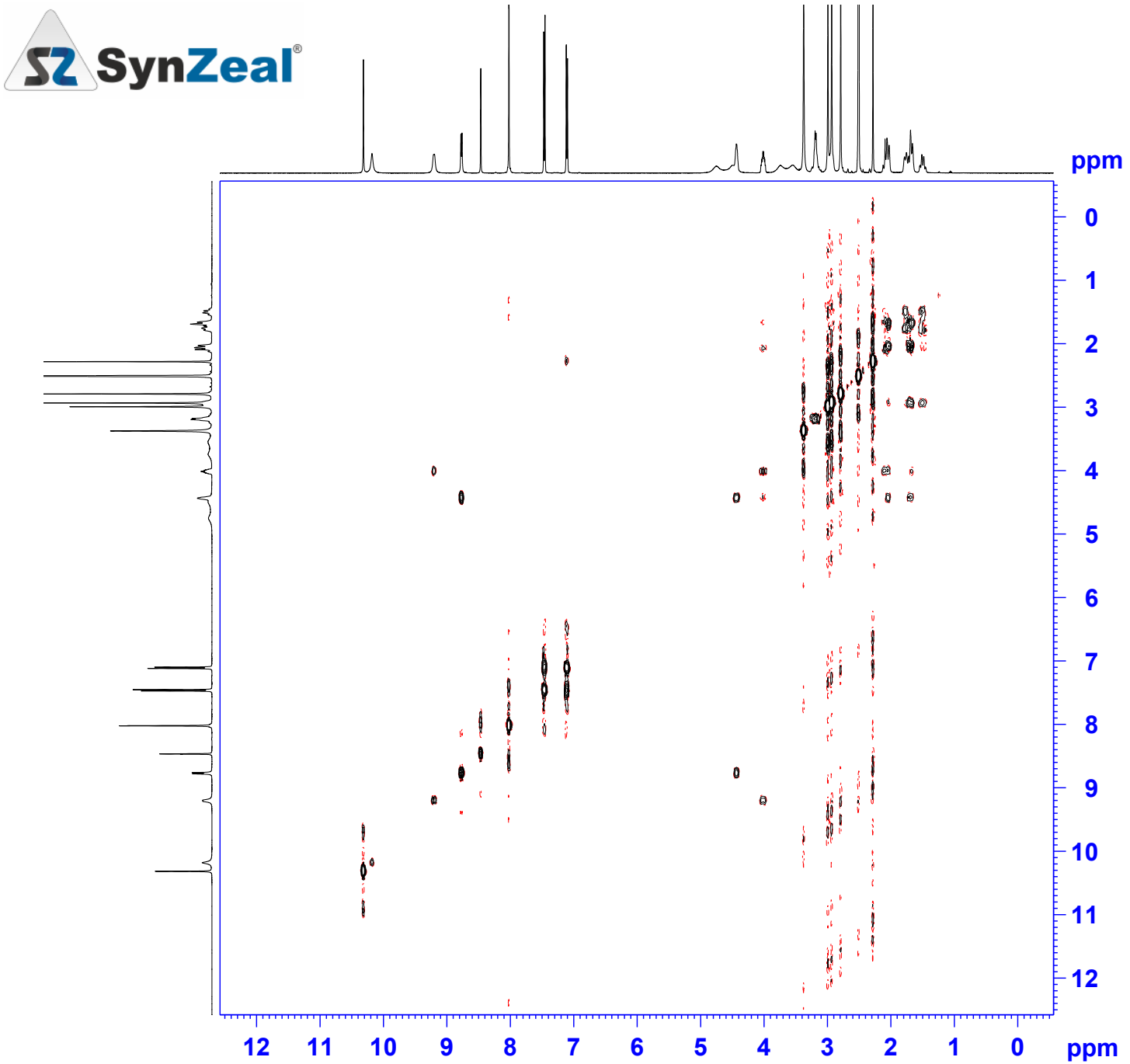
Chemical Formula -

Total Number of Proton -

Remarks -

Conclusion -

SynZeal Research Pvt.Ltd.
COSY SRL-1188-026 /DMSO-D6




```
Current Data Parameters
NAME        SRL-1188-026
EXPNO                  2
PROCNO                 1

F2 - Acquisition Parameters
Date_           20230211
Time              10.25 h
INSTRUM  Avance NEO 400
PROBHD   Z163739_0060 (
PULPROG       cosygpppqf
TD                 2048
SOLVENT            DMSO
NS                    1
DS                   16
SWH            5263.158 Hz
FIDRES         5.139802 Hz
AQ             0.1945600 sec
RG                   101
DW                95.000 usec
DE                 6.50 usec
TE                293.9 K
D0           0.00000300 sec
D1           2.00000000 sec
D11          0.03000000 sec
D12          0.00002000 sec
D13          0.00000400 sec
D16          0.00020000 sec
IN0          0.00019000 sec
TDav                  1
SFO1         400.1324008 MHz
NUC1                 1H
P0                10.00 usec
P1                10.00 usec
P17             2500.00 usec
PLW1         14.61900043 W
PLW10         1.62430000 W
GPNAM[1]      SMSQ10.100
GPZ1              10.00 %
P16             1000.00 usec

======== F1 INDIRECT DIMENSION ========
td1       128
sw_F1     13.153541

F1 - Acquisition parameters
TD                   128
SFO1           400.1324 MHz
FIDRES         82.236839 Hz
SW                13.154 ppm
FnMODE                QF

F2 - Processing parameters
SI                   1024
SF           400.1300000 MHz
WDW                 QSINE
SSB                     0
LB                      0 Hz
GB                      0
PC                   1.40

F1 - Processing parameters
SI                   1024
MC2                   QF
SF           400.1300000 MHz
WDW                 QSINE
SSB                     0
LB                      0 Hz
GB                      0
```