

CERTIFICATE OF ANALYSIS

Reference Standard

Product Name: Clopidogrel Bisulfate

Chemical Name: Methyl (2S)-(2-chlorophenyl)[6,7-dihydrothieno[3,2-c]pyridin-5(4H)-yl]acetate sulfate

Product information:

Product code: RLP-004

Lot No.: 170823-00401

Mol. Form: C₁₆H₁₆ClNO₂S·H₂SO₄

Mol. Wt.: 419.9g/mol

CAS Number: [120202-66-6]

QC Release Date: 04.01.2023

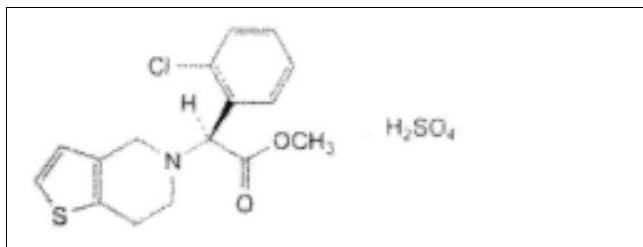
Recertified On: -

Retest due On: 03.01.2026

Long Term Storage: Store at 2-8 °C. Protect from moisture and light.

Shipping Condition: This product is stable to be shipped at ambient temperature.

Chemical structure:



Analytical Information

Characteristics	Test Results
Description	White powder
Melting Range	179.4-181.9°C
IR	Complies
Mass Spectroscopy	m/z 322.7 [M-H ₂ SO ₄] ⁺ Complies
¹ H NMR	Complies
¹³ C NMR	Complies
Residual solvents by NMR	0.14% of Acetone
Water content by KF	0.20%
Purity by HPLC	99.81%
Total Impurities (HPLC)	0.19%
Assay / Potency (as is)	99.5%

* The assay/potency (as is) is equivalent to the assay based of the not anhydrous and not dried substance respectively.

REFLABPHARM LLC

Chief Scientific Officer
Product Release

**System Information:**

Sample ID: 033400-2202

System Status: Good

File Location: BLR-WS-0133\SQLEXPRESS\VAIMDB_Public(000)\Public
Result\2022\Dec-2022\033400-2202_2022-12-27T11-59-38.a2r

PC/Workstation ID: FTIR-PC

Software Version: MicroLab PC(21CFR11): 5.3.1748.0

FW Version: 1.96.00.0

Data Information:

Method Name: Analytical

User: Group1\Project1\qc

Date/Time: 11-27-2022 11:59:38 AM

Instrumental Model: Carry 630

Instrument S/N: MY16402006

Reporting Information:

Report Template: Spectrum.docx

Report Generated By: Group1\Project1\qc

Report Generation Date: 2022-12-27T11:59:38.026+05:30

Report Generation GMT Date: 12-27-2022 6:30:05 AM

1227/2022 12:00:06 PM

Sample ID:033400-2202

Method Name:Analytical

Sample Scans:32

User:Group1\Project1\qc

Background Scans:32

Date/Time:12-27-2022 11:59:38 AM

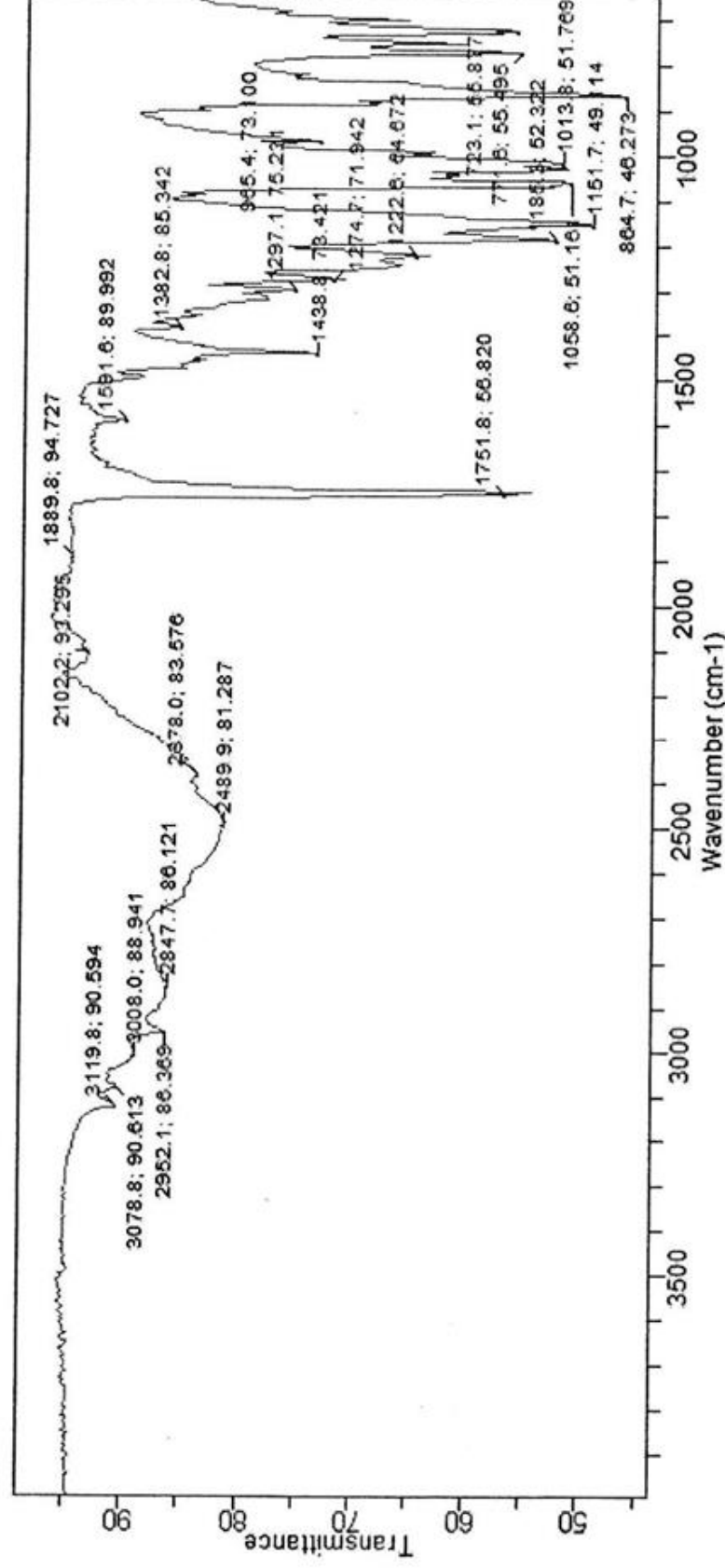
Resolution:8

Range:4000 - 650

System Status:Good

Apodization:Happ-Genzel

File Location: BLR-WS-0133\SQLXPRESS\VAIMDB_Public(000)|Public Results\2022\Dec-2022\

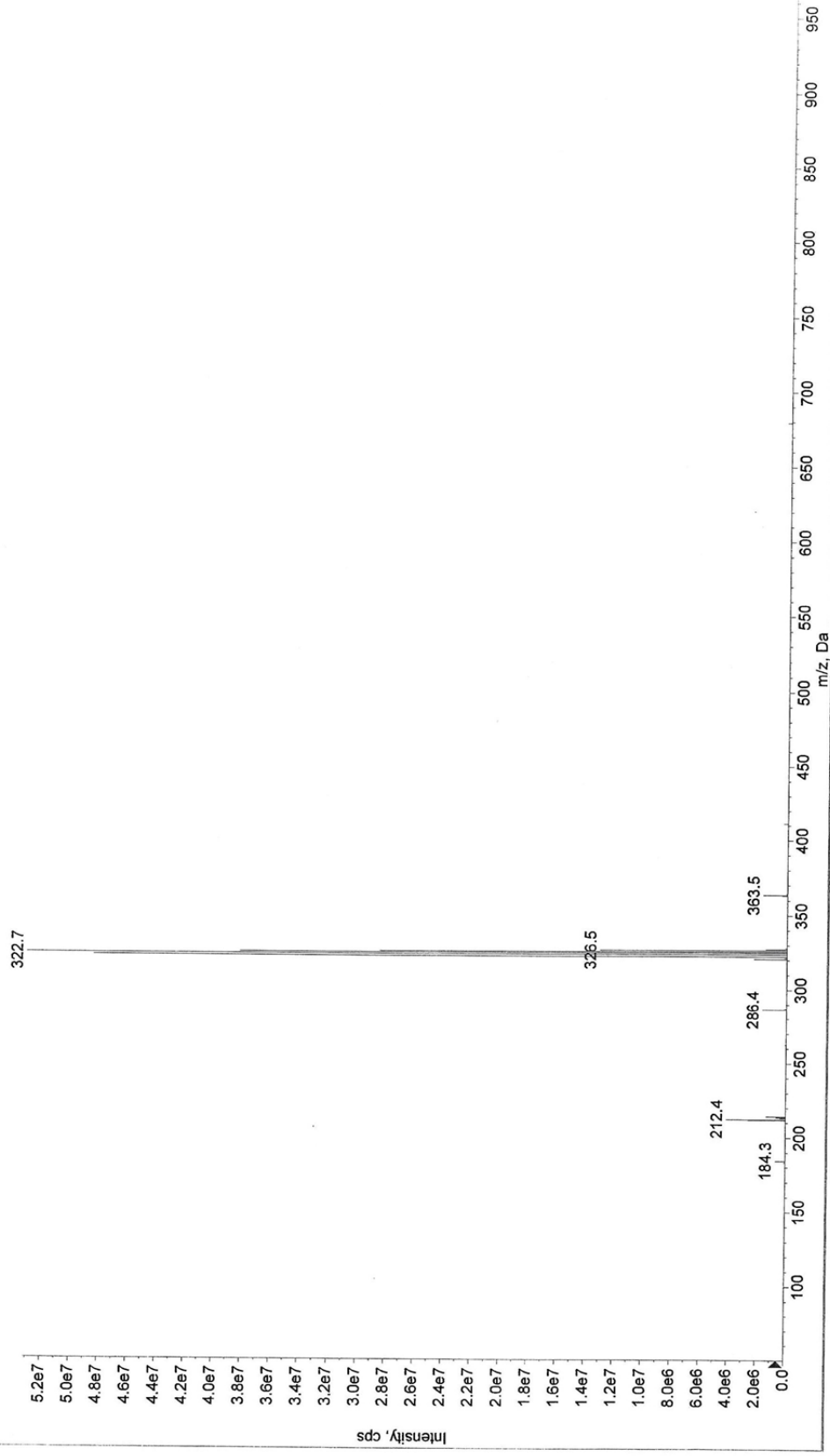


ANALYSED BY:

CHECKED BY:

■ +Q1: 2.679 min from Sample 19 (033400-2202) of 27122022.wiff (Turbo Spray), Centroided

Max. 5.3e7

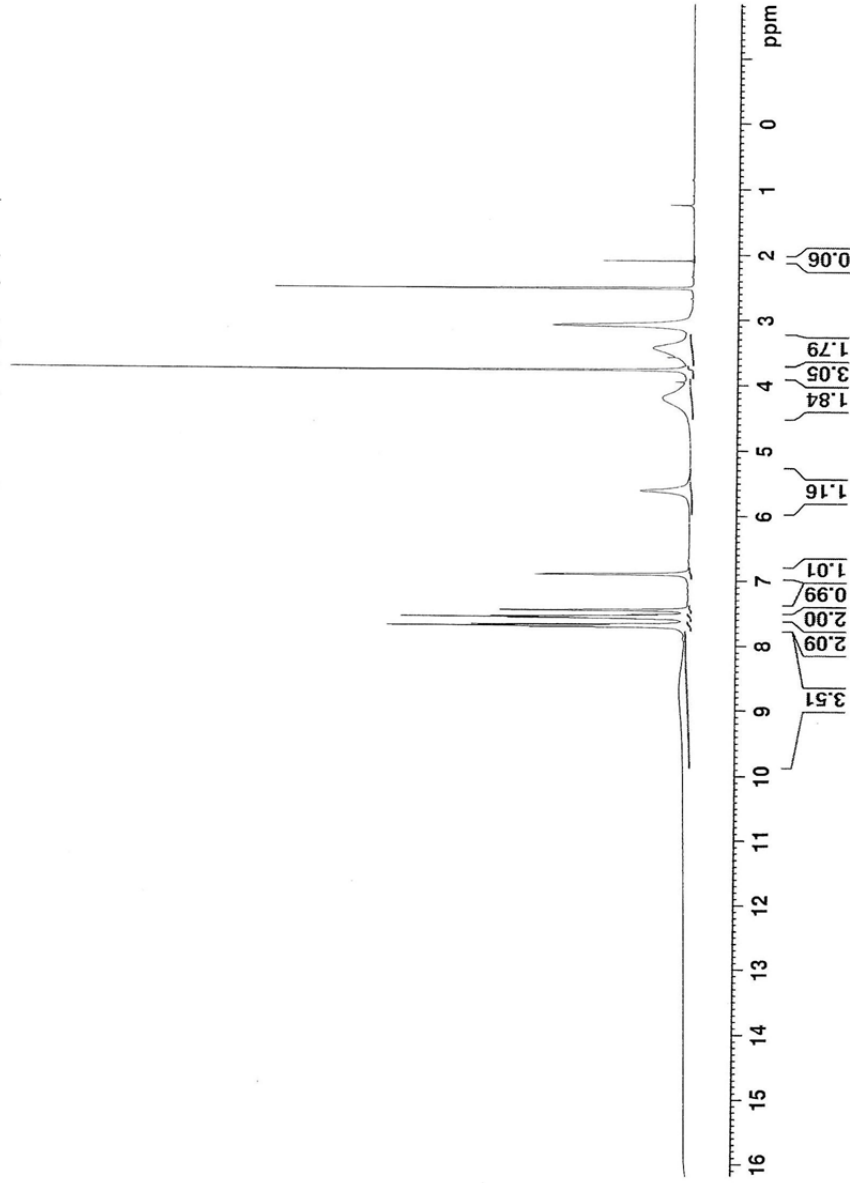


ANALYSED BY:

CHECKED BY:

033400-2202

8.67
7.71
7.70
7.69
7.68
7.66
7.58
7.57
7.56
7.55
7.54
7.53
7.52
7.45
7.44
6.90
6.89
5.61
4.19
3.76
3.44
3.07
2.52
2.51
2.51
2.50
2.50
2.09
1.24



Current Data Parameters
NAME 033400-2202
EXPNO 1
PROCNO 1

F2 - Acquisition Parameters
Date_ 20221228
Time 12.14
INSTRUM spect
PROBHD 5 mm PABBO BB/
PULPROG zg30
TD 65536
SOLVENT DMSO
NS 16
DS 2
SWH 8012.820 Hz
FIDRES 0.122266 Hz
AQ 4.089465 sec
RG 256
DW 62.400 usec
DE 6.50 usec
TE 297.4 K
D1 1.0000000 sec
TD0 1

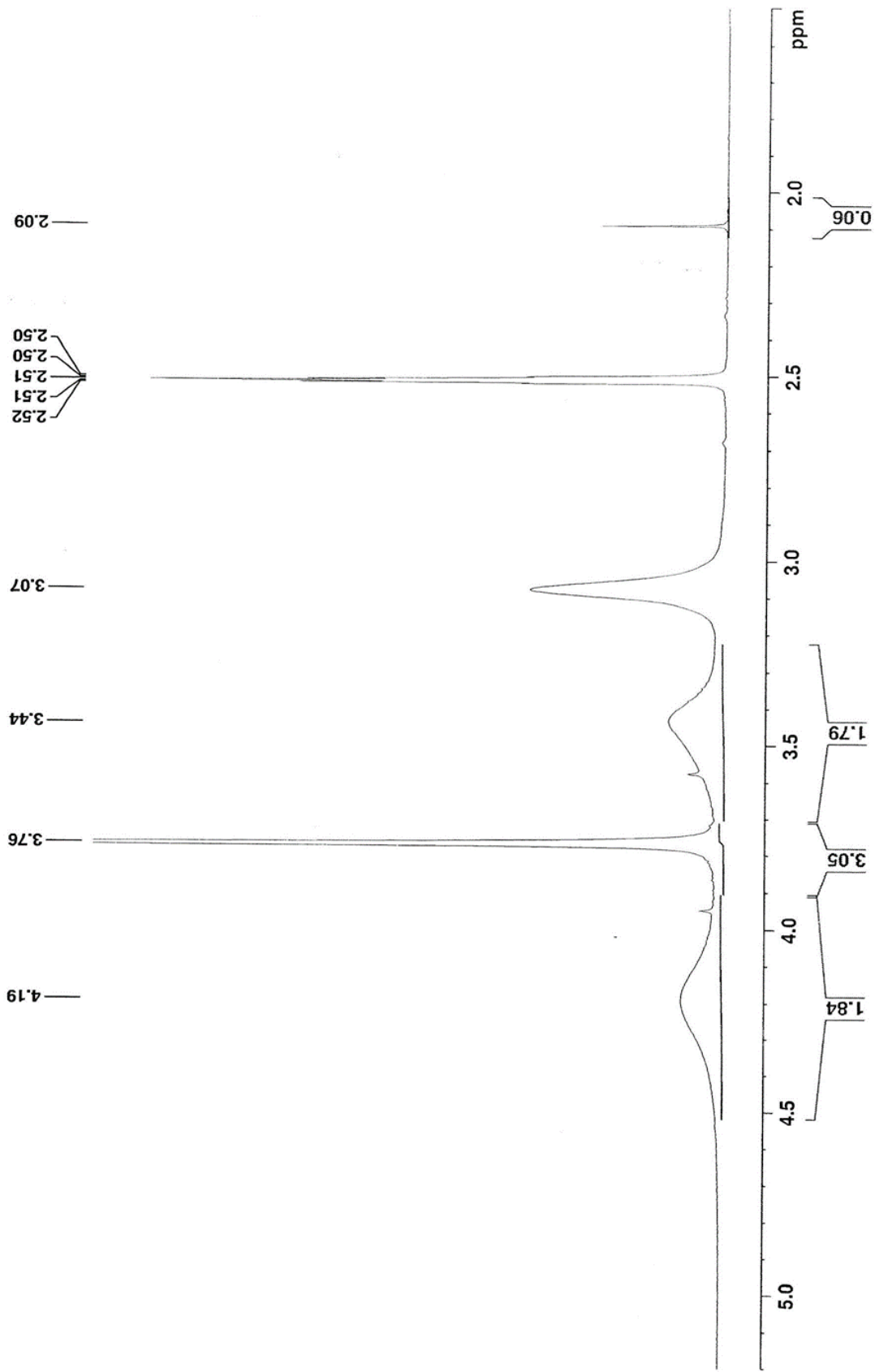
===== CHANNEL f1 =====
SFO1 400.1524711 MHz
NUC1 1H
P1 9.66 usec
PLW1 9.10000038 W

F2 - Processing parameters
SI 65536
SF 400.1500000 MHz
WDW EM
SSB 0
LB 0
GB 0
PC 1.00

ANALYSED BY:

CHECKED BY:

033400-2202



ANALYSED BY:

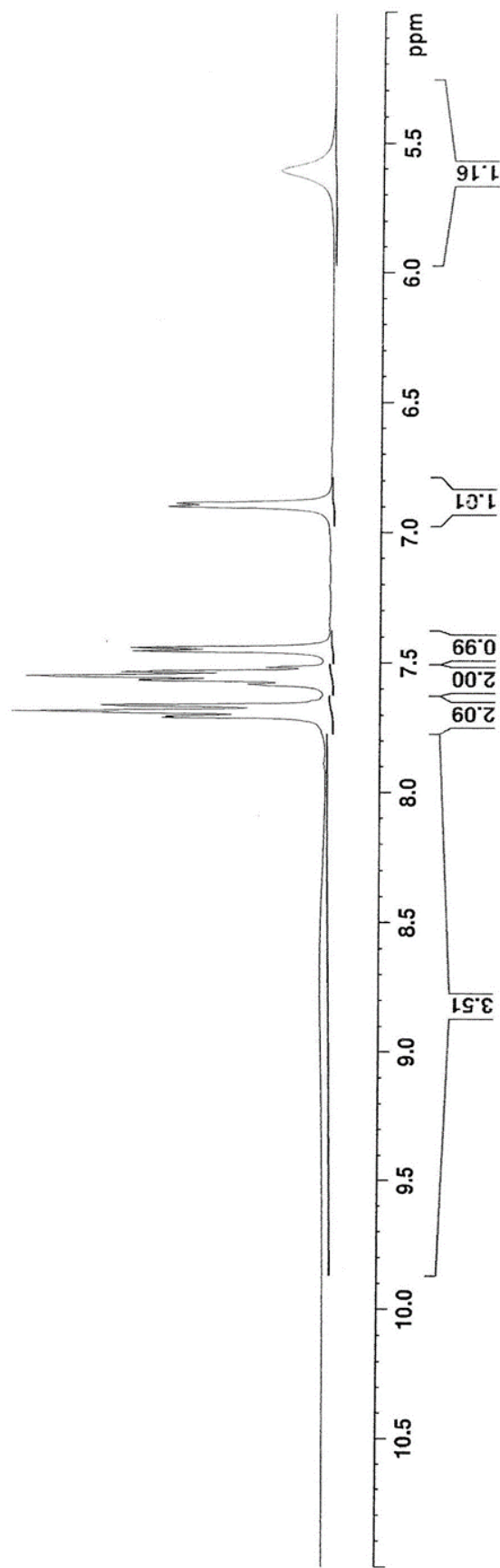
CHECKED BY:

033400-2202

7.71
7.70
7.69
7.68
7.66
7.58
7.57
7.56
7.55
7.54
7.53
7.52
7.45
7.44
6.90
6.89

8.67

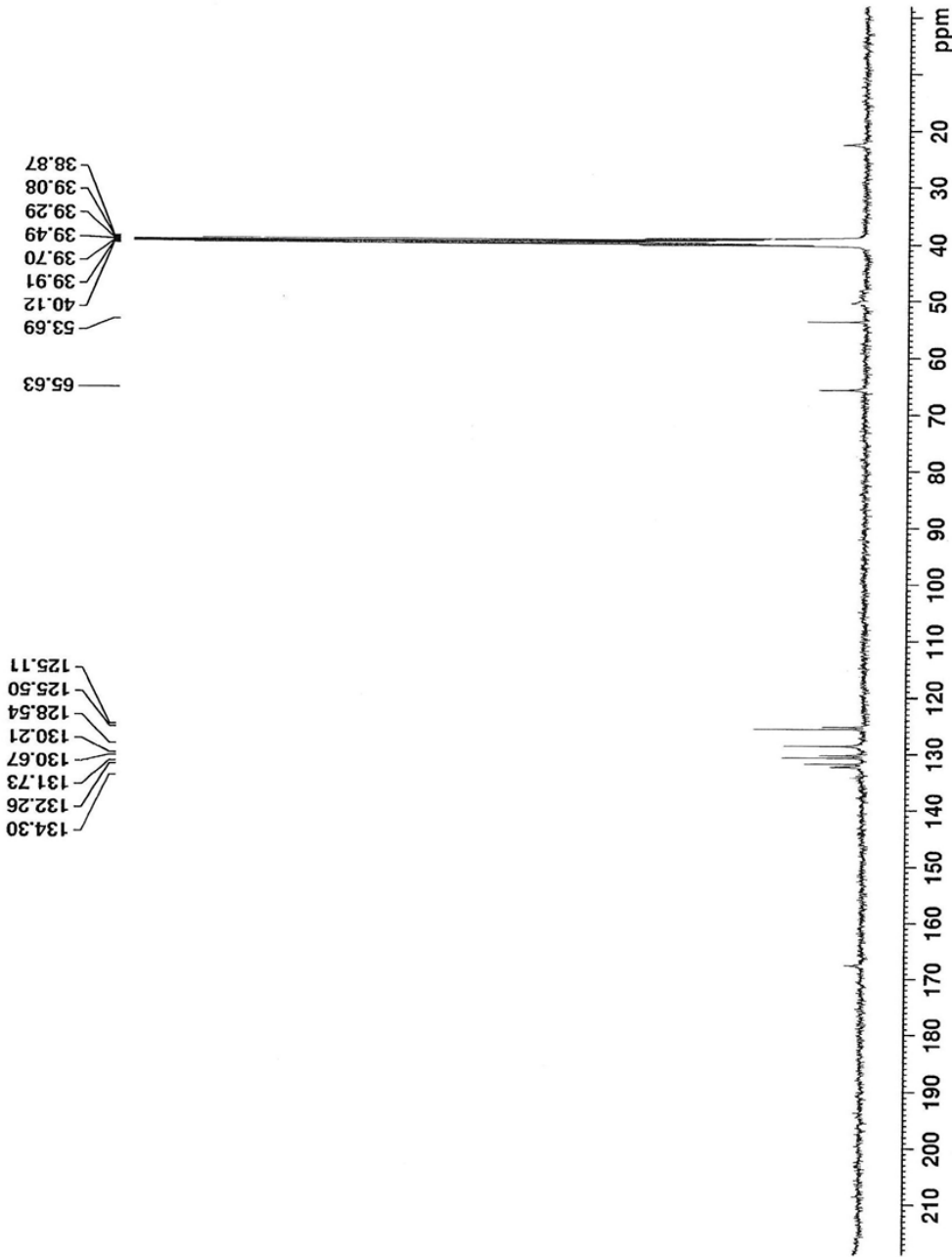
5.61



CHECKED BY:

ANALYSED BY:

033400-2202 13C



Current Data Parameters
 NAME 033400-2202 13C
 EXPNO 2
 PROCNO 1

F2 - Acquisition Parameters
 Date_ 20230103
 Time 10.46
 INSTRUM spect
 PROBHD 5 mm PABBO BB/
 PULPROG zgpg30
 TD 65536
 SOLVENT DMSO
 NS 600
 DS 4
 SWH 24038.461 Hz
 FIDRES 0.366796 Hz
 AQ 1.3631486 sec
 RG 724
 DW 20.800 usec
 DE 6.50 usec
 TE 297.9 K
 D1 2.00000000 sec
 D11 0.03000000 sec
 TD0 1

===== CHANNEL f1 =====
 SFO1 100.6278588 MHz
 NUC1 13C
 P1 9.00 usec
 PLW1 38.00000000 W

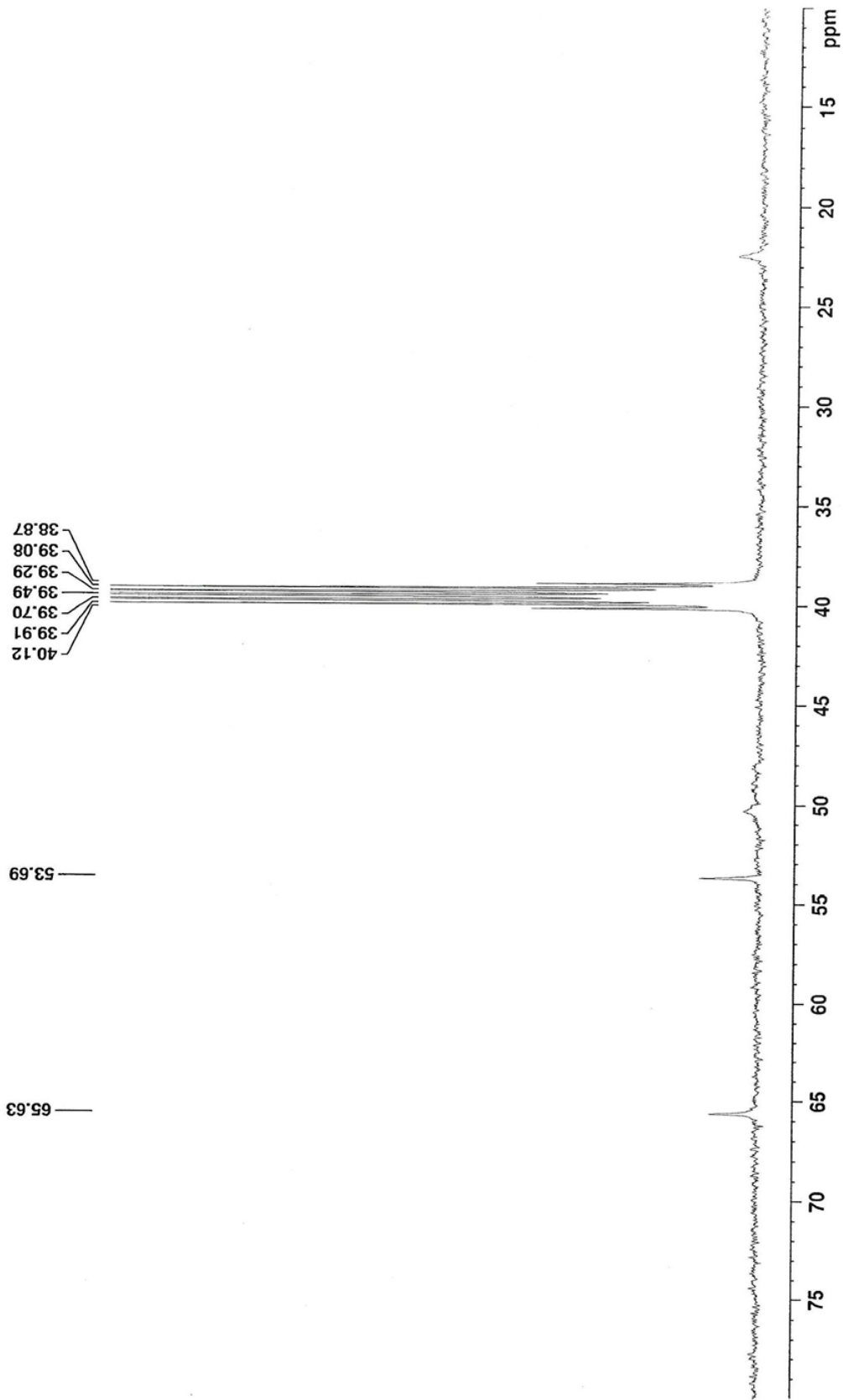
===== CHANNEL f2 =====
 SFO2 400.1516006 MHz
 NUC2 1H
 CPDPRG12 waltz16
 FCPD2 90.00 usec
 PLW2 9.10000038 W
 PLW12 0.10462000 W
 PLW13 0.05262300 W

F2 - Processing parameters
 SI 32768
 SF 100.6178453 MHz
 WDW EM
 SSB 0
 LB 3.00 Hz
 GB 0
 PC 1.40

ANALYSED BY:

CHECKED BY:

033400-2202 13C



CHECKED BY:

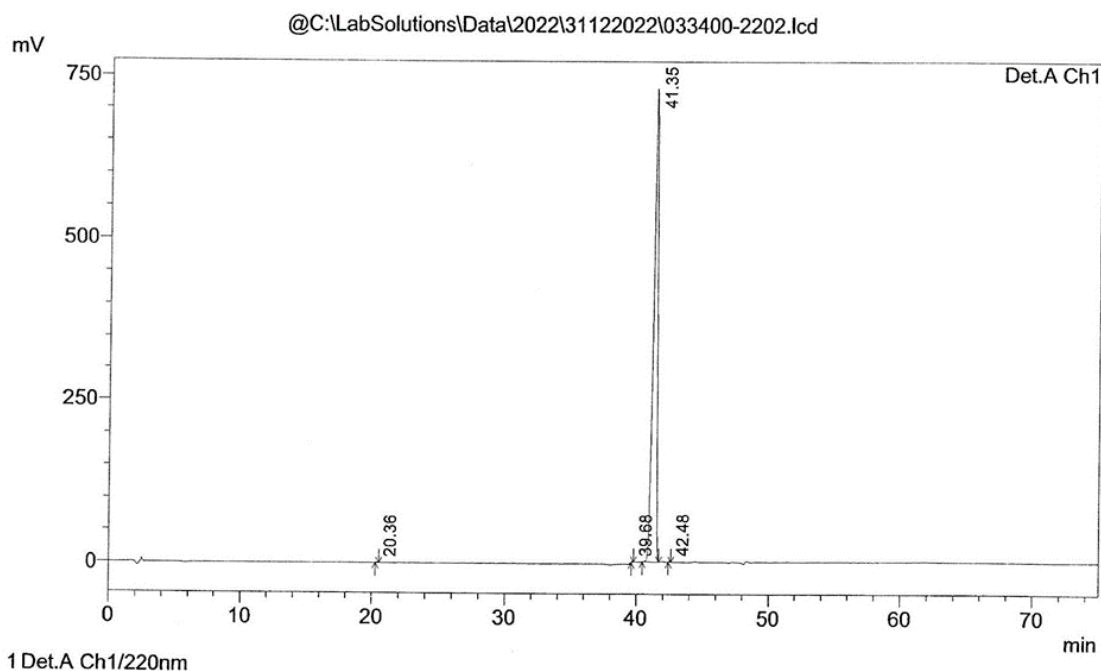
ANALYSED BY:

Injection Volume : 10 µL
 Data File Name : 033400-2202.lcd
 Data Acquired : 12/31/2022 15:08
 Data Processed : 1/2/2023 09:34

Column : Puritas Eximius C18 ,150x 4.6 mm ,5µ
 Mobile phase A : Mix 5 vol. of Methanol and 95 vol. of a 0.96 g/L solution of sodium pentane sulfonate monohydrate adjusted to pH 2.5 with phosphoric acid.
 Mobile phase B : Methanol, Acetonitrile(5:95v/v)
 Pump mode : Gradient

TIME	MP-A	MP-B
0-3 min	89.5	10.5
3-48 min	89.5-31.5	10.5-68.5
48-68 min	31.5	68.5
68-70 min	31.5-89.5	68.5-10.5
70-75 min	89.5	10.5

 Flow rate : 1.0 ml/min
 Sample conc. : 1.0 mg/ml.
 Diluent : Acetonitrile,water(70:30v/v)
 Column Temp.: Ambient.



Detector A Ch1 220nm

Peak#	Ret. Time	Area	Area %
1	20.36	11298	0.07
2	39.68	9940	0.07
3	41.35	15163933	99.81
4	42.48	6975	0.05
Total		15192146	100.00

ANALYSED BY:

CHECKED BY: