



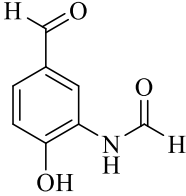
Certificate of Analysis

Certificate No:20220812001

Date: 20220811

Retest date:20250810

Compound: Formoterol Impurity 22

Synonyms:	N-(5-formyl-2-hydroxyphenyl)formamide	
Catalogue Number:	FL-015014	
CAS Number:	903563-43-9	
Molecular Weight:	165.15	
Molecular Formula:	C ₈ H ₇ NO ₃	
Source:	WZX	
Source Lot No.:	5095-171A3	
Storage Conditions:	Store at -10°C to -20°C	
Solubility:	Soluble in methanol	

Test Description	Specifications	Results
Visual Description	Yellow solid	Conforms
Identification		
MS	Conforms to structure	Conforms
HNMR	Conforms to structure	Conforms
Purity(HPLC)	Not less than 95.0%	99.4503%
Water Content(KF)	0.175%	
Residual Solvents(NMR)	0.3303% of acetonitrile	
Assay(%)	Not less than 90.0%	95.81%
Recommendation		

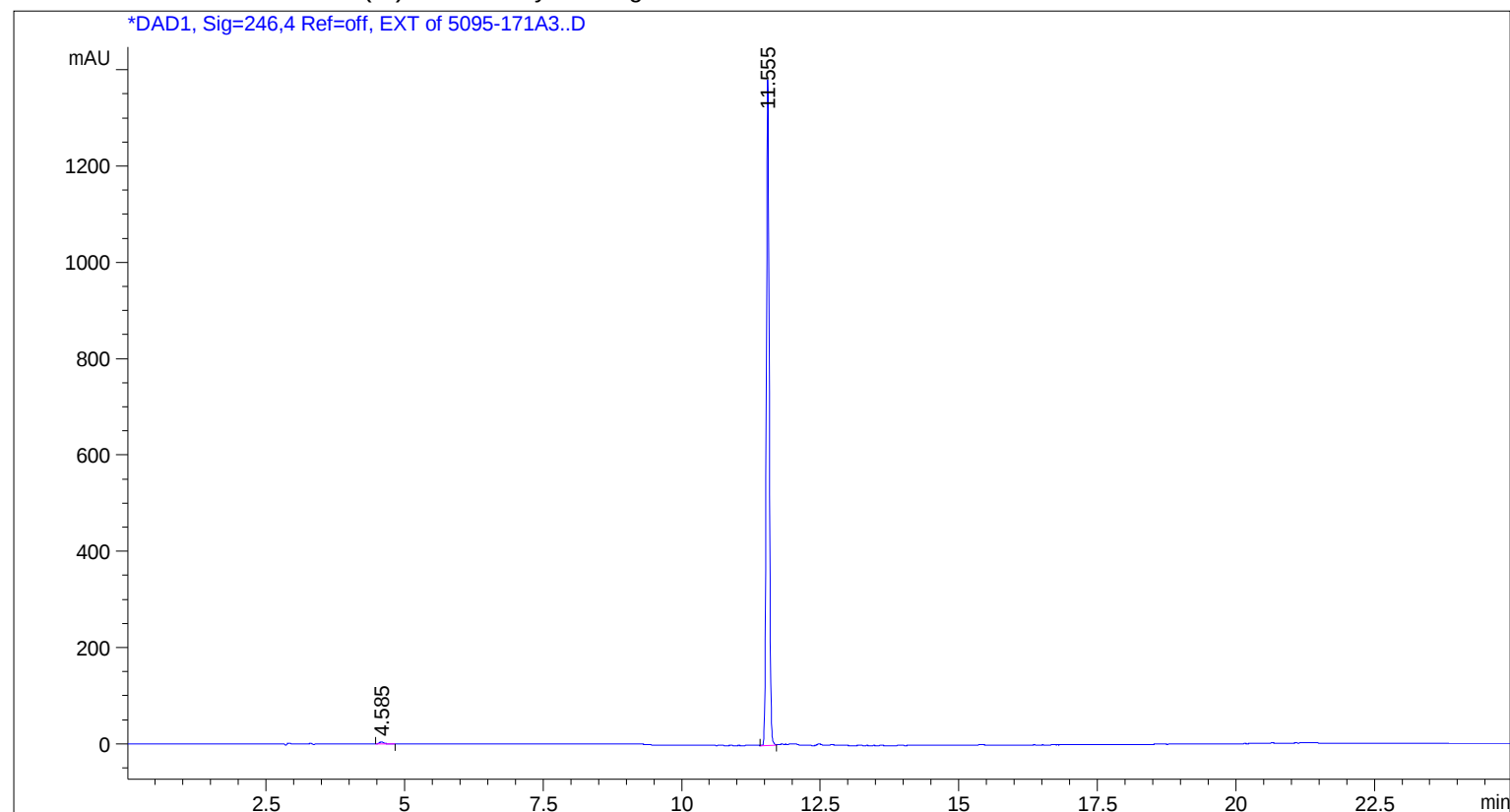
	Department	Signature	Date
Reviewed and approved by:	Quality Control	Liu Tingting	20221201
Approved by:	Quality Assurance		

Attachments HPLC, MS, TGA, KF, qNMR and NMR spectra.

Sample Name: 5095-171A3.

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :   10
Acq. Instrument : 1100-2                     Location  :    84
Injection Date  : 8/11/2022 3:50:10 PM       Inj       :    1
                                           Inj Volume: 5.000 µl
Different Inj Volume from Sample Entry! Actual Inj Volume : 0.300 µl
Acq. Method     : D:\HPLC\2022\20220811\1 1\5-95-25min-acid.M
Last changed    : 8/11/2022 10:57:28 AM by SYSTEM
Analysis Method : D:\HPLC\2022\20220811\1 1\5-95-25min-acid.M (Sequence Method)
Last changed    : 8/11/2022 5:00:10 PM by SYSTEM
                  (modified after loading)
Sample Info     : Waters XBridge-C18 (4.6*250mm,5.0um); F=1.0mL/min; T=25degree;
                  CH3CN/10mmol/L NaH2PO4+0.05%H3PO4=5/95(0-5min),5/95-95/5(5-18min),95/5(18-
                  22min),95/5-5/95(22min-25min)
=====
```

Additional Info : Peak(s) manually integrated



```
=====
                          Area Percent Report
=====
```

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

```
Signal 1: DAD1, Sig=246,4 Ref=off, EXT
Signal has been modified after loading from rawdata file!
```

Sample Name: Blank for 5095-171A3.

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	4.585	BV	0.0902	28.15769	4.54729	0.5497
2	11.555	BV	0.0570	5094.30420	1383.30615	99.4503

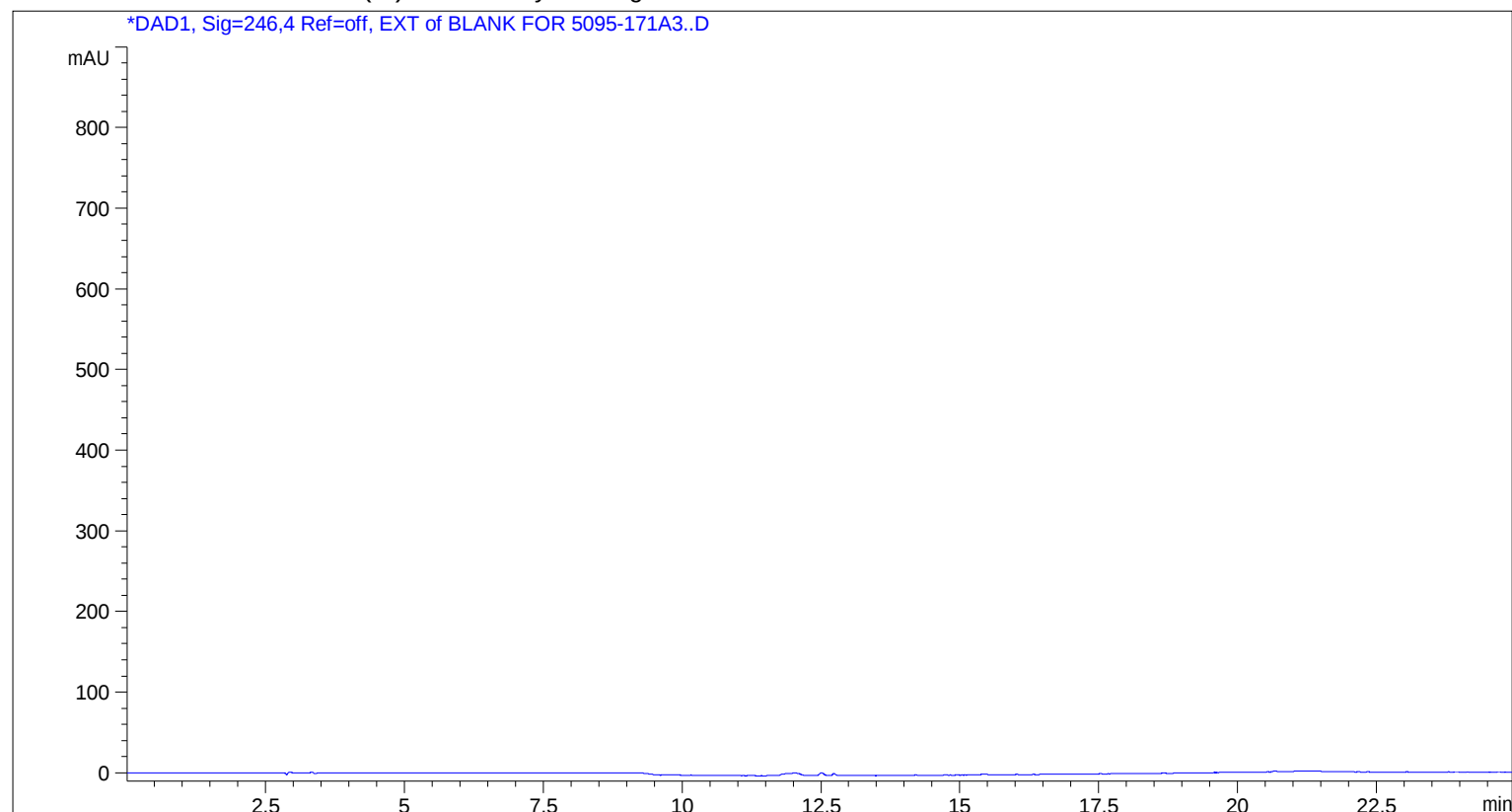
Totals : 5122.46189 1387.85344

*** End of Report ***

Sample Name: Blank for 5095-171A3.

```
=====
Acq. Operator   : SYSTEM                      Seq. Line :   10
Acq. Instrument : 1100-2                     Location  :    84
Injection Date  : 8/11/2022 3:50:10 PM        Inj       :    1
                                           Inj Volume: 5.000 µl
Different Inj Volume from Sample Entry! Actual Inj Volume : 0.300 µl
Acq. Method     : D:\HPLC\2022\20220811\1 1\5-95-25min-acid.M
Last changed    : 8/11/2022 10:57:28 AM by SYSTEM
Analysis Method : D:\HPLC\2022\20220811\1 1\5-95-25min-acid.M (Sequence Method)
Last changed    : 8/11/2022 5:03:21 PM by SYSTEM
                  (modified after loading)
Sample Info     : Waters XBridge-C18 (4.6*250mm,5.0um); F=1.0mL/min; T=25degree;
                  CH3CN/10mmol/L NaH2PO4+0.05%H3PO4=5/95(0-5min),5/95-95/5(5-18min),95/5(18-
                  22min),95/5-5/95(22min-25min)
=====
```

Additional Info : Peak(s) manually integrated



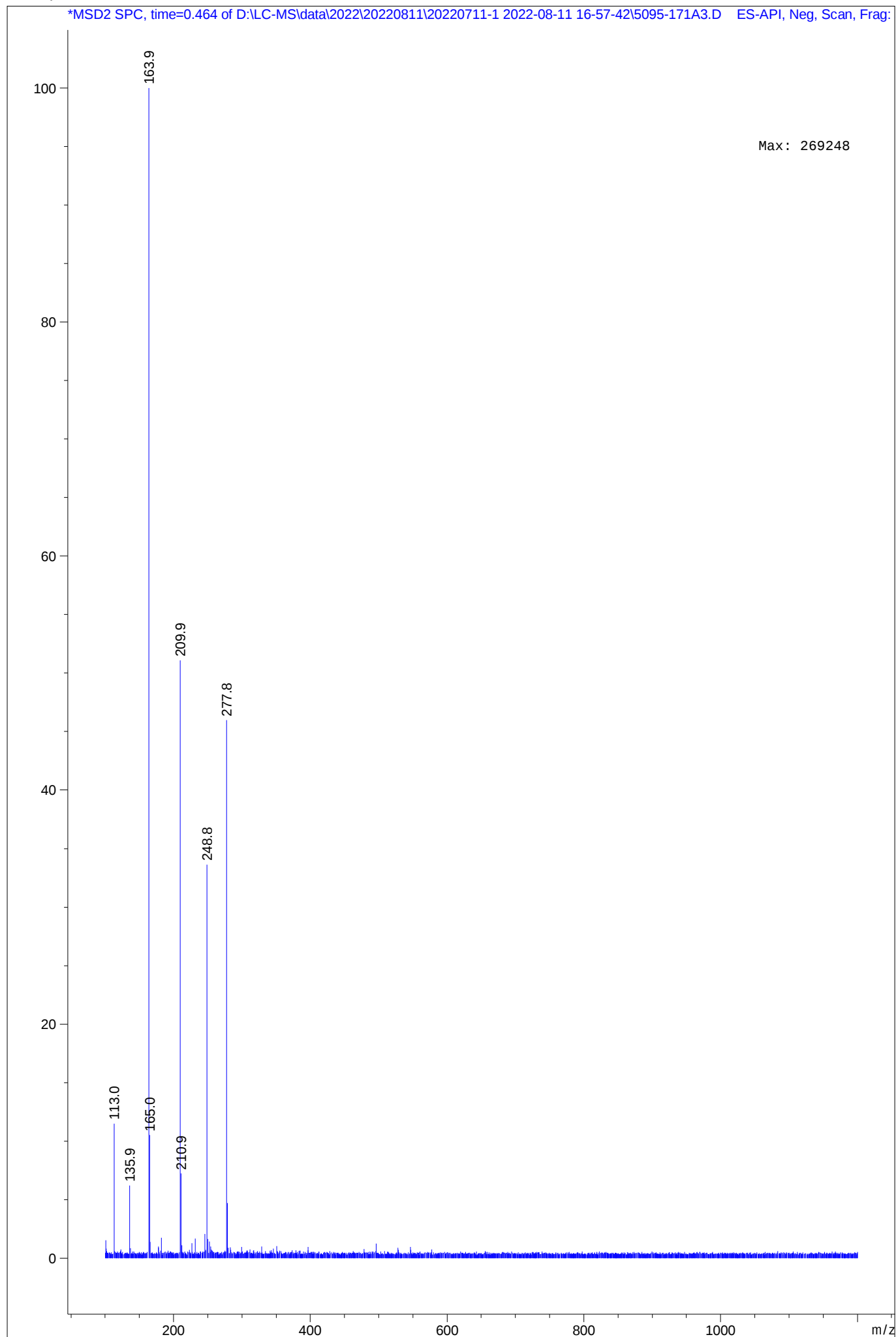
```
=====
                          Area Percent Report
=====
```

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

No peaks found

```
=====
*** End of Report ***
```

MS Spectrum

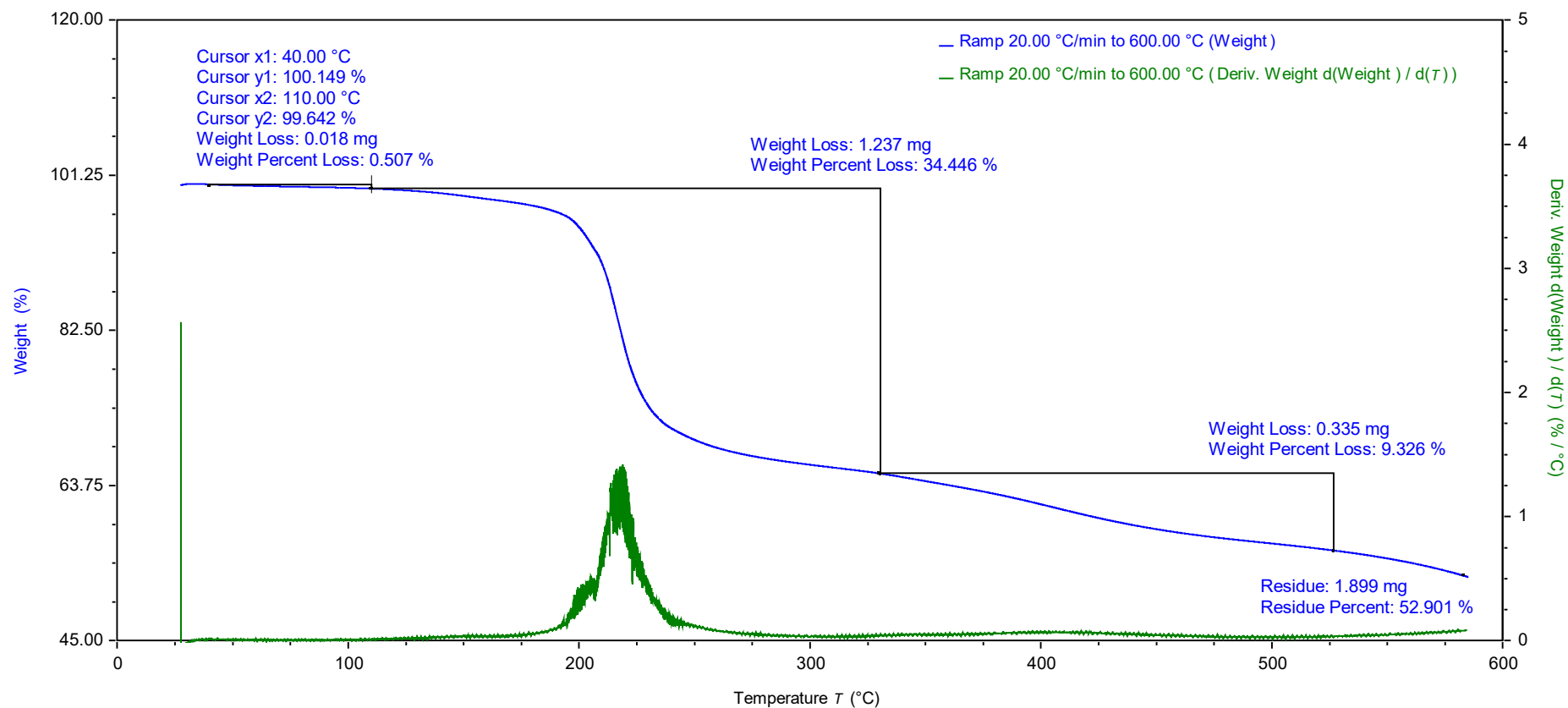


5095-171A3

TGA55,2022/9/13 15:34:22
3.59048 mg
Platinum HT

LTT
D:\TGA_2022.9.13\5095-171A3.tri

5095-171A3



南京望知星医药科技有限公司

ANALYTICAL SUMMARY

Sample Lot No.: 5095-171A3
Test Sample Amount: 11.1mg
Testing Date: 20220914
Instrument: ZSD-2J

TEST	METHOD	LIMIT	RESULT
Water Content	Coulometric KF	N/A	0.175%
TEST BY: Zhaohui Wang		APPROVED BY: Tingting Liu	



Analytical Report

Test Item: QNMR

Instrument: Bruker BioSpin GmbH

Sample ID: 5095-171A3

MW: 165.15

Compound ID: N/A

Internal Standard(ISTD): Maleic acid (99.80%)

MW: 116.07

Solvent: DMSO-d6

The peak for quantitative of sample: 7.03-7.06

1H

The peak for quantitative of standard:

6.26

2H

Results:

NO.	W _{Sam} (mg)	W _{ISTD} (mg)	A _{Sam} /A _{ISTD}	W _{Sam} %	Average(W%)	RSD(%)
1	3.06	0.29	1.0000/0.2826	95.24	95.81	0.84
2	3.14	0.32	1.0000/0.3003	96.38		

Note: The result of RSD should be less than or equal to 2.0%

Formula for calculation

$$W\% = \frac{W_{ISTD}}{W_{Sam}} \times \frac{A_{Sam}}{A_{ISTD}} \times \frac{MW_{Sam}}{MW_{ISTD}} \times \frac{n_{ISTD}}{n_{Sam}} \times W_{ISTD}\%$$

Among the formula:

W_{ISTD} is the weight of ISTD (mg);

W_{Sam} is the weight of sample (mg);

A_{Sam}/A_{ISTD} is the area ratio between sample and ISTD;

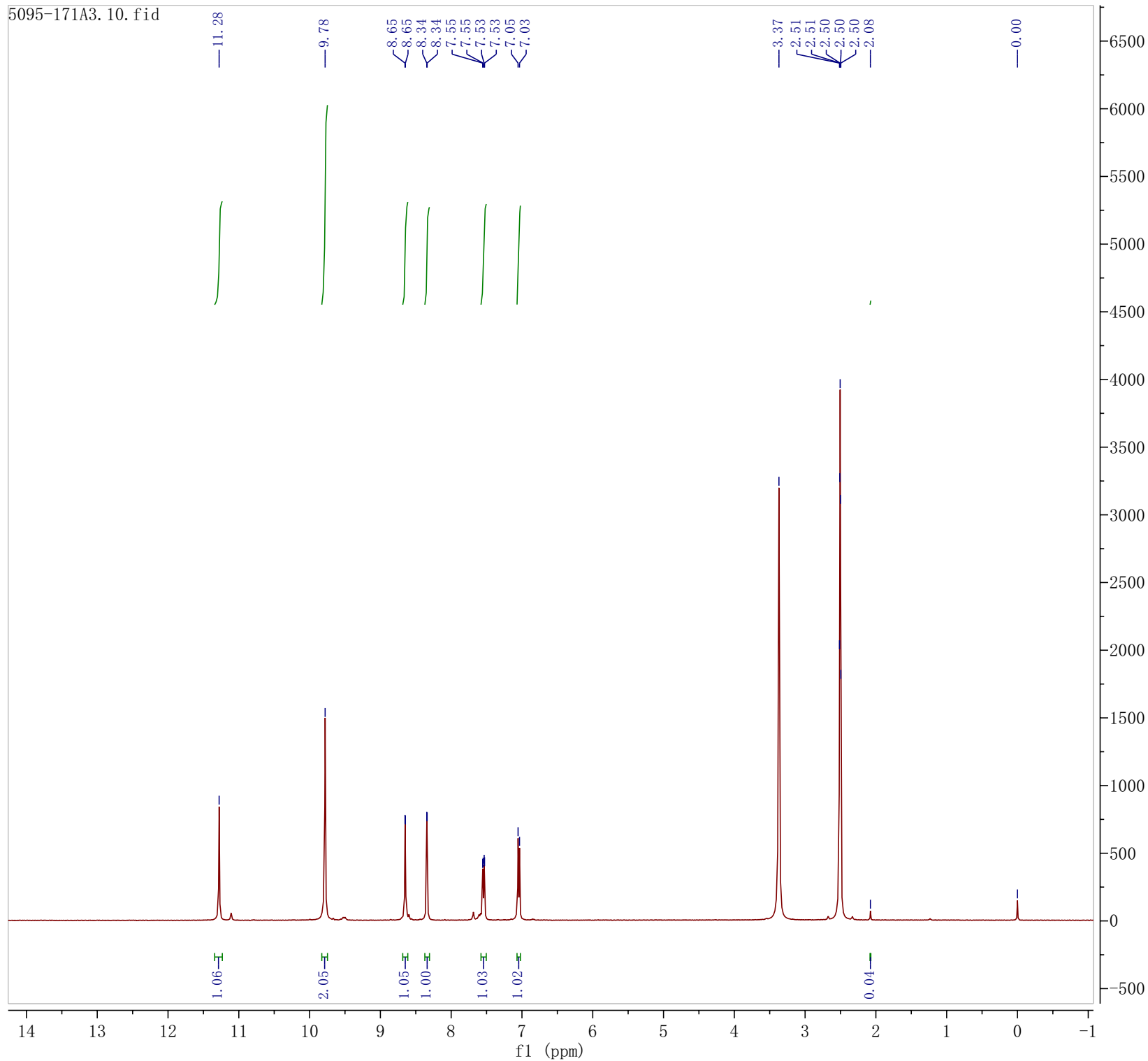
MW_{Sam} is the molecular weight of sample;

MW_{ISTD} is the molecular weight of ISTD;

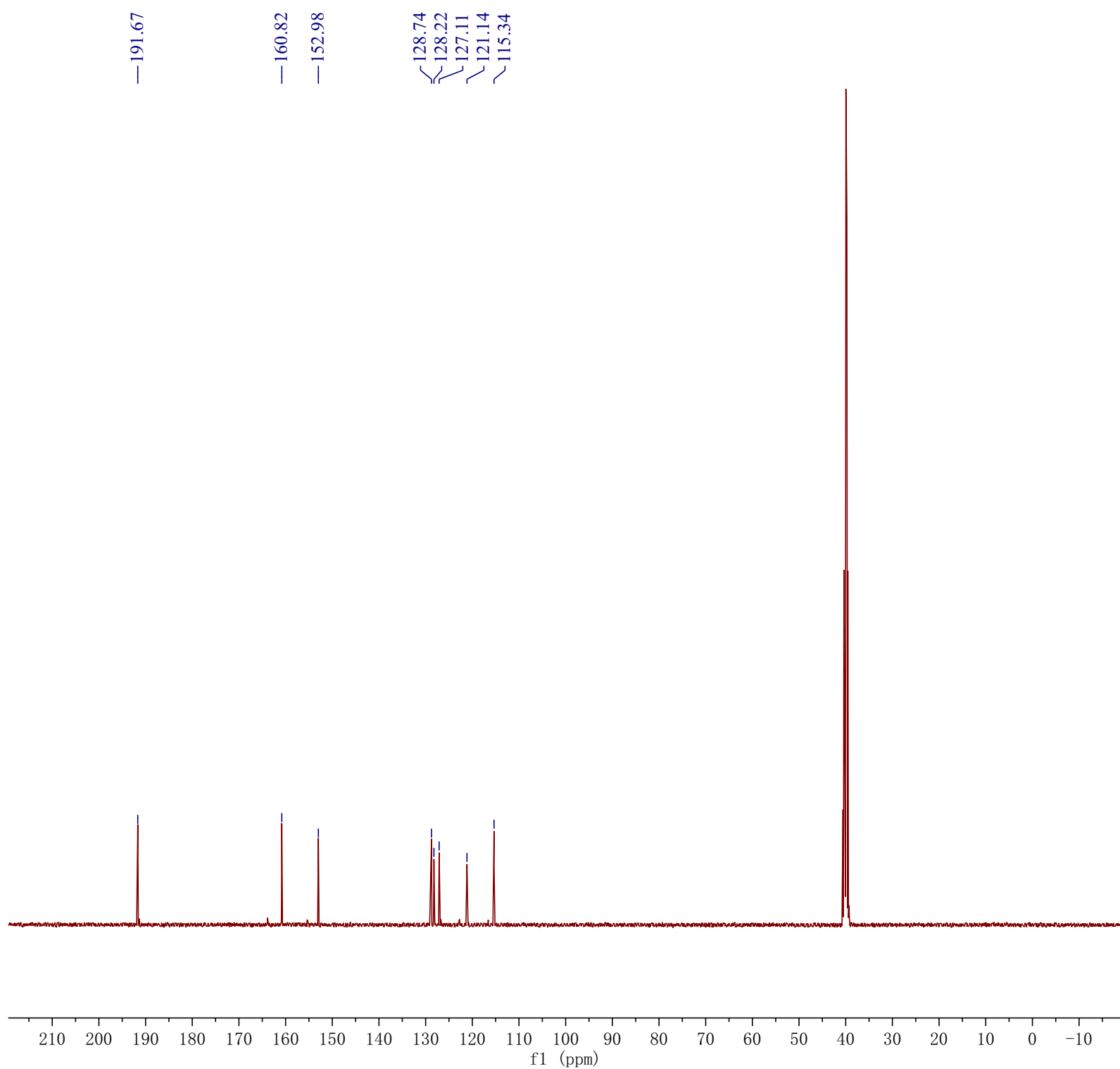
n_{ISTD} and n_{Sam} are the number of protons in the respective functional groups;

W_{ISTD}% is the weight percentage of ISTD.

5095-171A3.10.fid



Parameter	Value
1 Data File Name	C:/5095-171A3/ 10/ fid
2 Title	5095-171A3.10.fid
3 Comment	
4 Origin	Bruker BioSpin GmbH
5 Owner	root
6 Site	
7 Instrument	spect
8 Author	
9 Solvent	DMSO
10 Temperature	296.1
11 Pulse Sequence	zg30
12 Experiment	1D
13 Probe	Z116098_0538 (PA BBO 400S1 BBF-H-D-05 Z SP)
14 Number of Scans	16
15 Receiver Gain	78.9
16 Relaxation Delay	1.0000
17 Pulse Width	9.6000
18 Presaturation Frequency	
19 Acquisition Time	4.0894
20 Acquisition Date	2022-08-11T15:51:42
21 Modification Date	2022-08-11T15:51:42
22 Class	
23 Spectrometer Frequency	400.15
24 Spectral Width	8012.8
25 Lowest Frequency	-1536.9
26 Nucleus	1H
27 Acquired Size	32768
28 Spectral Size	65536



Parameter	Value
1 Data File Name	D:5095-171A3/ 20/ fid
2 Title	5095-171A3.20. fid
3 Comment	
4 Origin	Bruker BioSpin GmbH
5 Owner	root
6 Site	
7 Instrument	spect
8 Author	
9 Solvent	DMSO
10 Temperature	296.2
11 Pulse Sequence	zgpg30
12 Experiment	1D
13 Probe	Z116098_0538 (PA BBO 400S1 BBF-H-D-05 Z SP)
14 Number of Scans	1024
15 Receiver Gain	200.8
16 Relaxation Delay	2.0000
17 Pulse Width	10.0900
18 Presaturation Frequency	
19 Acquisition Time	1.3631
20 Acquisition Date	2022-08-16T19:54:02
21 Modification Date	2022-08-16T19:54:02
22 Class	
23 Spectrometer Frequency	100.63
24 Spectral Width	24038.5
25 Lowest Frequency	-1957.5
26 Nucleus	13C
27 Acquired Size	32768
28 Spectral Size	65536