



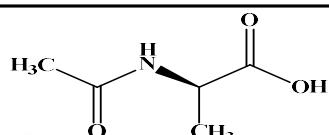
**GlobeSynth
Pharma Tech**

GlobeSynth Pharma Tech

Registered Office :

Plot No 7/8, Ward No 7, Street - Ettimarathupallam,
Soolaimedu, uthamasolapuram, Salem 636010. Tamil Nadu, India
Mob : +91 82830 85118 / +91 91157 96473
E-Mail : contact@gspharma.tech, info@gspharma.tech
Web : www.gspharma.tech

Certificate Of Analysis

Catalogue Name	N-Acetyl-D-alanine		
Product Category	OXYGEN-FUNCTION AMINO-COMPOUNDS ; STANDARDS		
Chemical Name / Synonyms	Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid ; Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetyl-amino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamido-propanoic acid		
Catalog Number	GS.NADA.00	Chemical Structure 	
Batch Number	GS-NAA-02100		
CAS Number	19436-52-3		
Manufacturing Date	10.02.2021		
Mol. Weight	131.13	Description	White to Off White Powder
Mol. Formula	C5H9NO3	Solubility	Methanol, DMSO, MDC
Date of Analysis	17.02.2021	Residual solvents	Method 'H-NMR
Retest Date	17.02.2022	Result (n = 1) 'H-NMR No significant amounts of residual solvents were detected and it is (< 0.05 %)	
Storage conditions	Store in a tight container at Room Temp. For long term storage keep in between 2-8°C temperature (Refrigerator).		

I. Identity

S.No	Test'(s)	Specification	Results
1	Purity(%) TLC	NLT 98%	Conforms ≥98% (TLC) (Attached)
2	Quantitative assay by NMR	NLT 97%	Conforms Assay in % 97.721 (Attached)
3	IR	To conform to structure	Conforms (Spectra Attached)
4	HNMR	To conform to structure	Conforms (Spectra Attached)
5	Mass/LC MS	To conform to structure	Conforms (Spectra Attached)
6	C13 NMR	To conform to structure	Conforms (Spectra Attached)
7	Elemental Analysis (CHN)	Carbon 44.8-46.8% Nitrogen 10.4-11.1%	Conforms C _{45.8} % N _{10.82} % (Spectra Attached)
8	Specific Optical Rotation	c = 1, H ₂ O, 25 deg C 60-66	61.5 (Attached)
9	LOD with (TGA)	Maximum 0.5 %	0.2% (Attached)
10	Loss on drying	Maximum 0.5 %	0.12% (Attached)
11	Residue on Ignition	Maximum 0.1 %	0.001% (Attached)
12	Heavy Metals	Maximum 10 ppm	Complies (Results Attached)
13	Assay By Potentiometric Titration	NLT 98%	99.7% (Attached)
14	Microbial enumeration & BET	1. Total Aerobic Microbial count 2. Total Yeast and Mould 3. E.Coli 4. Staphylococcus Aureus 5. Salmonella sp. 6. Pseudomonas Aeruginosa	Complies (Results Attached)

Application(s)	Differentiation and characterization of D-aminoacylase(s)/amidohydrolase(s) and study of aglycon pocket specific binding on vancomycin.				
Product Shipment Date:	N/A	Pack Size:	500 GM	Vial(s)	1*500 GM

This certificate is valid for one year from the date of shipment provided the substance is stored under the recommended conditions. (Note: Use for research and Analytical purpose only)

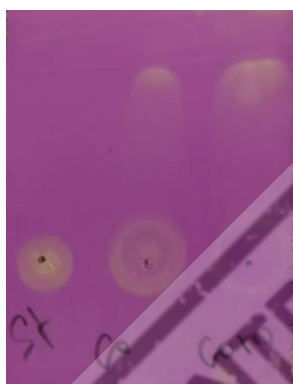
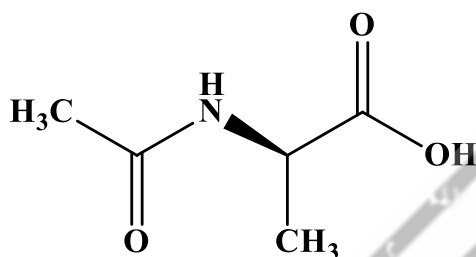
Prepared By	Checked By	Approved By
Mr. R. Mani (Sr. Executive)	Mr. Nandalal Mali (Jr. Scientist)	Mr. Mohamed Rafi (Head R&D)

TLC DETAILS OF N-ACETYL-D-ALANINE

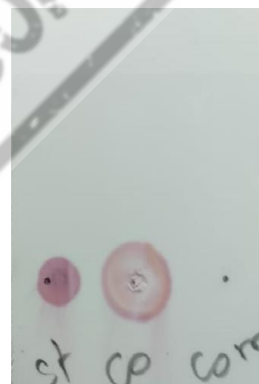
Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



MOBILE PHASE
ETHANOL(20%) : ETHYL ACETATE (80%)
KMnO₄ STAIN



MOBILE PHASE
ETHANOL(20%) : ETHYL ACETATE (80%)
Ninhydrin STAIN

In compound spot ninhydrin solution does not develop the colour

Ninhydrin test shows free amine from D-alanine turns purple and in title compound spot does not develop the colour. Product confirms.

TLC Purity seems to be NLT 98%

Results: Conforms

Checked By

Approved By

GS-NAA-02100 QNMR
NMR Internal Standard: Maleic acid
Molecular Weight: 116.07 g/mol
Weight taken: 7.269mg
Potency :99.98%

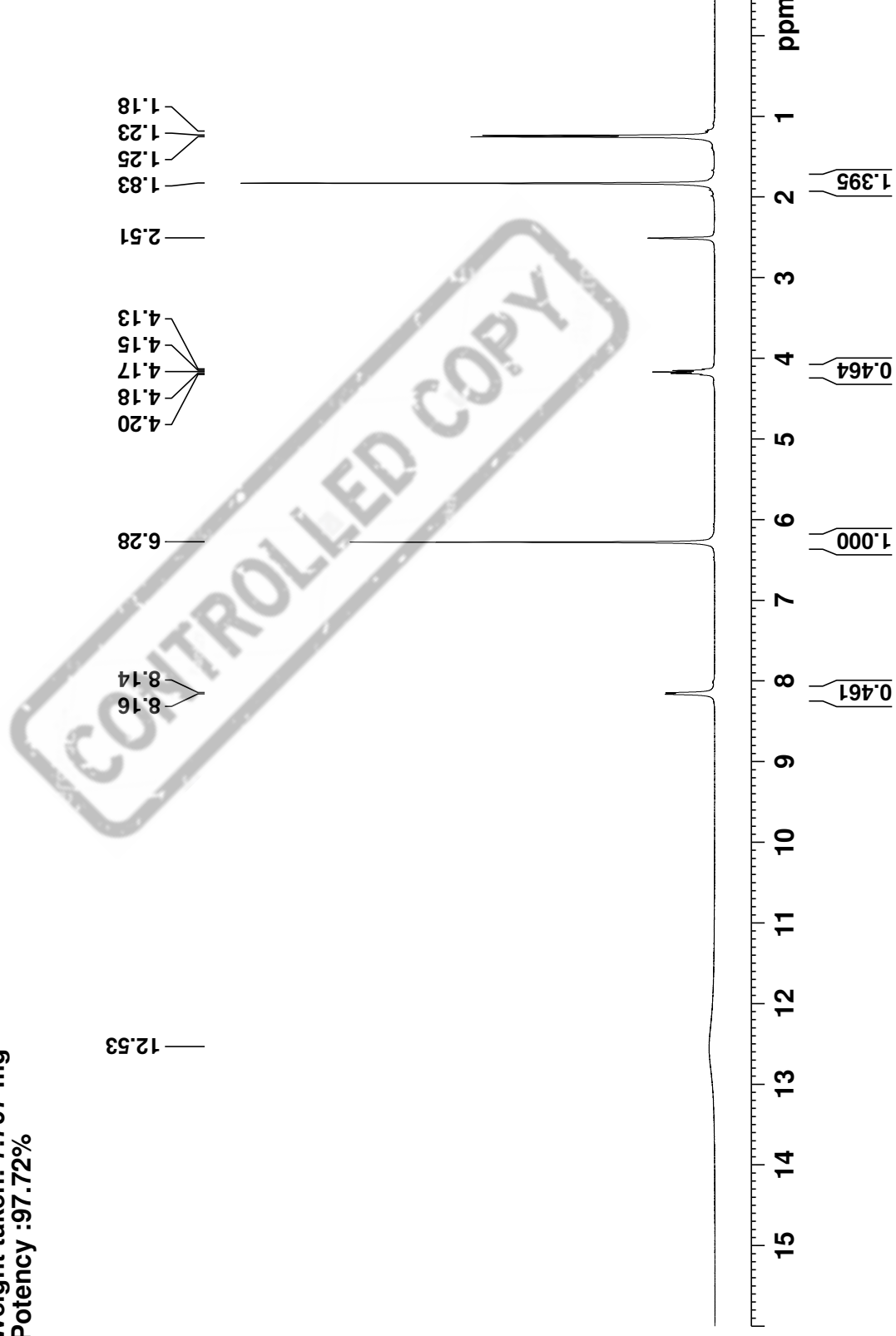
Sample Code: GS-NAA-02100
Molecular Weight: 131.13 g/mol
Weight taken: 7.797 mg
Potency :97.72%

Current Data Parameters
NAME GS-NAA-02100 QNMR
EXPNO 1
PROCNO 1

F2 - Acquisition Parameters
Date_ 20210216
Time 14.56
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 90.5
DW 62.400 use
DE 6.50 use
TE 295.8 K
D1 60.0000000 sec
TD0 1

===== CHANNEL f1 =====
SF01 400.1524711 MHz
NUC1 1H
P1 9.66 use
PLW1 9.10000038 W

F2 - Processing parameters
SI 65536
SF 400.1500000 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00



Sample code	GS-NAA-02100 QNMR
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P sample=	$\frac{I \text{ sample}}{I \text{ crm}}$	x	$\frac{N \text{ crm}}{N \text{ sample}}$	x	$\frac{M \text{ sample}}{M \text{ crm}}$	x	$\frac{m \text{ crm}}{m \text{ sample}}$	x	P crm
Sample 1	$\frac{0.464}{1}$	x	$\frac{2}{1}$	x	$\frac{131.13}{116.07}$	x	$\frac{7.269}{7.797}$	x	99.98

Assay in %

97.72154396

I sample =	Integral of the sample signal
I crm =	Integral of the reference signal
N sample =	Number of the sample protons
N crm =	Number of the reference protons
P sample =	Purity of sample as mass fraction (%)
M sample =	Molecular mass of the sample
M crm =	Molecular mass of the reference
m sample =	Gravimetric Mass of the sample
m crm=	Gravimetric Mass of the reference material
P crm =	Purity of reference as mass fraction

This Report was generated under a 21 CFR 11 Environment

System Information:

Sample ID: GS-NAA-02100

System Status: Good

File Location: BLR-WS-

0133\SQLXPRESS\VAIMDB_Public(000)|Public
Results\2020\May-2020\GS-NAA-02100_2021-02-
16T12-22-15.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 Chemie-1

User: Group1\Project1\QC

Date/Time: 02-16-2021 12:22:15 PM

Instrument Model: Carry 630

Instrument S/N: MY16402006

Reporting Information:

Report Template: Spectrum.docx

Report Generated By: Group1\Project1\QC

Report Generation Date: 2021-02-
16T12:22:15.639+05:30

Report Generation GMT Date:02-16-2021 6:52:22 AM

2/16/2021 12:22:22 PM

page 1 of 2

Sample ID:GS-NAA-02100

Method Name:Analytical Chemie-1

Sample Scans:8

User:Group1\Project1\QC

Background Scans:8

Date/Time:02-16-2021 12:22:15 PM

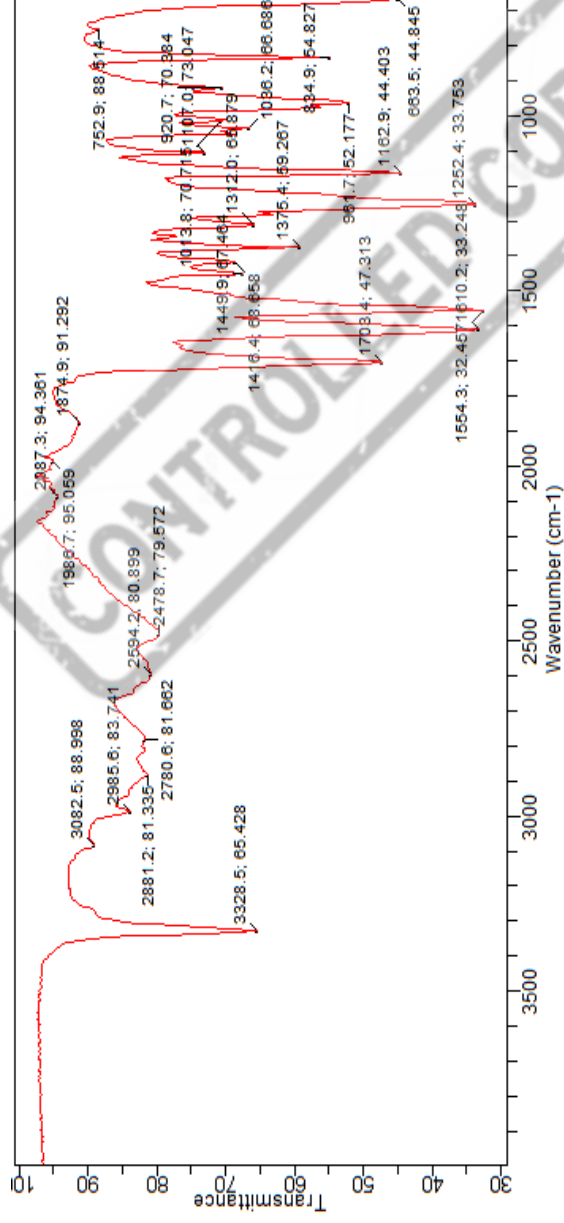
Resolution:8

Range:4000 - 650

System Status:Good

Apodization:Happ-Genzel

File Location: BLR-WS-0133\SQLXPRESS\VAIMDB_Public(000)\Public Results\2020\May-2020\



E-SIGNATURES

Signature

2/16/2021 12:22:22 PM

page 2 of 2

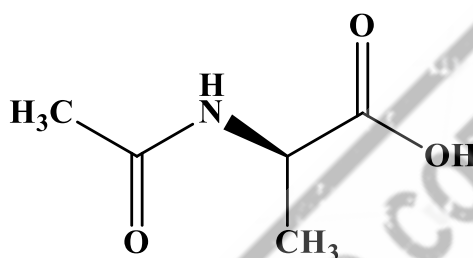
IR INTERPRETATION OF N-ACETYL-D-ALANINE

Method: (ATR-FTIR) Spectroscopy Recorded on (16-Feb-2021)

Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



N-Acetyl-D-alanine **OXYGEN-FUNCTION AMINO-COMPOUNDS; STANDARDS** Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetylamino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamidopropanoic acid

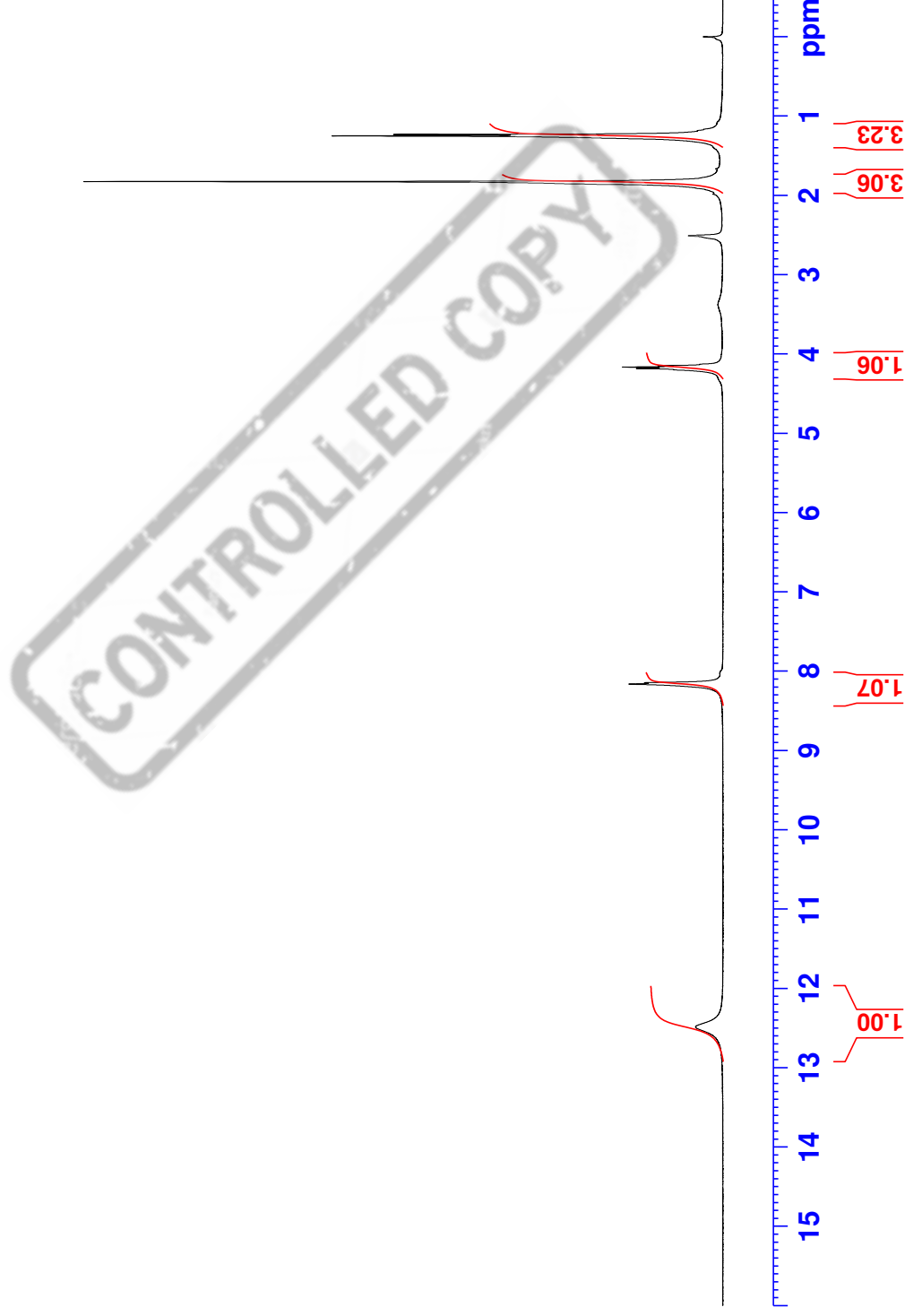
S.No	Wave number (cm ⁻¹)	Group	Stretch
1	1610.49	Carbonyl group of N-Acetyl D-alanine	C=O
2	1703.4	Carbonyl group of carboxylic acid	C=O
3	3328.5	Amide group of N-Acetyl	N-H

The signals of the IR spectrum and their interpretation are consistent with the structural formula.

Checked By

Approved By

GS-NAA-02100



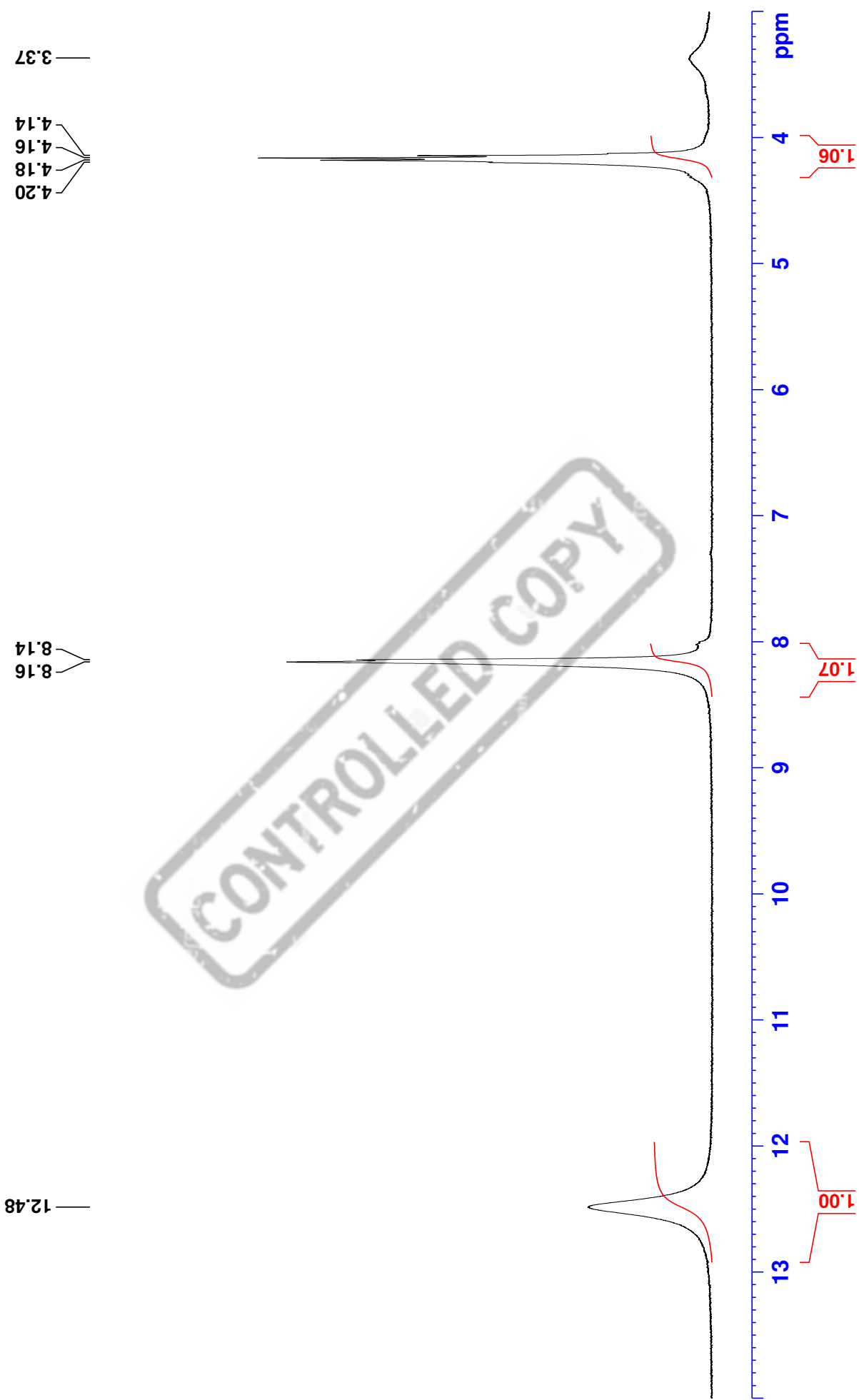
Current Data Parameters
NAME GS-NAA-02100
EXPNO 1
PROCNO 1

F2 - Acquisition Parameters
Date_ 20210206
Time 11.43
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 4.0894465 sec
RG 57
DW 62.400 usec
DE 6.50 usec
TE 295.1 K
D1 4.0000000 sec
TD0 1

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

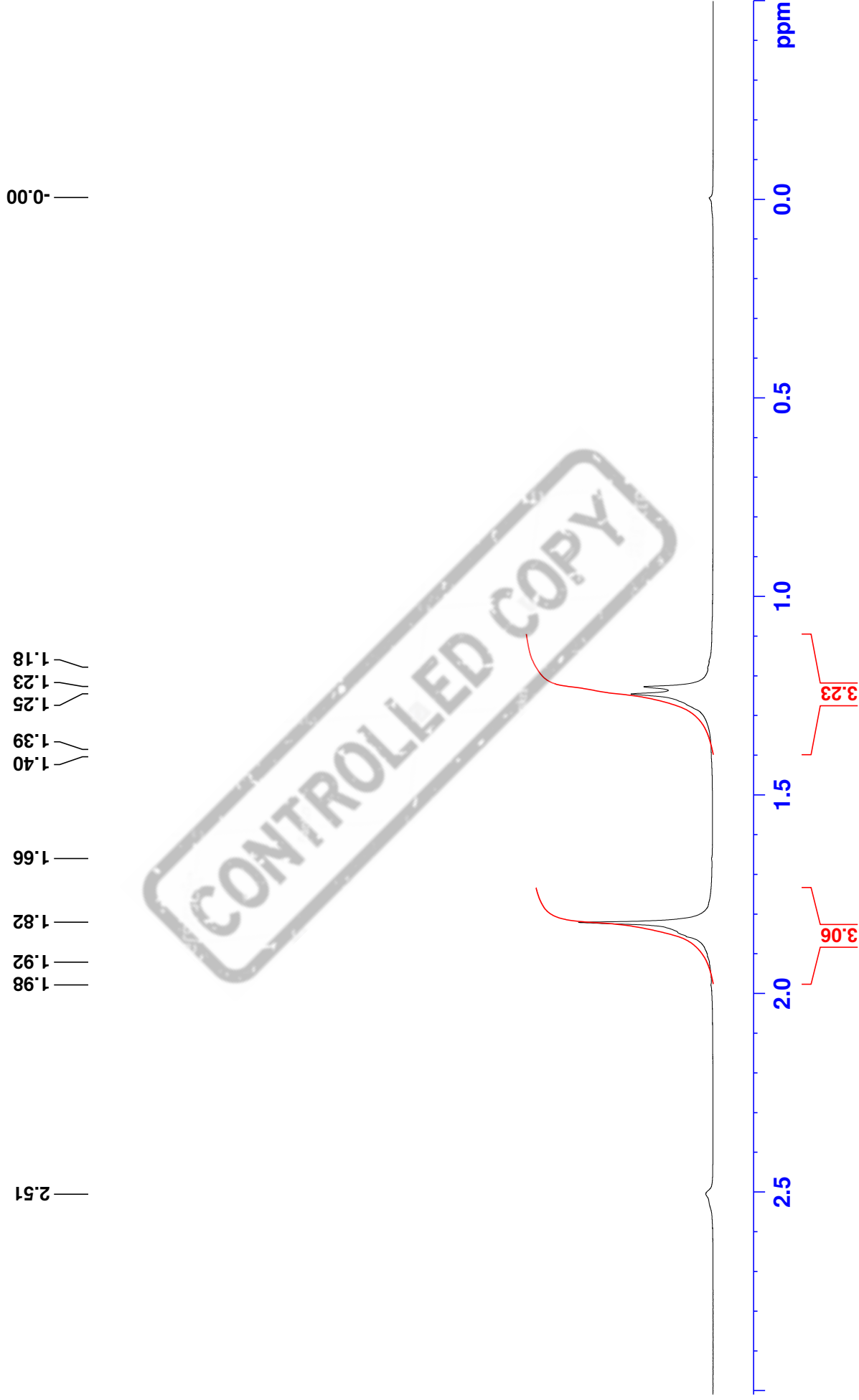
F2 - Processing parameters
SI 65536
SF 400.1500000 MHz
WDW EM
SSB 0
LB 0.30 Hz
GB 0
PC 1.00

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GS-NAA-02100

GS-NAA-02100



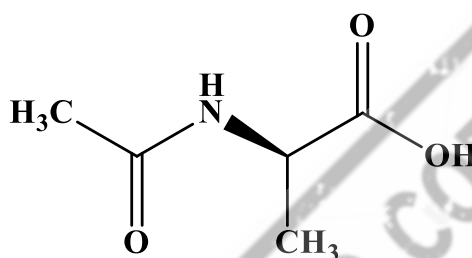
HNMR INTERPRETATION OF N-ACETYL-D-ALANINE

SOLVENT USED : **DMSO (d6)**

Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



N-Acetyl-D-alanine **OXYGEN-FUNCTION AMINO-COMPOUNDS ; STANDARDS**
Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetylamino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamido-propanoic acid

δ 1.18-1.25 ppm (3H,d,-CH₃)_J=8.01 Hz , δ 1.82 ppm (3H, s,-COCH₃),

δ 4.14-4.20 ppm (1H, m,-CH), δ 8.14-8.16 ppm (1H, d,-NH),

δ 12.48 ppm (1H, s,-COOH)

Checked By

Approved By

GS-NAA-02100

MASS REPORT

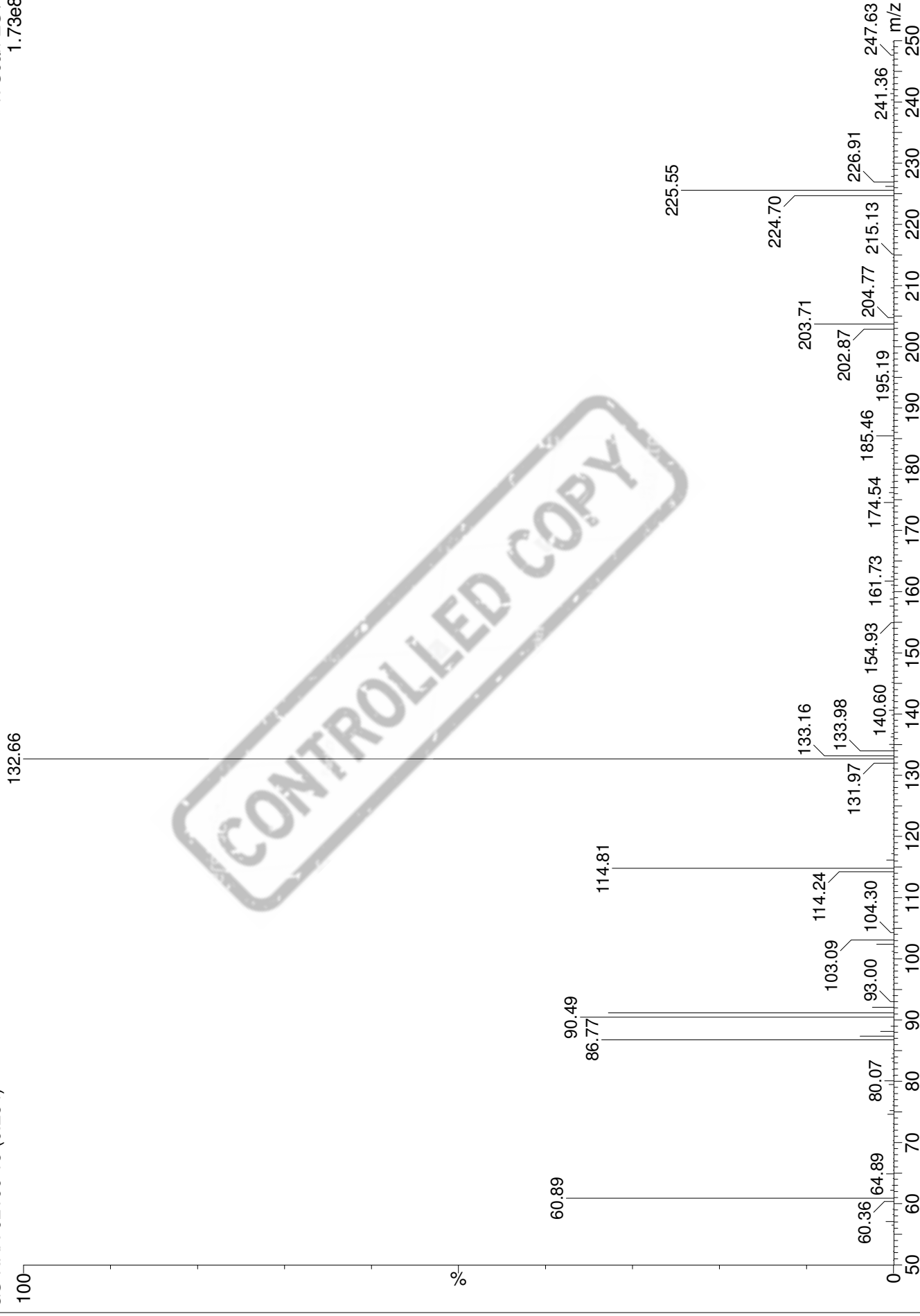
19-Feb-2021

11:36:41

1: Scan ES+

1.73e8

GS-NAA-02100 15 (0.254)



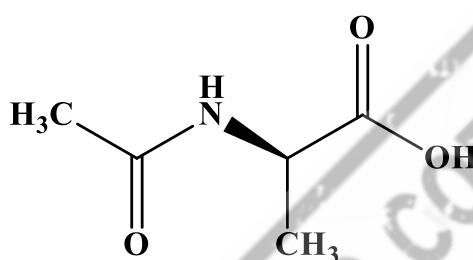
MASS INTERPRETATION OF N-ACETYL-D-ALANINE

Date Acquired (19-Feb-2021)

Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



N-Acetyl-D-alanine **OXYGEN-FUNCTION AMINO-COMPOUNDS; STANDARDS** Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetylamino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamido-propanoic acid

m/z	fragments
132.66 (+ve mode)	[M+1]

The molecular mass of **N-Acetyl-D-Alanine** (131.13) has been confirmed with fragments appears [M+1] **132.66** in positive mode and the signals of the mass spectrum and their interpretation are consistent with the structural formula.

Checked By

Approved By

Sample code:GS-NAA-02100

¹³C NMR

VARIAN 400MHz NMR

Solvent: dmso

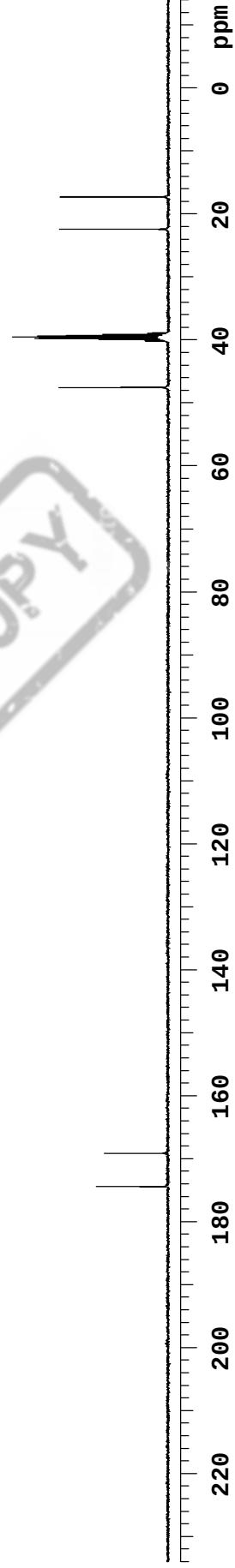
Date:Feb 14 2021

174.416
169.134

47.514
39.917
39.713
39.500
39.295
39.083

22.378
17.256

CONTROLLED COPY



Sample code:GS-NAA-02100

¹³C NMR

VARIAN 400MHz NMR

Solvent: dmsd

Date:Feb 14 2021

169.134

174.416

CONTROLLED COPY

ppm

160

162

164

166

168

170

172

174

176

178

180

182

184

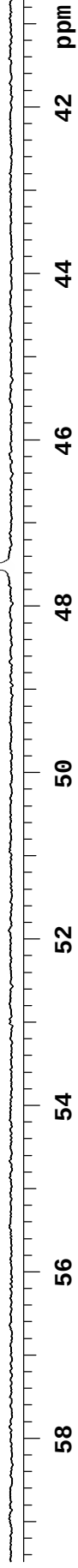
186

Sample code: GS-NAA-02100
13C NMR

VARIAN 400MHz NMR
Solvent: dmso
Date: Feb 14 2021

47.514

CONTROLLED COPY



Plotname: GS-NAA-02100 CARBON 01_plot03

Sample code:GS-NAA-02100

¹³C NMR

VARIAN 400MHz NMR

Solvent: dmso

Date:Feb 14 2021

17.256

22.378

CONTROLLED COPY

ppm

8

10

12

14

16

18

20

22

24

26

28

30

Sample code:GS-NAA-02100

¹³C NMR
VARIAN 400MHz NMR
Solvent: dmsd
Date:Feb 14 2021

INDEX	FREQUENCY	PPM	HEIGHT
1	17533.6	174.416	11.3
2	17002.6	169.134	10.1
3	4776.5	47.514	17.3
4	4012.8	39.917	10.9
5	3992.2	39.713	21.1
6	3970.8	39.500	24.7
7	3950.2	39.295	20.7
8	3928.9	39.083	10.3
9	2249.6	22.378	17.2
10	1734.6	17.256	17.1

CONTROLLED COPY

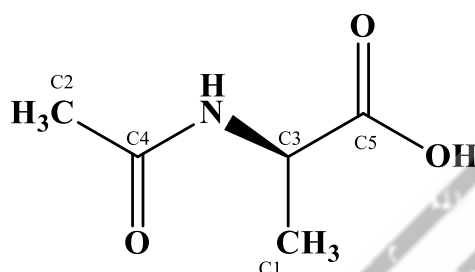
C13 NMR INTERPRETATION OF N-ACETYL-D-ALANINE

Method: (Spin Changes of Carbon Nuclei) C13 NMR based on Chemical Shifts

Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



N-Acetyl-D-alanine **OXYGEN-FUNCTION AMINO-COMPOUNDS; STANDARDS** Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetylamino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamidopropanoic acid

S.No	Chemical Shifts (ppm)	Carbon Number	Assign of Spin Changes of Carbon Nuclei
1	17.256	C1	CH ₃
2	22.378	C2	Acetyl CH ₃
3	47.514	C3	CH
4	169.134	C4	Acetyl C=O
5	174.416	C5	Carboxylic Acid C=O

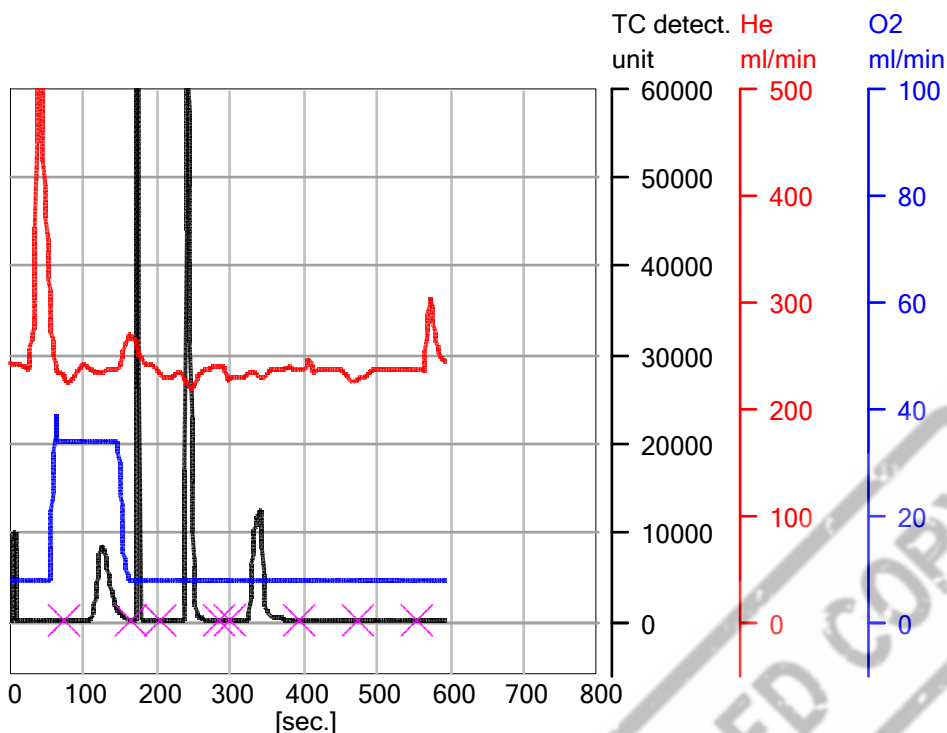
The signals of the C13 NMR spectrum and their interpretation are consistent with the structural formula.

Checked By

Approved By

Graphic report

No.	Weig...	Name	Method	N [%]	C [%]	H [%]	S [%]
18	3.9140	GS-NAA-02100 AR#009550	5mg90s	10.82	45.68	6.910	0.000



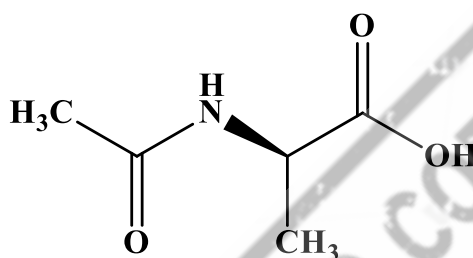
CHNS INTERPRETATION OF N-ACETYL-D-ALANINE

Analysed on (20.02.2021)

Catalog Number : GS.NADA.02100 CAS Number : 19436-52-3

Batch Number : GS-NAA-02100

Mol.Wt : 131.13 Mol. For : C₅H₉NO₃



N-Acetyl-D-alanine **OXYGEN-FUNCTION AMINO-COMPOUNDS; STANDARDS** Ac-D-Ala-OH ; (R)-2-Acetamidopropanoic acid Acetyl-D-Alanine ; (2R)-2-acetamidopropanoic acid ; (R)-2-Acetylamino-propionic acid ; N-alpha-Acetyl-D-alanine ; (R)-2-acetamidopropanoic acid

Component Name	Theoretical Element %	Actual Element%	Deviation
Nitrogen	10.68	10.82	-0.14
Carbon	45.80	45.68	0.12
Hydrogen	6.92	6.91	0.01

The signals of the CHN and their interpretation are consistent with the structural formula.

Checked By

Approved By



TAMILNADU TEST HOUSE PRIVATE LIMITED

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www.tamilnadutesthouse.com

CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-8271/2020-21

DATE:16.02.2021

SAMPLE SUBMITTED BY CUSTOMER

CUSTOMER DETAILS

M/s.GlobeSynth Pharma Tech

ADDRESS

No.6/115A, New No 4/155

Soolaimedu, Uthamacholapuram

Salem 636010, Tamilnadu

SAMPLE DESCRIPTION

N-Acetyl-D-Alanine

BATCH NUMBER

GS-NAA-02100

MANUFACTURED ON

10.02.2021

SAMPLE QUANTITY

150 MG

PACKING

In packed condition

SAMPLE RECEIVED ON

13.02.2021

ANALYSIS STARTED ON

13.02.2021

ANALYSIS COMPLETED ON

16.02.2021

S. NO	PARAMETERS	METHODS	UNITS	RESULTS
1	Specific Optical Rotation , c = 1, H ₂ O, 25 deg C	BP	°	61.5

For Tamilnadu Test House Private Limited

Verified By

Authorised Signatory

Filename: C:\Program Files\Perkin...GS-NAA-02100.t6d

Data Collected: 13-02-2021 15:55:34

Sample ID: GS-NAA-02100

Sample Weight: 4.848 mg

Serial Number: 020012309

Software Version: 13.3.2.0030

Comment: GS-NAA-02100

GS-NAA-02100: GS-NAA-02100

Weight % (%) : Steps: 1-3





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CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-8271/2020-21

DATE:16.02.2021

SAMPLE SUBMITTED BY CUSTOMER

CUSTOMER DETAILS	M/s.GlobeSynth Pharma Tech
ADDRESS	No.6/115A, New No 4/155 Soolaimedu, Uthamacholapuram Salem 636010, Tamilnadu
SAMPLE DESCRIPTION	N-Acetyl-D-Alanine
BATCH NUMBER	GS-NAA-02100
MANUFACTURED ON	10.02.2021
SAMPLE QUANTITY	150 MG
PACKING	In packed condition
SAMPLE RECEIVED ON	13.02.2021
ANALYSIS STARTED ON	13.02.2021
ANALYSIS COMPLETED ON	16.02.2021

Terms and Conditions

This report in full or in part shall not be published, advertised, used for any legal action, unless prior permission has been secured. This test report pertains only for the sample tested and such samples are retained for 7 days (in case of perishable) and 15 days for all other samples. In case of Complaint received from customers sample will be kept for 30 days. The samples from regulatory bodies are to be retained as specified. This document cannot be reproduced except in full, without prior written approval of the company.

For Tamilnadu Test House Private Limited

Managing Director

Page 1 of 2



TAMILNADU TEST HOUSE PRIVATE LIMITED

NABL ACCREDITED & DRUG CONTROL LICENSED

www.tamilnadutesthouse.com

CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-8271/2020-21

DATE:16.02.2021

SAMPLE DESCRIPTION N-Acetyl-D-Alanine

ANALYSIS STARTED ON 13.02.2021

ANALYSIS COMPLETED ON 16.02.2021

S. NO	PARAMETERS	METHODS	UNITS	RESULTS
1	Appearance	BP	-	White Powder
2	Loss on drying	BP	%	0.12
3	Residue On Ignition	BP	%	0.001
4	Assay By Potentiometric Titration	BP	%	99.7
5	Heavy Metals			
5.1	Lead	BP	µg/g	BQL(LOQ: 0.001)
5.2	Cadmium	BP	µg/g	BQL(LOQ: 0.001)
5.3	Arsenic	BP	µg/g	BQL(LOQ: 0.03)
5.4	Mercury	BP	µg/g	BQL(LOQ: 0.01)
6	Endotoxin	BP	EU/mcg	LT 0.1
7	Specific Optical Rotation , c = 1, H ₂ O, 25 deg C	BP	°	61.5

***** END OF THE REPORT*****

For Tamilnadu Test House Private Limited

Verified By

Authorised Signatory

Page 2 of 2



TAMILNADU TEST HOUSE PRIVATE LIMITED

NABL ACCREDITED & DRUG CONTROL LICENSED

www.tamilnadutesthouse.com

CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-8271/2020-21

DATE:16.02.2021

SAMPLE SUBMITTED BY CUSTOMER

CUSTOMER DETAILS	M/s.GlobeSynth Pharma Tech
ADDRESS	No.6/115A, New No 4/155 Soolaimedu, Uthamacholapuram Salem 636010, Tamilnadu
SAMPLE DESCRIPTION	N-Acetyl-D-Alanine
BATCH NUMBER	GS-NAA-02100
MANUFACTURED ON	10.02.2021
SAMPLE QUANTITY	150 MG
PACKING	In packed condition
SAMPLE RECEIVED ON	13.02.2021
ANALYSIS STARTED ON	13.02.2021
ANALYSIS COMPLETED ON	16.02.2021

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For Tamilnadu Test House Private Limited

Managing Director

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TAMILNADU TEST HOUSE PRIVATE LIMITED

NABL ACCREDITED & DRUG CONTROL LICENSED

www.tamilnadutesthouse.com

CERTIFICATE OF ANALYSIS

Form 39 [See Rule 150 E (f)]

The Drugs and cosmetics Act, 1940 and the Rules there after

Approval Number: TN00004381

TEST REPORT NO: TNTH/M-8271/2020-21

DATE:16.02.2021

SAMPLE DESCRIPTION N-Acetyl-D-Alanine

ANALYSIS STARTED ON 13.02.2021

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S. NO	PARAMETERS	METHODS	UNITS	RESULTS
1	Appearance	BP	-	White Powder
2	Loss on drying	BP	%	0.12
3	Residue On Ignition	BP	%	0.001
4	Assay By Potentiometric Titration	BP	%	99.7
5	Heavy Metals Analysis			
5.1	Lead	BP	µg/g	BQL(LOQ: 0.001)
5.2	Cadmium	BP	µg/g	BQL(LOQ: 0.001)
5.3	Arsenic	BP	µg/g	BQL(LOQ: 0.03)
5.4	Mercury	BP	µg/g	BQL(LOQ: 0.01)
6	Endotoxin	BP	EU/mcg	LT 0.1
7	Specific Optical Rotation , c = 1, H ₂ O, 25 deg C	BP	°	61.5
8	MICROBIOLOGY ANALYSIS			
8.1	Total Aerobic Microbial count	USP <61>. USP<62>, USP<1111>	cfu/ml	<2
8.2	Total Yeast and Mould		cfu/ml	Nil
8.3	E.Coli		per ml	Absent
8.4	Staphylococcus Aureus		Per ml	Absent
8.5	Salmonella sp.		Per 10ml	Absent
8.6	Pseudomonas Aeruginosa		Per ml	Absent

***** END OF THE REPORT*****

For Tamilnadu Test House Private Limited

Verified By

Authorised Signatory

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Final Results: (N-Acetyl-D-Alanine)

1. Chromatographic purity (TLC) : $\geq 98\%$ (TLC)

2. Residual solvents : Method $^1\text{H-NMR}$

Result (n = 1) $^1\text{H-NMR}$ No significant amounts of residual solvents were detected and it is ($< 0.05\%$).

3. Assay : (100 % method) 98 % the assay is assessed to be 98 % 'as is' The assay 'as is' is equivalent to the assay based on the not anhydrous and not dried substance respectively.

4. Release Date : 15.03.2021

5. Place : Salem, Tamilnadu