AQUIGEN BIO SCIENCE PVT LTD
281/1, Plot No 41, Hinjawadi - Pirangut Rd, Kasar Amboli, Pirangut, Maharashtra 412108
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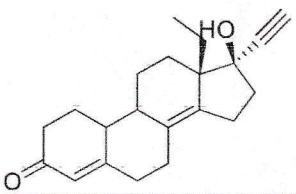
CERTIFICATE OF ANALYSIS

Name of Product: LEVONORGESTREL IMPURITY A			
Batch No	: AQ-TR-182-004	CAS NO	: 110785-09-6
Analysis Date	: 15 SEP 2022	Retest Date	: 14 SEP 2024
Molecular weight	: 310.44	Molecular Formula	: C21H26O2
Cat No	: AQ-IMP46148	Batch Qty	: 1250.0 mg



Chemical Name: - (13S,17R)-13-ethyl-17-ethynyl-17-hydroxy-1,2,6,7,9,10,11,12,13,15,16,17-dodecahydro-3H-cyclopenta[a]phenanthren-3-one

Sr. No.	Test	Result
1	Description	White Solid
2	Chromatographic Purity by HPLC	96.72%
3	Solubility	Methanol
4	MASS by LCMS	Confirms to structure
5	^{1}H NMR	Confirms to structure
6	^{13}C NMR	Confirms to structure
7	FTIR	Confirms to structure
8	Loss on drying (LOD) by TGA (%W/W)	2.91%
9	Potency (%W/W)	93.81%
10	RRF	1.28 with respect to API

Conclusion: The product complies as per above specifications.

- Storage Conditions: Store at $2^{0}C$ to 8^{0} C
- Transportation Storage Condition : Room temperature

NOTE:

1.Retest date depends on material storage condition and handling of material.

2.If you have any query, it may be solved before in three months. After that, it is irreplaceable.

Prepared By :	Checked By:	Approved By :
Date : 24 NOV 2023	Date : 24 NOV 2023	Date : 24 NOV 2023

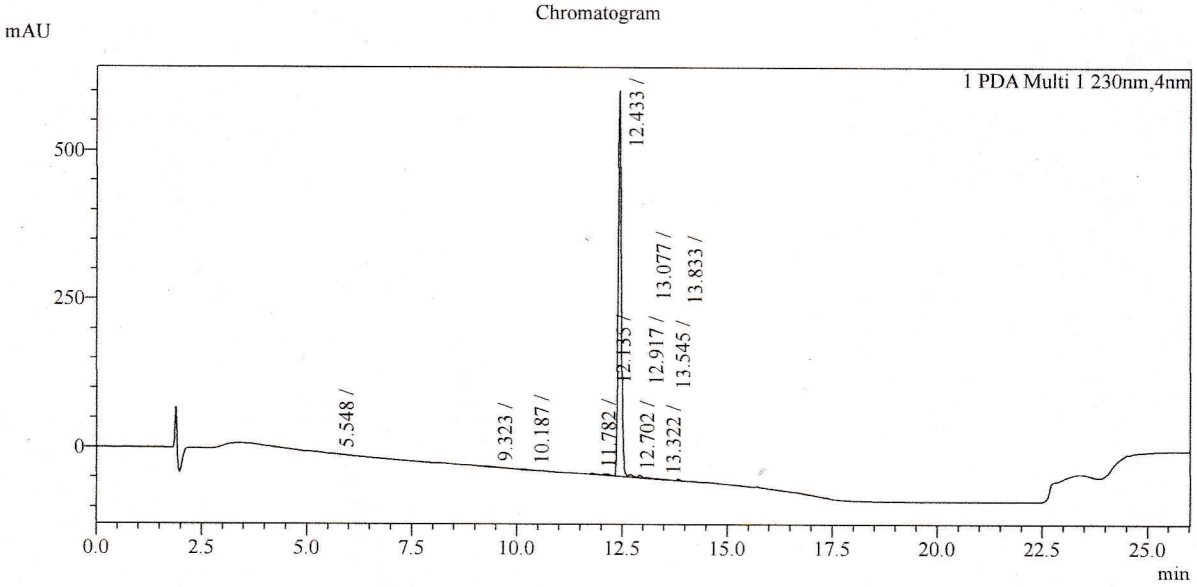
Aquigen Bio Science Pvt. Ltd.

Sample Information

Acquired by	: AQUIGEN
Sample Name	: Levonorgestrel EP Impurity A
Sample ID	: AQ-TR-182-004
Tray#	: 3
Vial#	: 50
Injection Volume	: 10 uL
Data Filename	: 11_22080394.lcd
Method Filename	: GEN_C+B_26min.lcm
Batch Filename	: 11_2208026.lcb
Report Filename	: DEFAULT.lsr
Date Acquired	: 8/30/2022 11:38:58 AM
Date Processed	: 8/30/2022 12:08:45 PM

Chromatographic Conditions:
Column:-Zorbax SB-C18 (150 X 4.6)mm 3.5µm,,
M.P-A:- 0.1%TFA in water,
M.P-B:- ACN(100%),
Time/% B:-0/10,15/95,20/95,21/10,26/10,
Flowrate:- 1.0 mL/min, COT:- 25°C,
Diluent:- ACN:WATER (30:70)
Test Con:0.1 mg/ml.

Chromatogram



Peak Table

PDA Ch1 230nm

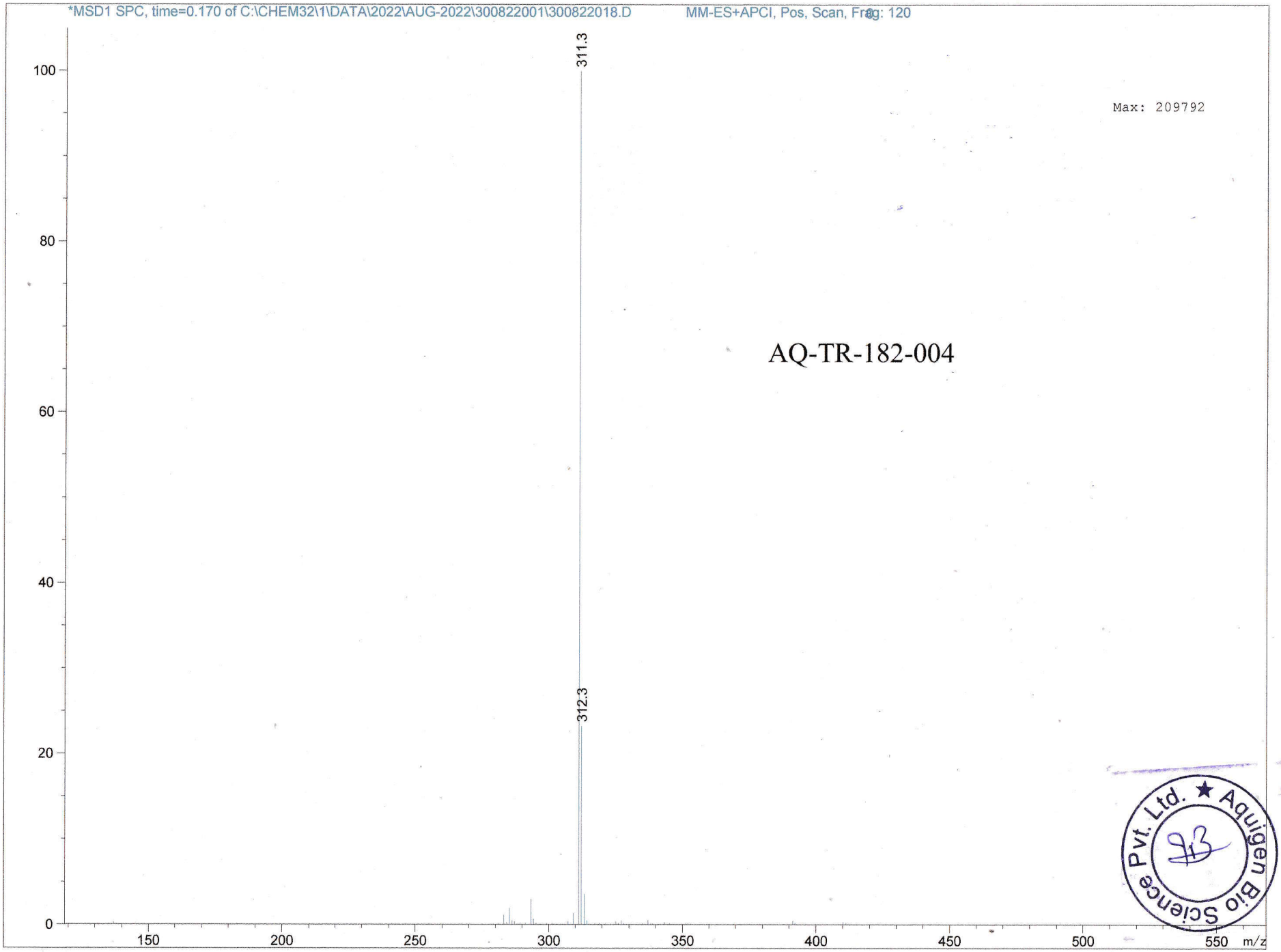
Peak#	Ret. Time	Area	Area%	Relative Retention Time
1	5.548	2270	0.07	--
2	9.323	3021	0.09	--
3	10.187	3043	0.09	--
4	11.782	9245	0.27	--
5	12.135	19237	0.57	--
6	12.433	3290955	96.72	--
7	12.702	28210	0.83	--
8	12.917	23283	0.68	--
9	13.077	5723	0.17	--
10	13.322	1784	0.05	--
11	13.545	2333	0.07	--
12	13.833	13485	0.40	--
Total		3402589	100.00	

Analysed by:
Date: 30 Aug 2022

Aquigen Bio Science Pvt. Ltd.

Checked by:
Date: 30 Aug 2022

MS Spectrum

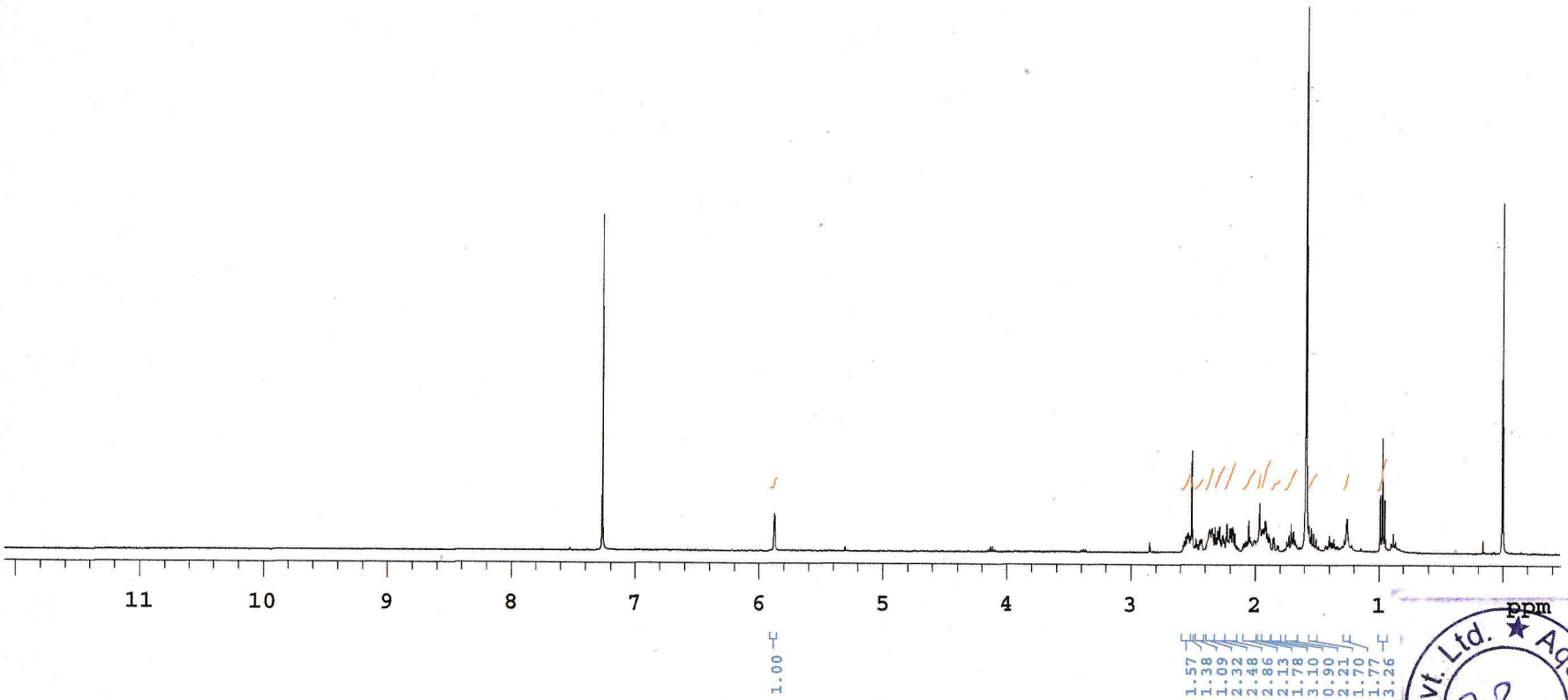


AQ-TR-182-004

Aquigen Bio Science Pvt. Ltd.

Sample code:AQ-TR-182-004
1H NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

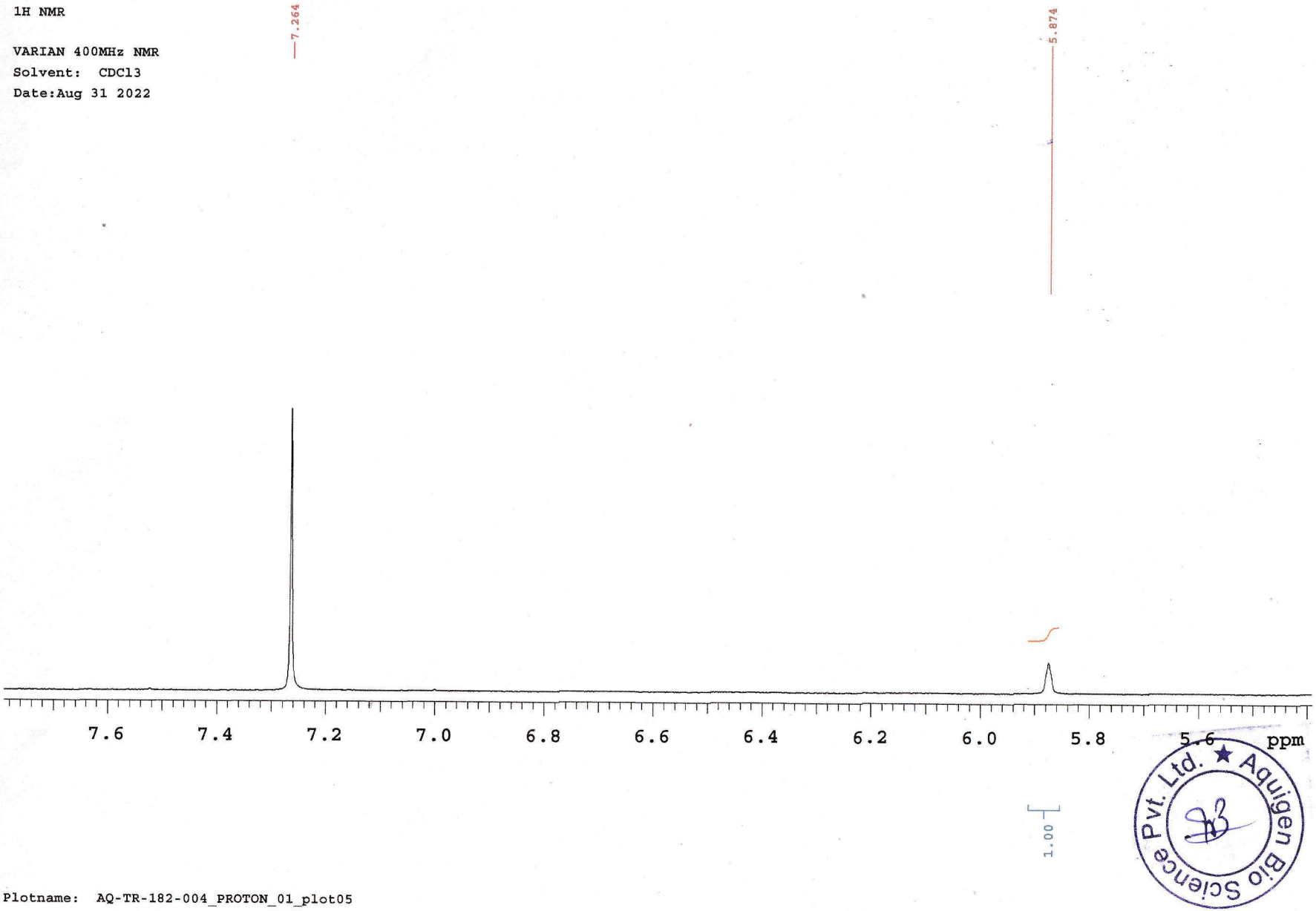


Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_PROTON_01_plot04

Sample code:AQ-TR-182-004
1H NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022



Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_PROTON_01_plot05

Sample code:AQ-TR-182-004

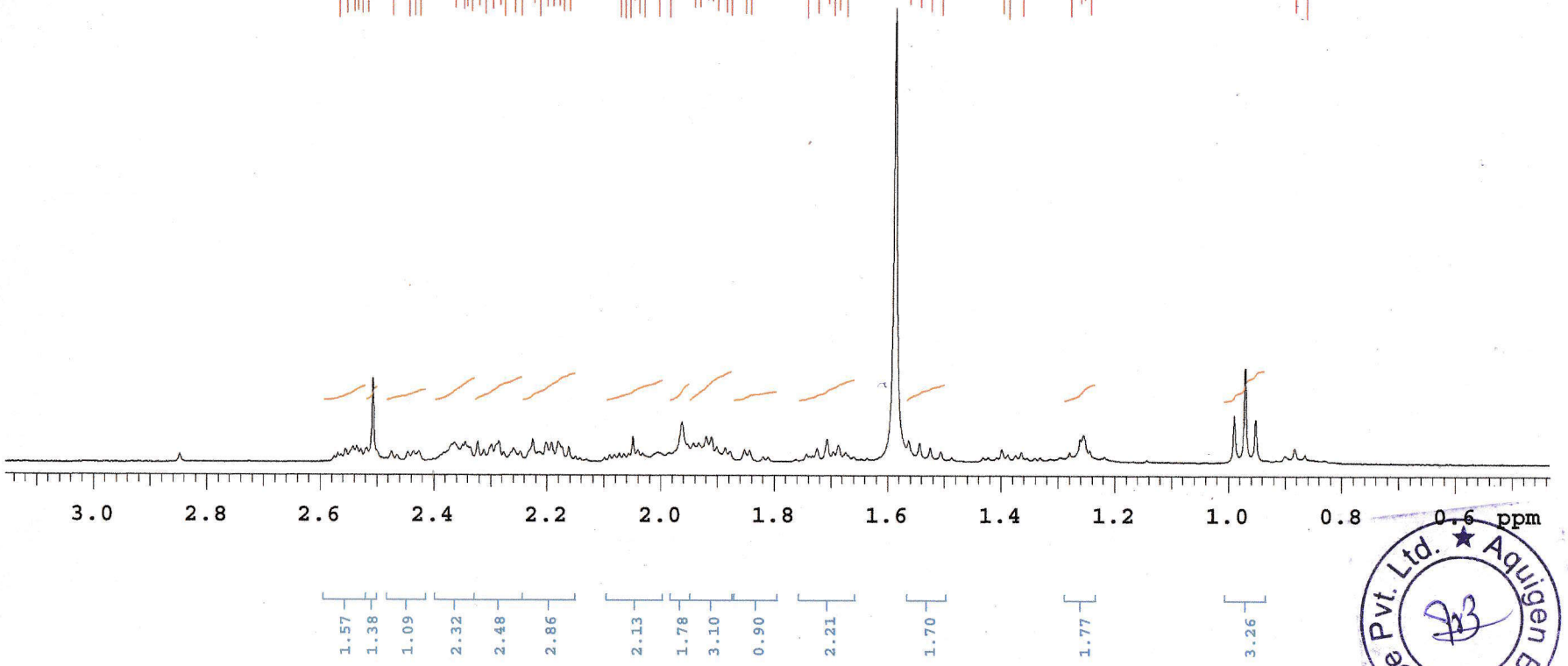
1H NMR

VARIAN 400MHz NMR

Solvent: CDCl3

Date:Aug 31 2022

2.565 2.555 2.542 2.535 2.528 2.518 2.507 2.474 2.445 2.435 2.426 2.364 2.349 2.344 2.335 2.322 2.312 2.298 2.285 2.276 2.259 2.247 2.225 2.214 2.202 2.192 2.180 2.173 2.162 2.073 2.064 2.057 2.049 2.040 2.031 2.005 1.986 1.962 1.942 1.933 1.919 1.911 1.901 1.886 1.877 1.852 1.843 1.743 1.724 1.706 1.696 1.686 1.673 1.587 1.562 1.543 1.525 1.506 1.398 1.388 1.364 1.279 1.261 1.255 1.244 0.989 0.970 0.951 0.883 0.864



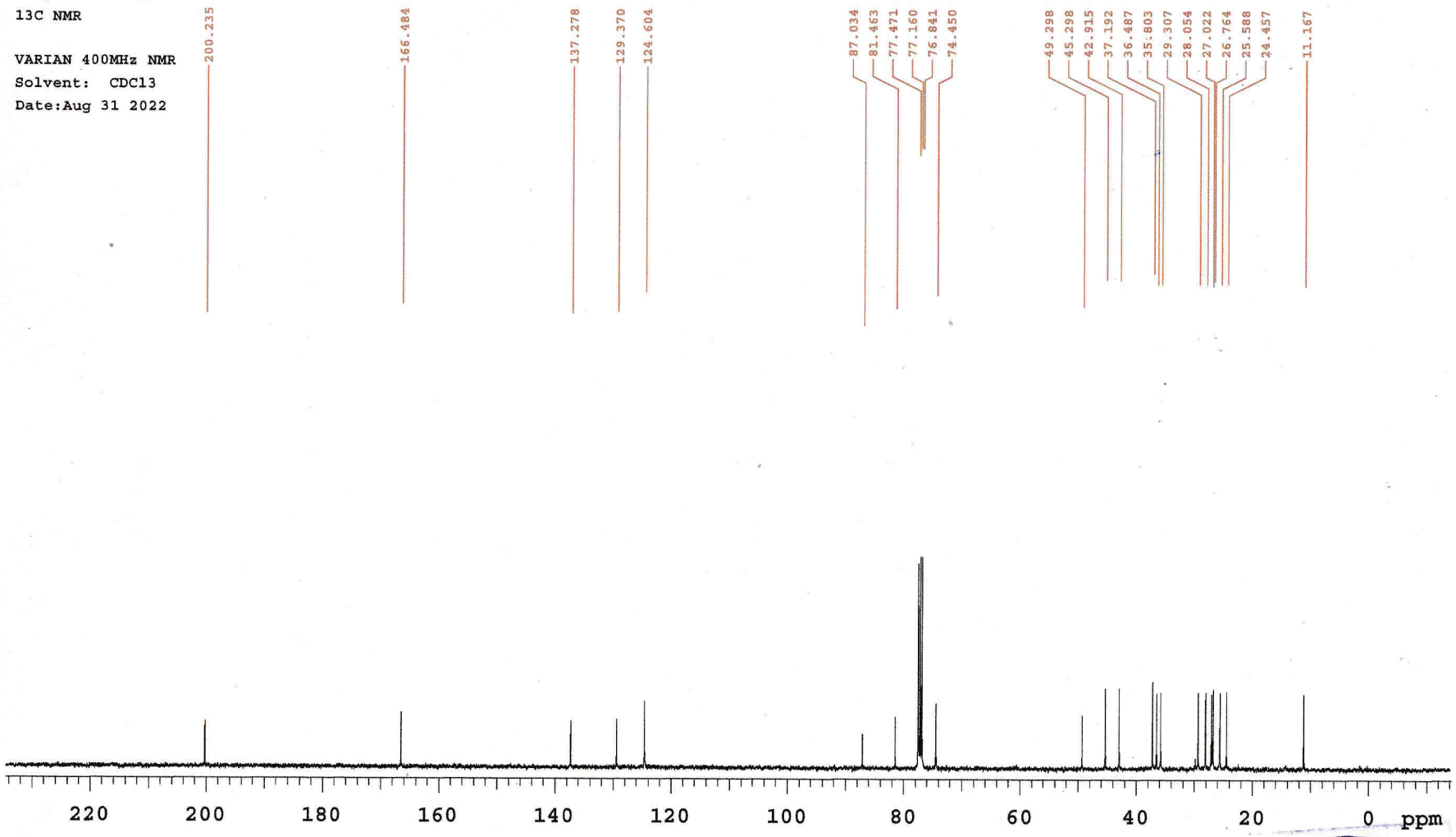
1.57 1.38 1.09 2.32 2.48 2.86 2.13 1.78 3.10 0.90 2.21 1.70 1.77 3.26

Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_PROTON_01_plot06

Sample code:AQ-TR-182-004
13C NMR

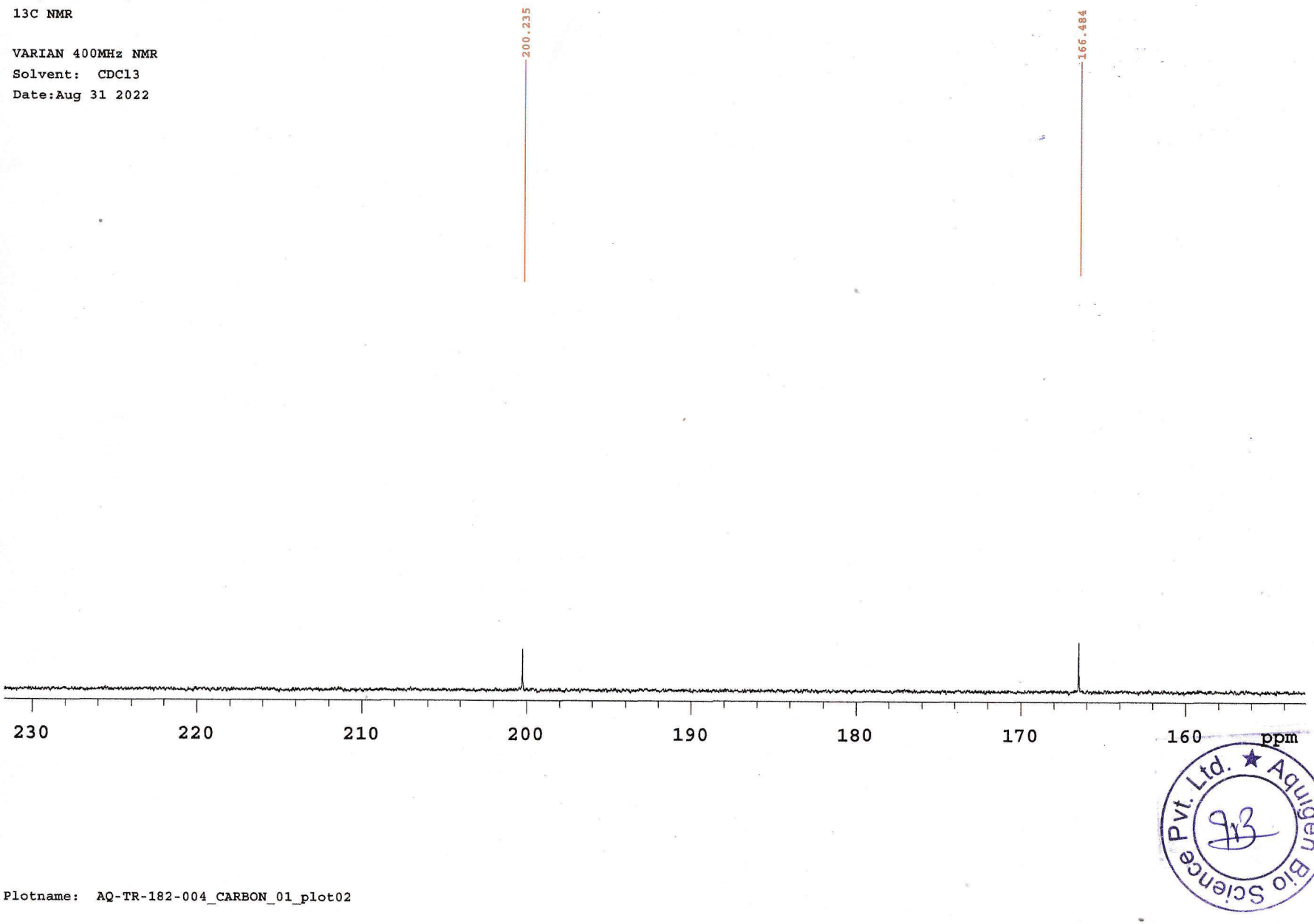
VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022



Plotname: AQ-TR-182-004_CARBON_01_plot01

Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

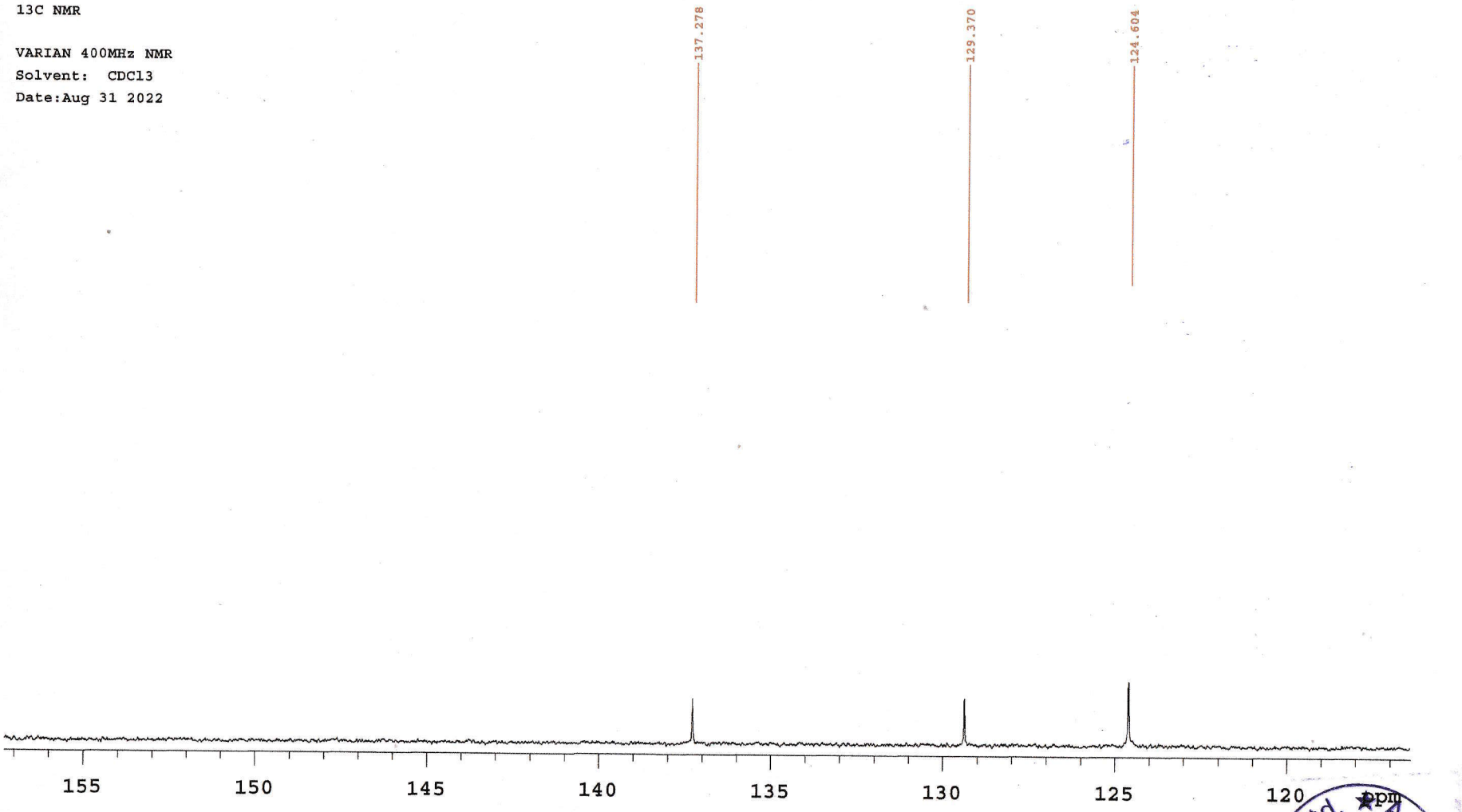


Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_CARBON_01_plot02

Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

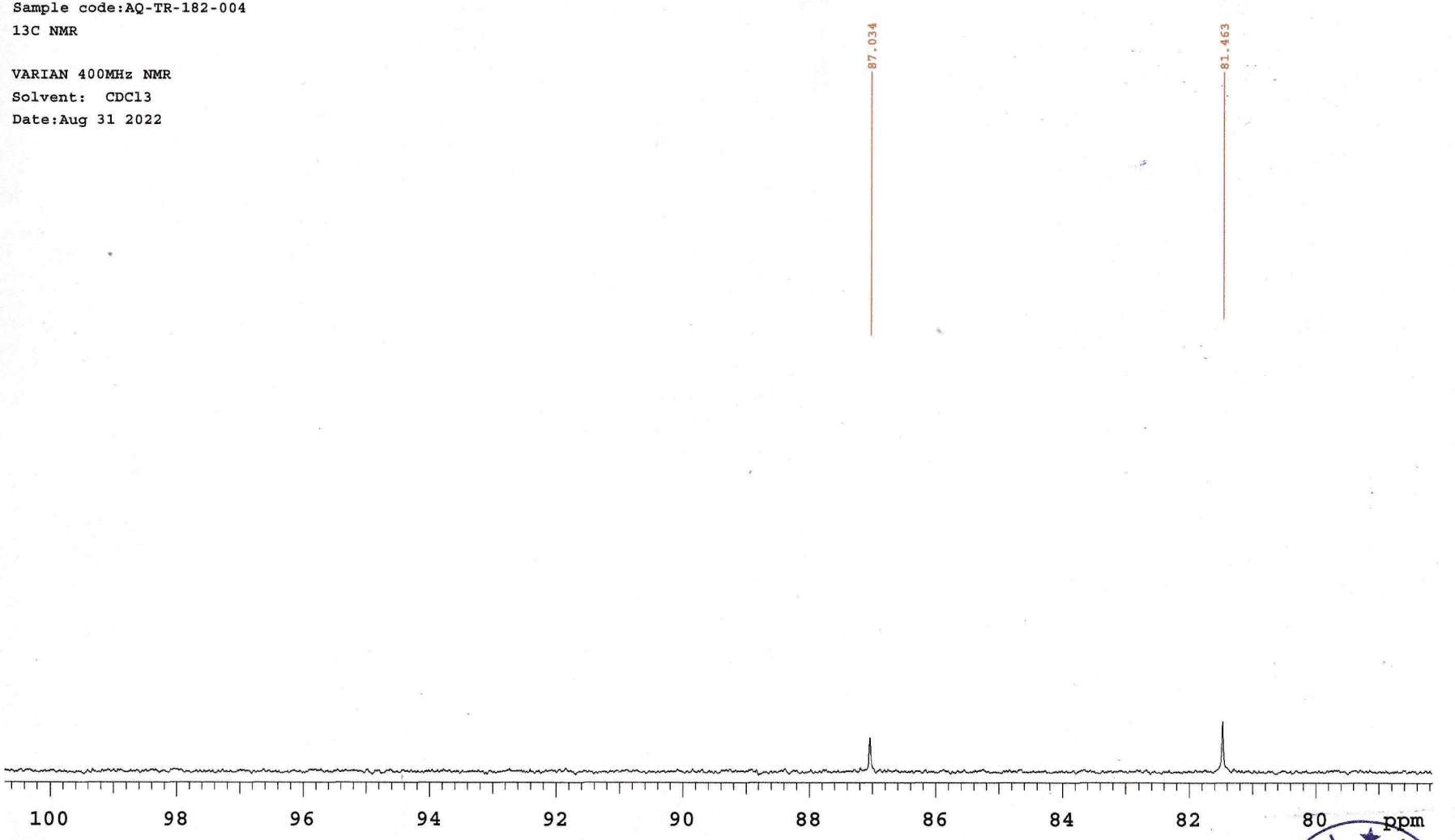


Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_CARBON_01_plot03

Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

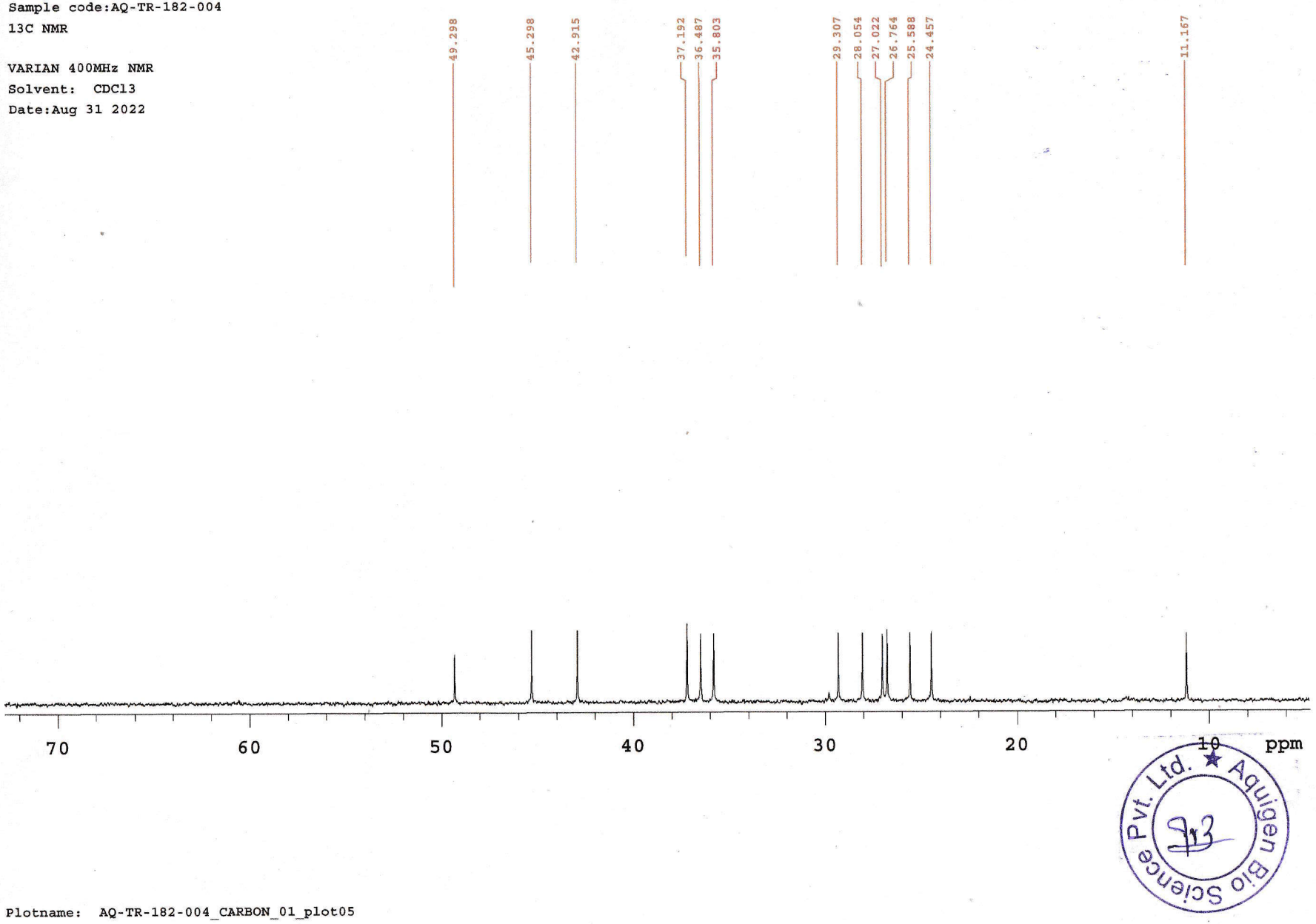


Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_CARBON_01_plot04

Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

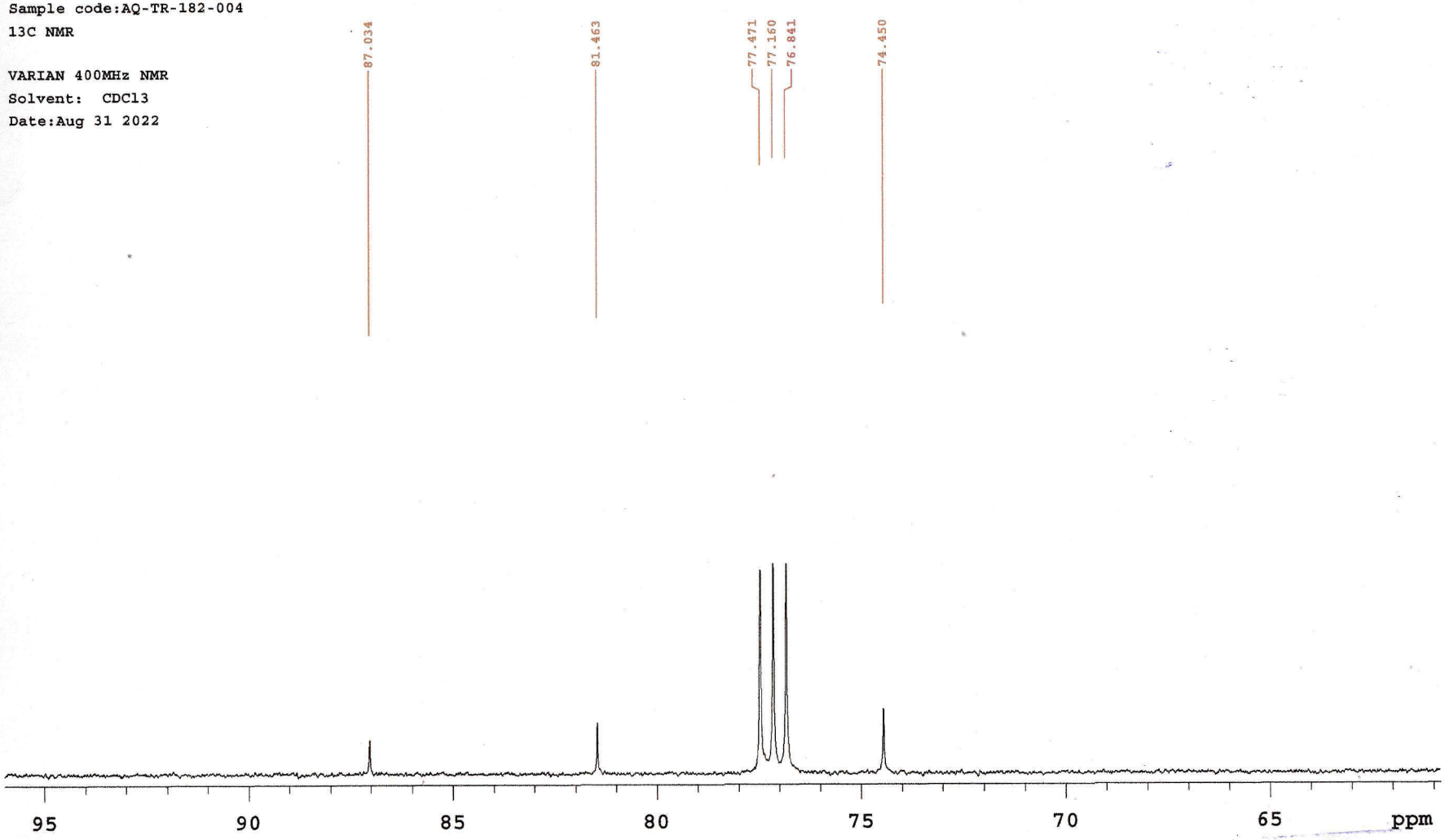


Plotname: AQ-TR-182-004_CARBON_01_plot05

Aquigen Bio Science Pvt. Ltd.

Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022

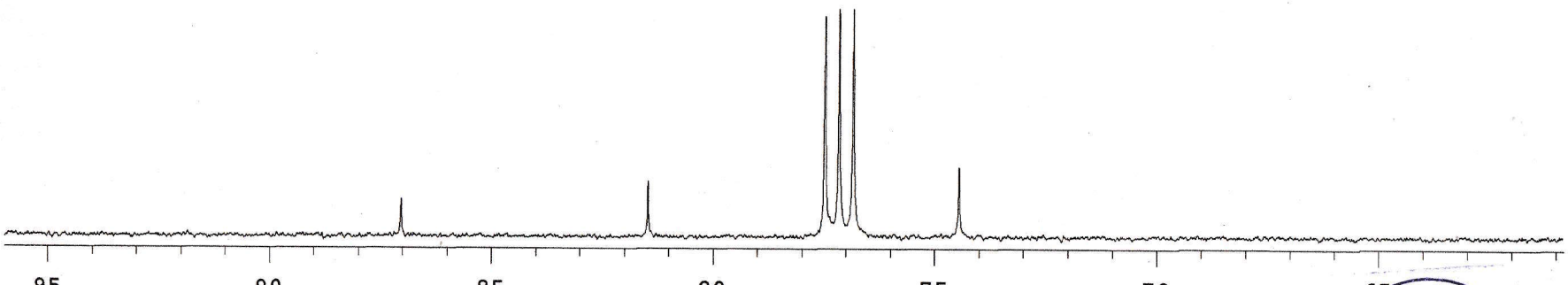


Plotname: AQ-TR-182-004_CARBON_01_plot06

Aquigen Bio Science Pvt. Ltd.

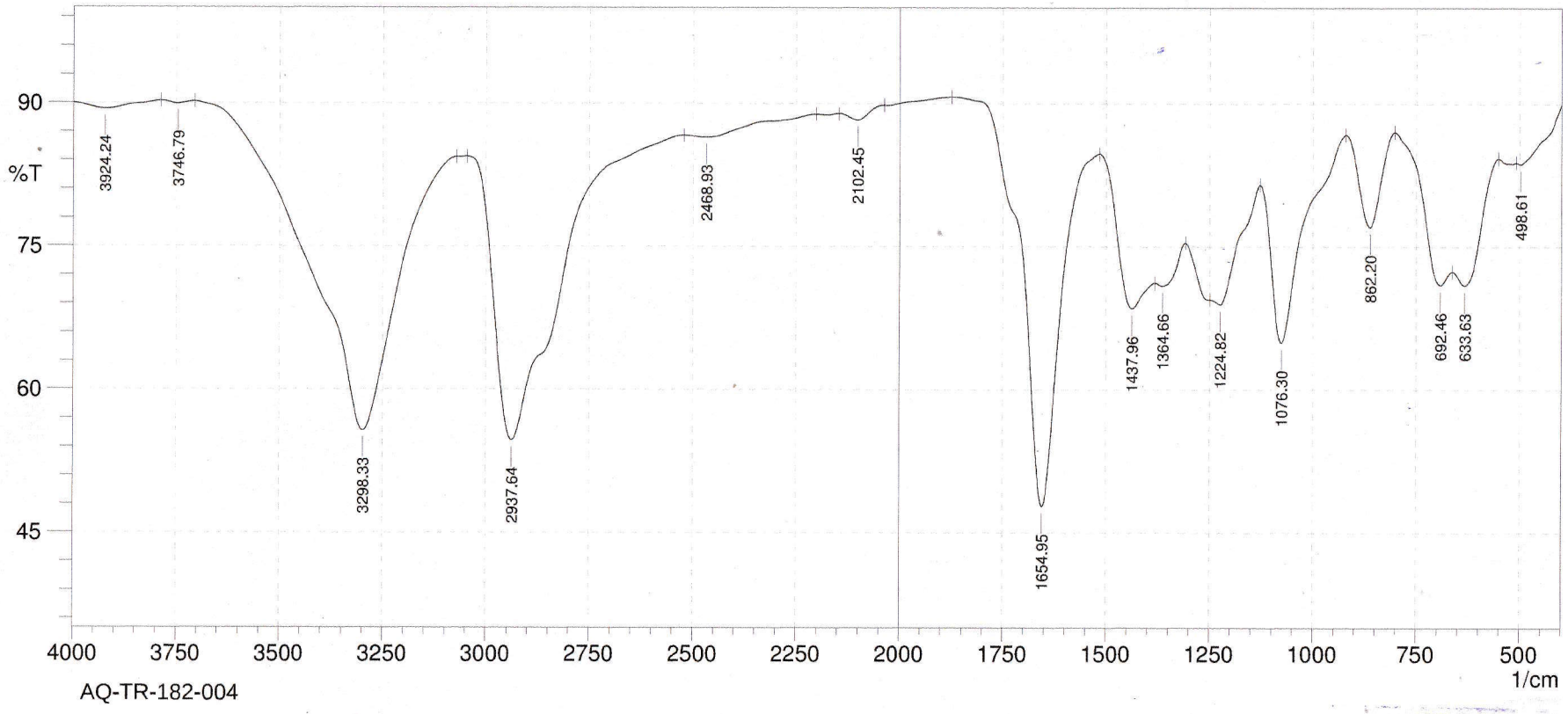
Sample code:AQ-TR-182-004
13C NMR

VARIAN 400MHz NMR
Solvent: CDCl3
Date:Aug 31 2022



Aquigen Bio Science Pvt. Ltd.

Plotname: AQ-TR-182-004_CARBON_01_plot07



Sample Name
AQ-TR-182-004

No. of SCANS :60 , Phase: KBr

E:\IR\data\2022\AUG\AQ-TR-182-004-.smf

Date/Time: 8/31/2022 2:03:08 PM

Analysed by:SIVA KRISHNA

Signature

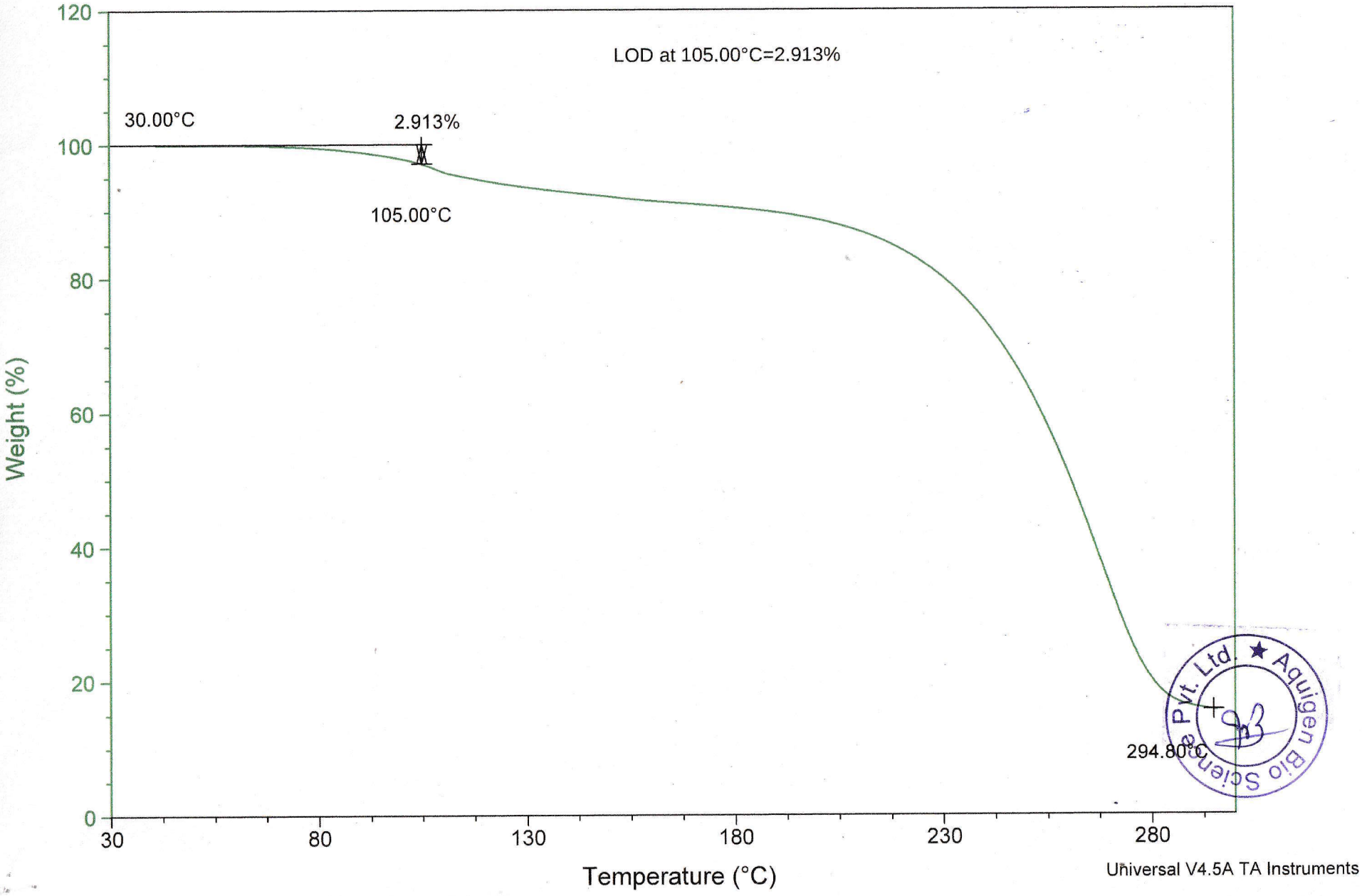
31/Aug/2022

Aquigen Bio Science Pvt. Ltd.

Sample: AQ-TR-182-004
Size: 5.0240 mg
Method: Ramp
Comment: Batch No:AQ-TR-182-004;Ramp:10°C/Min;Max Temp:300°C

TGA

File: C:...\AQ-TR-182-004TGA.002
Operator: Venkatesh
Run Date: 03 SEP 2022 13:46
Instrument: TGA Q50 V20.13 Build 39

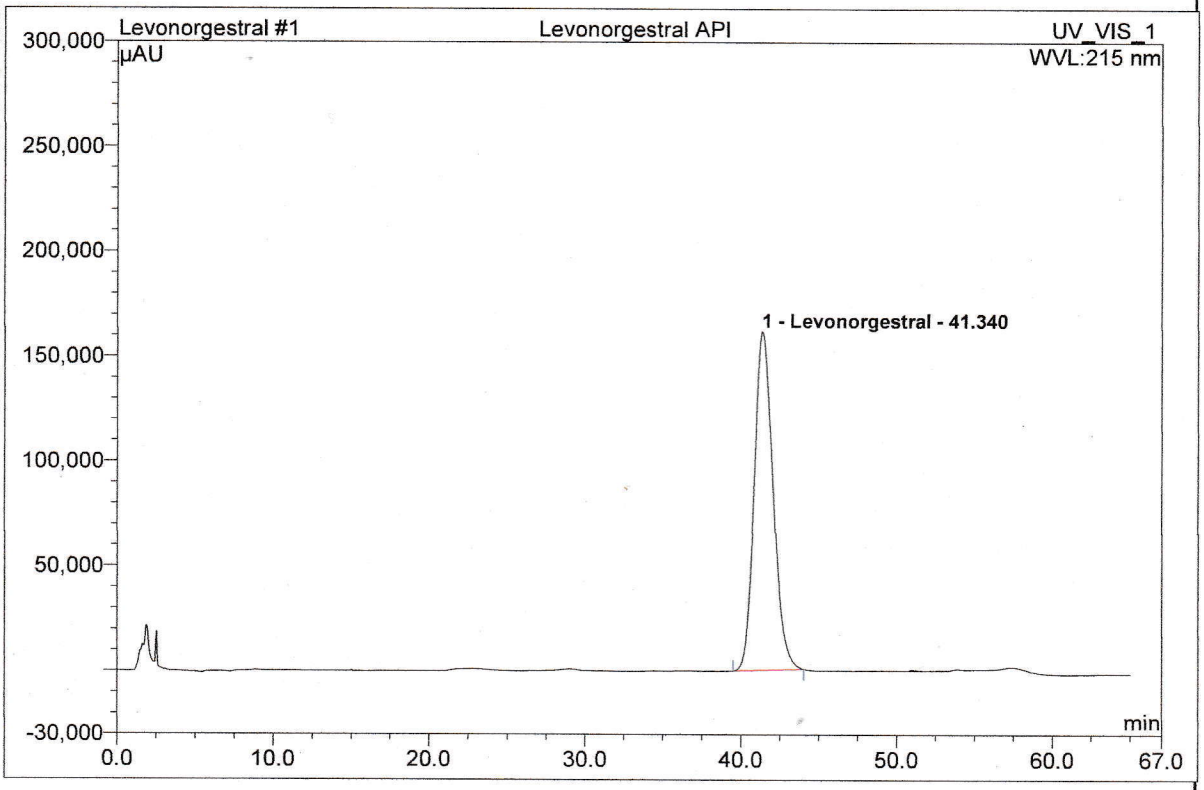


Aquigen Bio Sciences Pvt. Ltd.

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	**Levonorgestral API**	*Injection Volume:*	**20.0**
Vial Number:	**RA2**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**215.0**
Control Program:	**Levonorgestral**		
Quantif. Method:	**Levonorgestral**	*Run Time:*	**65.00**
Recording Time:	**9/15/2022 12:58**	*Sample Weight:*	**1.0000**



Peak No.	Ret.Time min	Peak Name	Area µAU*sec	Area %	Asymmetry	Plates	Resolution
1	41.340	Levonorgestral	13538135	100.00	1.26	11518	n.a.
Total:			13538135	100.00	1.26	11518	

Analysed By 15 Sept 2022

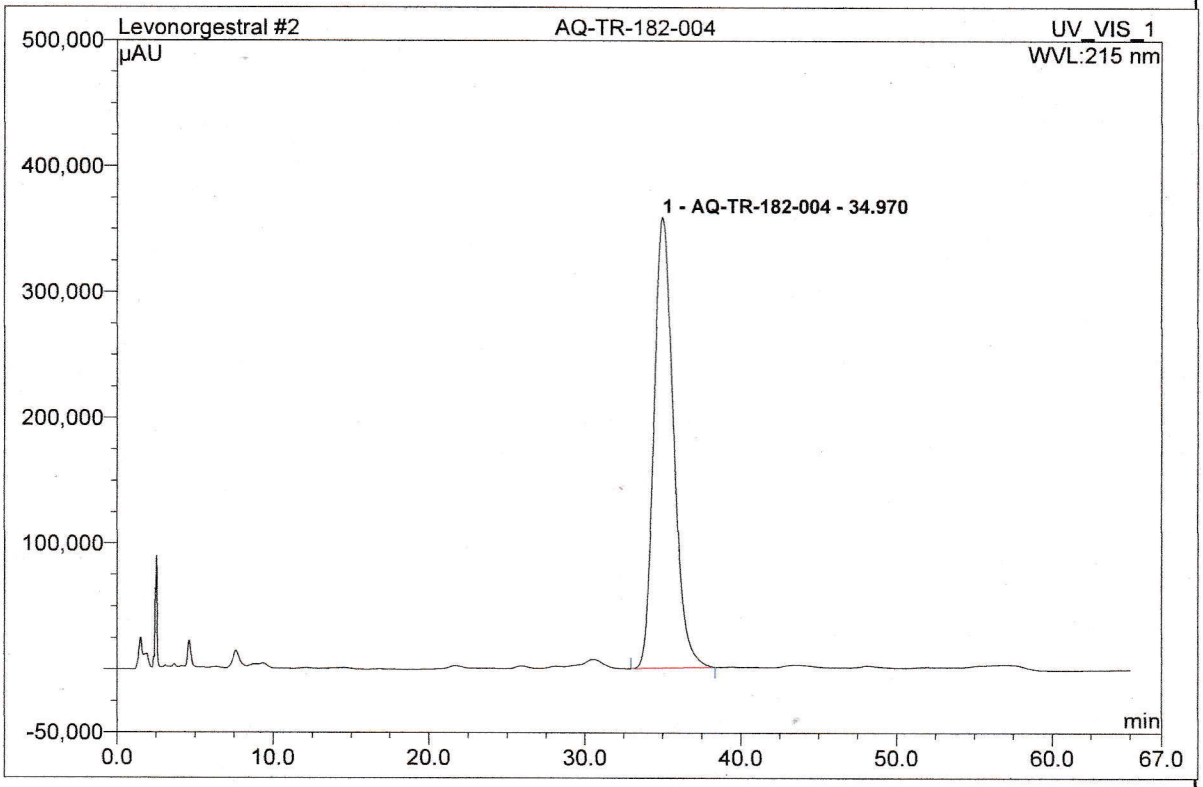
Checked By 15 Sept 2022

Aquigen Bio Science Pvt. Ltd.

IMMENSE CULTURE PVT. LTD., PUNE

HPLC CHROMATOGRAM

Sample Name:	**AQ-TR-182-004**	*Injection Volume:*	**20.0**
Vial Number:	**RA3**	*Channel:*	**UV_VIS_1**
Sample Type:	**unknown**	*Wavelength:*	**215.0**
Control Program:	**Levonorgestral**		
Quantif. Method:	**Levonorgestral**	*Run Time:*	**65.00**
Recording Time:	**9/15/2022 14:04**	*Sample Weight:*	**1.0000**



Peak No.	Ret.Time min	Peak Name	Area µAU*sec	Area %	Asymmetry	Plates	Resolution
1	34.970	AQ-TR-182-004	31175661	100.00	1.26	7750	n.a.
Total:			31175661	100.00	1.26	7750	

Analysed By 15 sept 2022

Checked By 15 Sept 2022

Aquigen Bio Science Pvt. Ltd.

Levonorgestral RRF Calculation								
Name of Sample	**RT (min)**	**RRT**	**Area**	**wt of Sample (mg)**	**Diluted to (ml)**	**Conc (ppm)**	**Response to Conc Ratio**	**RRF**
Levonorgestral	41.340	**1.00**	13538135	5.1	5	1020.0	13273	
AQ-TR-182-004	34.970	**0.85**	31175661	9.2	5	1840.0	16943	**1.28**

Aquigen Bio Science Pvt. Ltd.