CERTIFICATE OF ANALYSIS

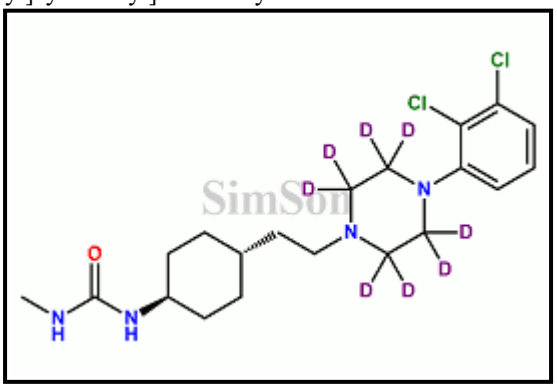
(Certificate No.: 250902 - 001 / V.03)

ISO 17034:2016 17025:2017 ACCAB

SimSon Pharma Limited
Reference Standards | Research Chemicals | Research Services

Analysis Date : 12/06/2025 **Re-test Date:** 11/06/2028

Product Name	**: N-DESMETHYL CARIPRAZINE-D8**
Chemical Name	: 1-((1r,4r)-4-(2-(4-(2,3-Dichlorophenyl)piperazin-1-yl-2,2,3,3,5,5,6,6-d8)ethyl)cyclohexyl)-3-methylurea
Synonyms	: N-[trans-4-[2-[4-(2,3-Dichlorophenyl)-1-piperazinyl-2,2,3,3,5,5,6,6-d8]ethyl]cyclohexyl]-N`-methylurea
CAT No.	: C1260034
Batch Number	: SL-DTR-324-160
CAS No.	: 1308278-85-4
Molecular Formula	: $C_{20}H_{22}D_8Cl_2N_4O$
Molecular Weight	: 421.43 g/mol
Long term Storage Condition	: Store at -20 °C
Shipping Condition	: Ice shipment



ANALYTICAL INFORMATION:

Sr No	TESTS	RESULTS
1	**DESCRIPTION**	Off white to pale yellow solid
2	**SOLUBILITY**	Soluble in DMSO & Methanol
3	**IDENTIFICATION** 1. 1H-NMR 2. 13C-NMR 3. MASS 4. IR	 Conforms to the structure Conforms to the structure Conforms to the structure Conforms to the structure
4	**ISOTOPIC ENRICHMENT**	96.4%
5	**PURITY (By HPLC)**	96.07%
6	**WEIGHT LOSS (By TGA)** Weight Loss: (30°C to 105°C)(30° to 900°C, rate: 40°C/min)	2.13%w/w
7	**DEFINED POTENCY (By Mass Balance Method)** % = [100-(Weight Loss by TGA) x HPLC Purity/100]	94.02%w/w

Not for Human or Animal Consumption. Only for Analytical Testing Purpose

Prepared By : **Devesh.V.Mishra**
(Sign & Date) **02/09/2025**

Approved By : **Dipali Thakur**
(Sign & Date) **02/09/2025**

Quality Accreditations: ISO 9001:2015, ISO 17034:2016, ISO/IEC 17025:2017, GLP Certified, DSIR

Simson Pharma Limited :Office :B-307, Sarita Building, Prabhat Indl. Estate. Nr. Dahisar Toll Naka, Dahisar (East), Mumbai - 400068.
Simson Life Sciences Pvt.Ltd :Shed No.6A, Type III, TSIIC, Prashanthi Nagar, Kukatpally, Hyderabad, Telangana-500072

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I. IDENTIFICATION BY ^{1}HNMR SPECTROSCOPY

A. Experimental:

Product name	: N-DESMETHYL CARIPRAZINE-D8	**Instrument Name**	: FT-NMR Spectrometer
Batch No.	: SL-DTR-324-160	**Instrument Model**	: BRUKER 400MHZ
Solvent	: CD3OD	**Instrument ID**	: SATL/EQ/197

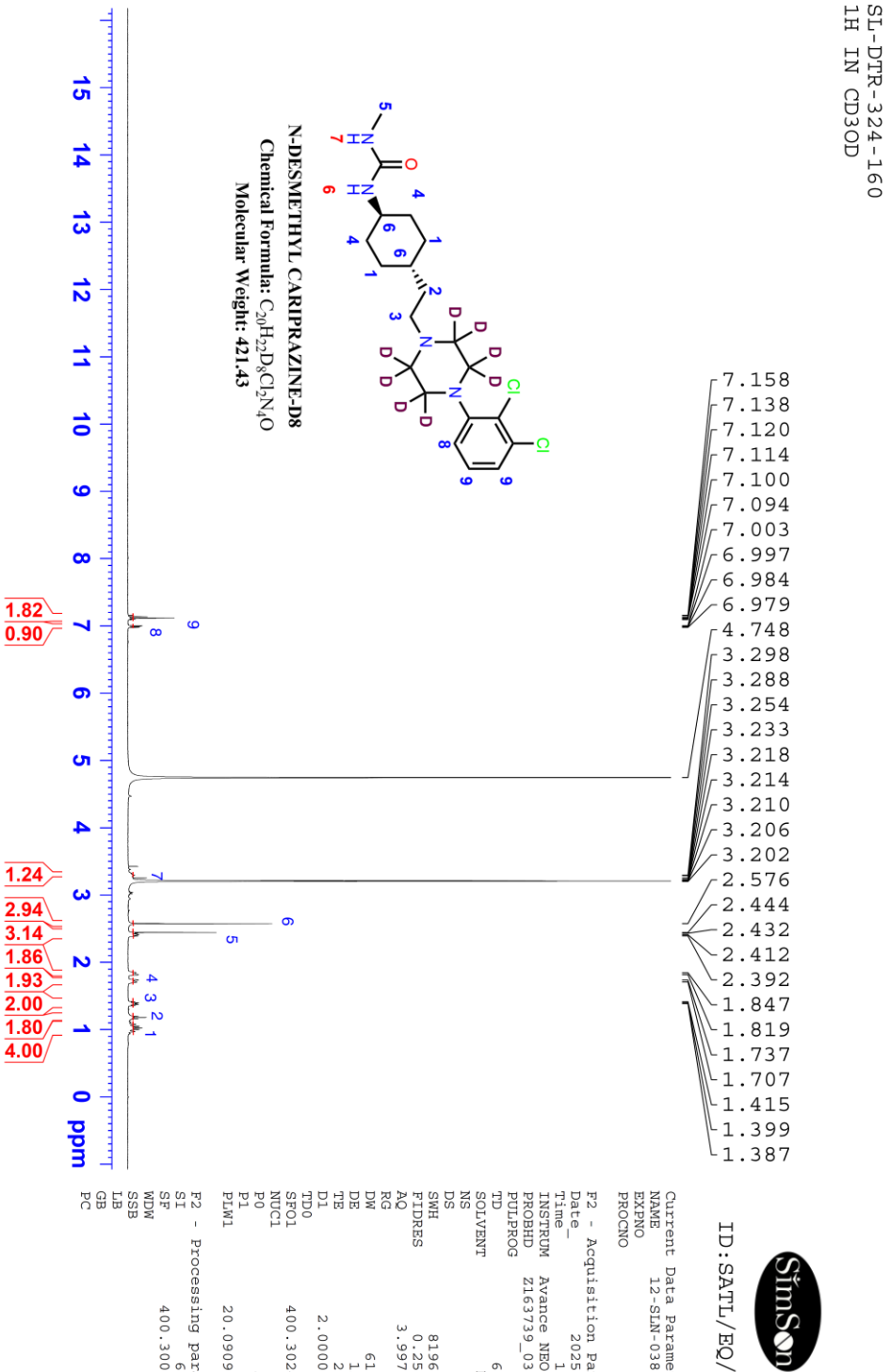
B. Methodology: The NMR experiments were performed in 400 MHZ Bruker FT-NMR Spectrometer using CD3OD Solvent. ^{1}H NMR Chemical shifts are reported on the δ scale in ppm in relative to TMS. The assignment of protons is given below.

C. Results:

S.No.	**Chemical Shift δ, ppm**	***Multiplicity***	***No. of protons***	***'J' coupling constant***	***Assignment of proton(s)***
1.	1.02-1.11	M	4H	-	4
2.	1.14-1.19	M	2H	-	2
3.	1.35- 1.41	M	2H	-	2
4.	1.70- 1.73& 1.81- 1.84	D&D	4H	-	4
5.	2.39- 2.44	M	3H	-	3
6.	2.576	S	3H	-	3
7.	3.28- 3.29	D	1H	-	1
8.	6.97- 7.00	M	1H		1
9.	7.094- 7.15	M	2H	-	2
Total No. of protons					**22**
Remark :-			Confirms to the structure		

Note: The Assignments are based on chemical shifts and multiplicities

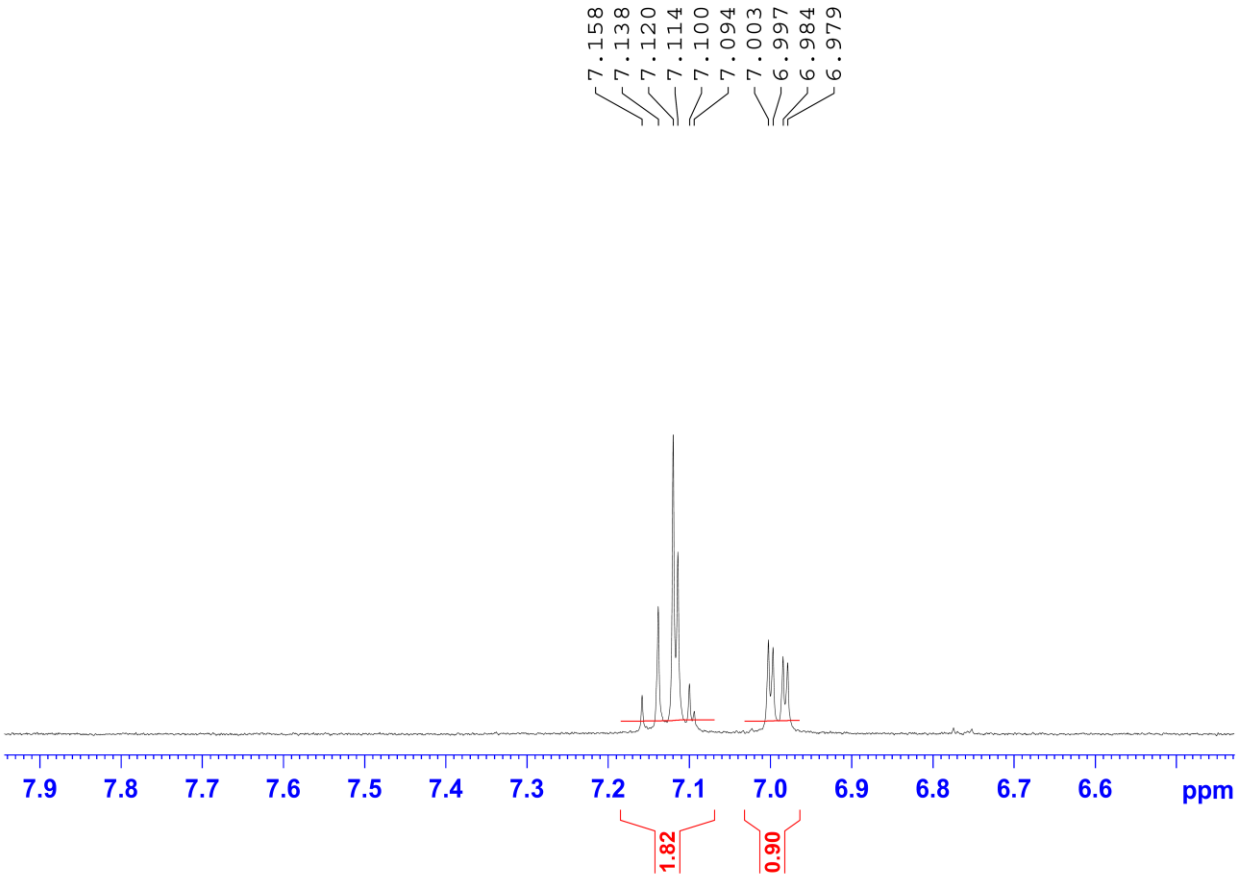
Prepared By: **Reviewed By:**



Prepared By:

Reviewed By:

SL-DTR-324-160
1H IN CD3OD



ID:SATL/EQ/197

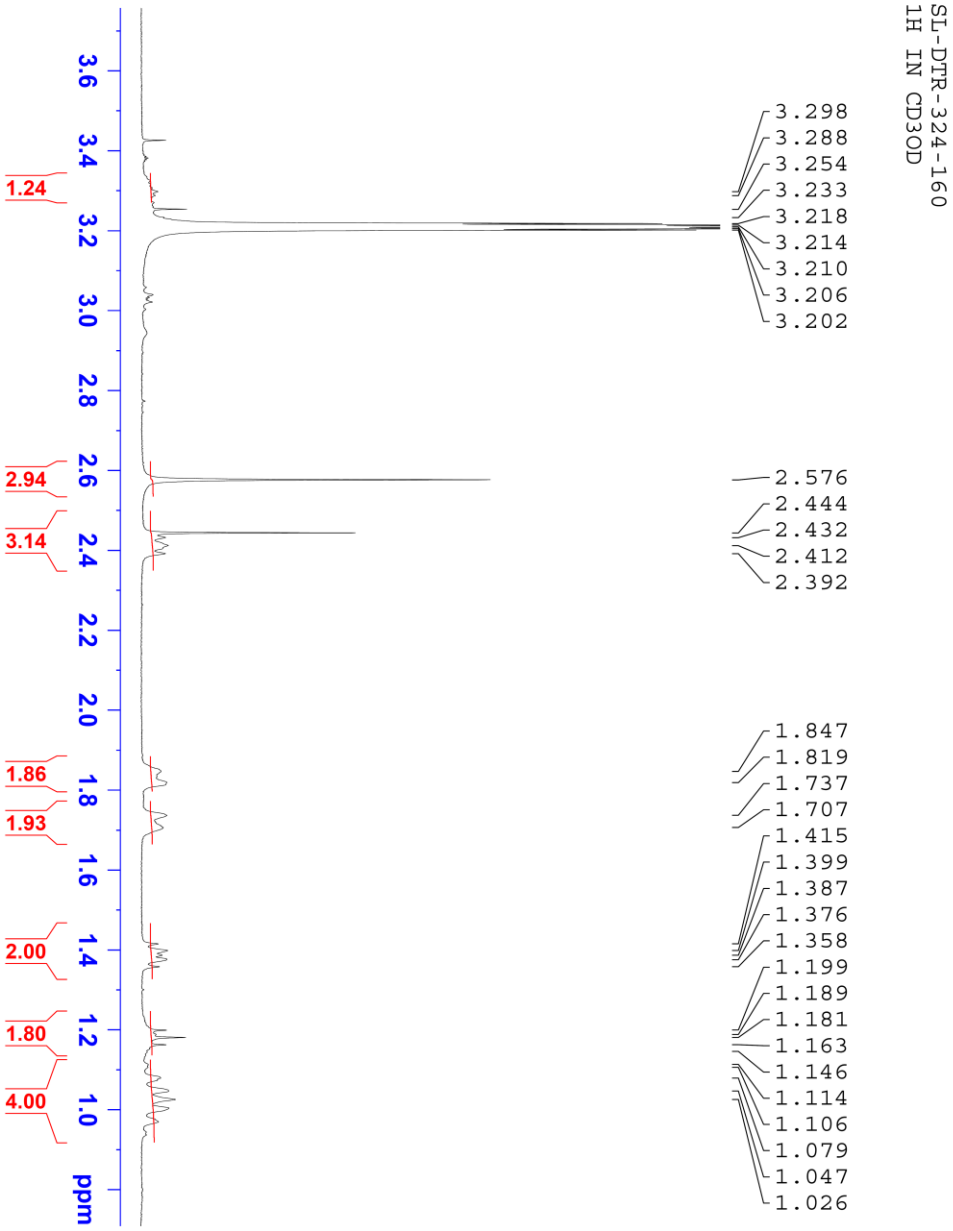
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EXPNO                1
PROCNO               1

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Time             13.37 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG            zg30
TD                65536
SOLVENT             MeOD
NS                    12
DS                     2
SWH             8196.722 Hz
FIDRES          0.250144 Hz
AQ              3.9976959 sec
RG                   101
DW                61.000 usec
DE                13.89 usec
TE                299.3 K
D1           2.00000000 sec
TD0                   1
SFO1         400.3024719 MHz
NUC1                 1H
P0                2.67 usec
P1                8.00 usec
PLW1         20.09099960 W

F2 - Processing parameters
SI                65536
SF           400.3000478 MHz
WDW                  EM
SSB                   0
LB                 0.30 Hz
GB                    0
PC                 1.00
```

Reviewed By: B. Sujatha

Prepared By:



Prepared By:

Reviewed By:

II. IDENTIFICATION BY ^{13}C NMR SPECTROSCOPY:

A. Experimental:

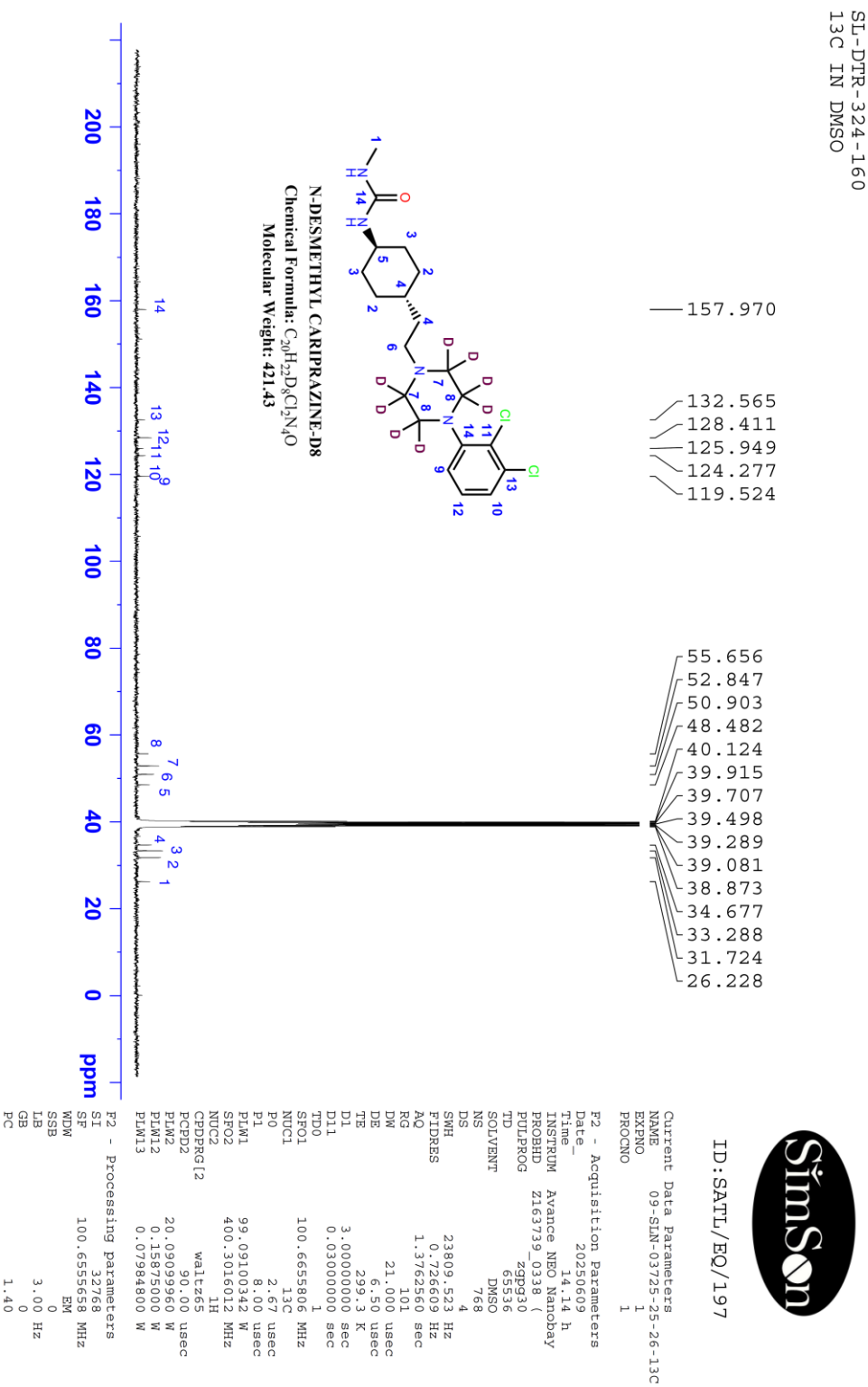
Product name	**:** N-DESMETHYL CARIPRAZINE-D8	**Instrument Name**	**:** FT-NMR Spectrometer
Batch No.	**:** SL-DTR-324-160	**Instrument Model**	**:** BRUKER 400MHZ
Solvent	**:** DMSO	**Instrument ID**	**:** SATL/EQ/197

B. Methodology: The NMR experiments were performed in 400 MHZ Bruker FT-NMR Spectrometer using DMSO Solvent.^{13}C NMR Chemical shifts are reported on the δ scale in ppm in relative to TMS.The assignment of carbons is given below.

C. Results:

S.No.	**Chemical Shift δ, ppm**	***Multiplicity***	***No. of Carbons***	***Assignment of Carbons(s)***
1.	26.22	S	1C	1
2.	31.72	S	2C	2
3.	33.28	S	2C	2
4.	34.67	S	2C	2
5.	48.482	S	1C	1
6.	50.90	S	1C	1
7.	52.84	S	2C	2
8.	55.65	S	2C	2
9.	119.52	S	1C	1
10.	124.27	S	1C	1
11.	125.94	S	1C	1
12.	128.41	S	1C	1
13.	132.56	S	1C	1
14.	157.97	S	2C	2
Total No. of Carbons				**20**
Remark :-			**Confirms to the structure**	

Prepared By: **Reviewed By:**



Prepared By:

Reviewed By:

SL-DTR-324-160
13C IN DMSO

157.970
132.565
128.411
125.949
124.277
119.524

ID:SATL/EQ/197

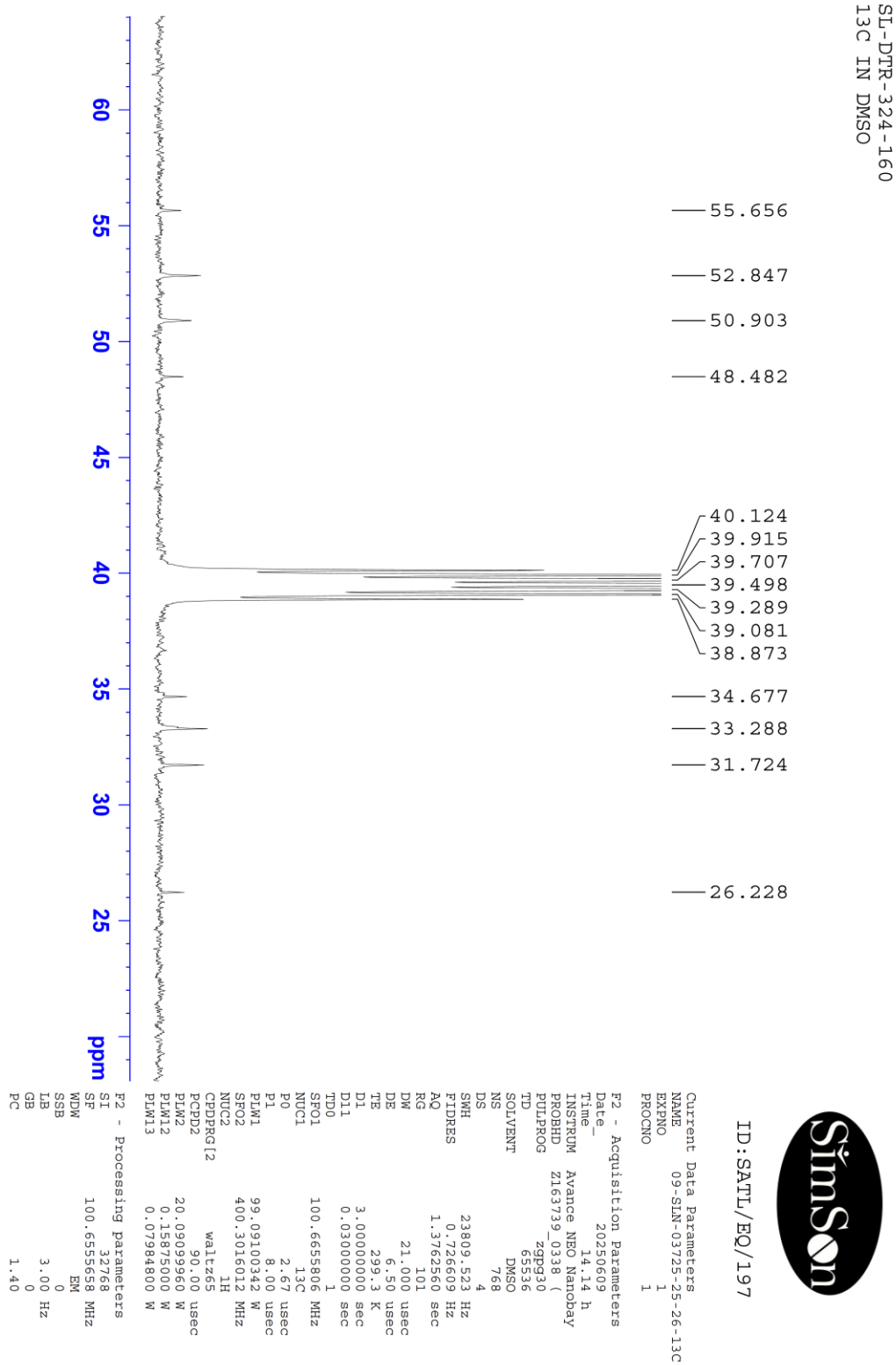

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EXPNO                                      1
PROCNO                                     1

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PROBHD           Z163739_0338 (
PULPROG                          zgpg30
TD                                    65536
SOLVENT                            DMSO
NS                                      768
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                                299.3 K
D1                             3.00000000 sec
D11                            0.03000000 sec
TD0                                       1
SFO1                      100.6655806 MHz
NUC1                                   13C
P0                                  2.67 usec
P1                                  8.00 usec
PLW1                      99.09100342 W
SFO2                      400.3016012 MHz
NUC2                                   1H
CPDPRG[2                          waltz65
PCPD2                              90.00 usec
PLW2                      20.09099960 W
PLW12                      0.15875000 W
PLW13                      0.07984800 W

F2 - Processing parameters
SI                                    32768
SF                        100.6555658 MHz
WDW                                      EM
SSB                                       0
LB                                 3.00 Hz
GB                                        0
PC                                     1.40
```

Prepared By:

Reviewed By: B. Sujatha



Prepared By:

Reviewed By:

III. IDENTIFICATION BY MASS SPECTROSCOPY:

A. Experimental:

Product name	**:** N-DESMETHYL CARIPRAZINE-D8	**Instrument Name**	**:** Mass Spectrometer
Batch No.	**:** SL-DTR-324-160	**Instrument Model**	**:** API 2000
Solvent used	**:** METHANOL	**Instrument ID**	**:** SATL/EQ/016

B. Methodology: The mass spectroscopy studies were performed on API 2000 mass spectrometer triple quadruple. The mass spectrum in positive mode displayed a protonated molecular ion at m/z 421.3 g/mol corresponding to $[M+H]^+$confirms the monoisotopic mass as m/z corresponding to the Molecular formula $C_{20}H_{22}D_8Cl_2N_4O$

Solvent: methanol.

C. Results:

S. No.	Composition	Exact Mass	Molecular Weight	m/z value
1.	$C_{20}H_{22}D_8Cl_2N_4O$	420.23	421.43	421.3(+ve mode)

Remarks:

1. Mass peak at m/z 421.3 corresponds to product mass peak.
2. Other peaks are unidentified peaks

Prepared By: **Reviewed By:**

Batch Name: ManualTune.bat

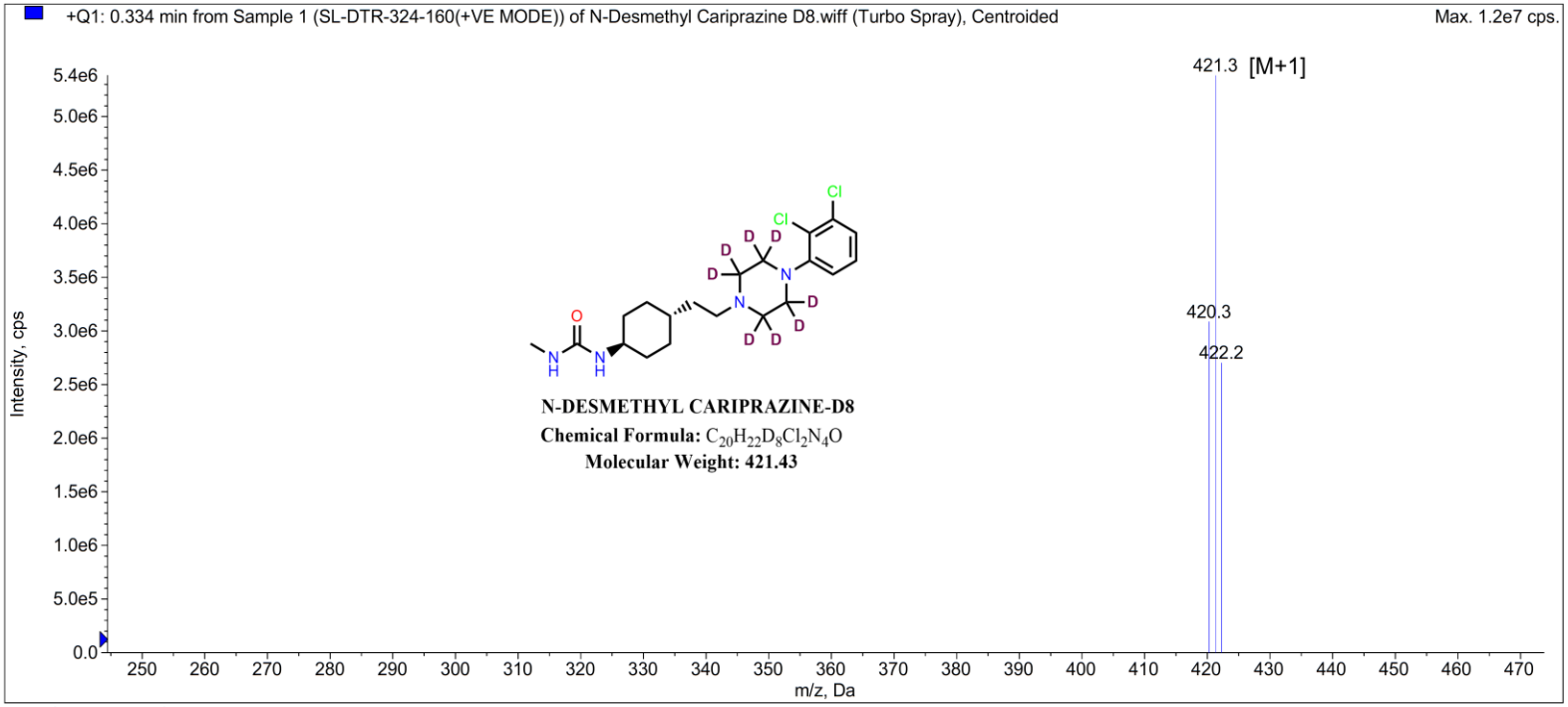
Sample Comment: Solvent:Methanol
No:CSL/02037/25-26

Reg

Acq. File: N-Desmethyl Cariprazine D8.wiff
Sample Name: SL-DTR-324-160(+VE MODE)
Acq. Date: Monday, June 09, 2025
Operator: Rupali Lahare
Acq. Time: 14:35

Sample ID: TuneSampleID

InstrumentID:SATL/EQ/016



Algorithm: IntelliQuan

*Analysed By:

*Checked By:

Reviewed By:

Prepared By:

IV. IDENTIFICATION BY FT-IR SPECTROSCOPY:

A. Experimental:

Product name	**:** N-DESMETHYL CARIPRAZINE-D8	**Instrument Name**	**:** FT-IR Spectrometer
Batch No.	**:** SL-DTR-324-160	**Instrument Model**	**:** BRUKER
Sample Preparation	**:** KBr pellet	**Instrument ID**	**:** SATL/EQ/025

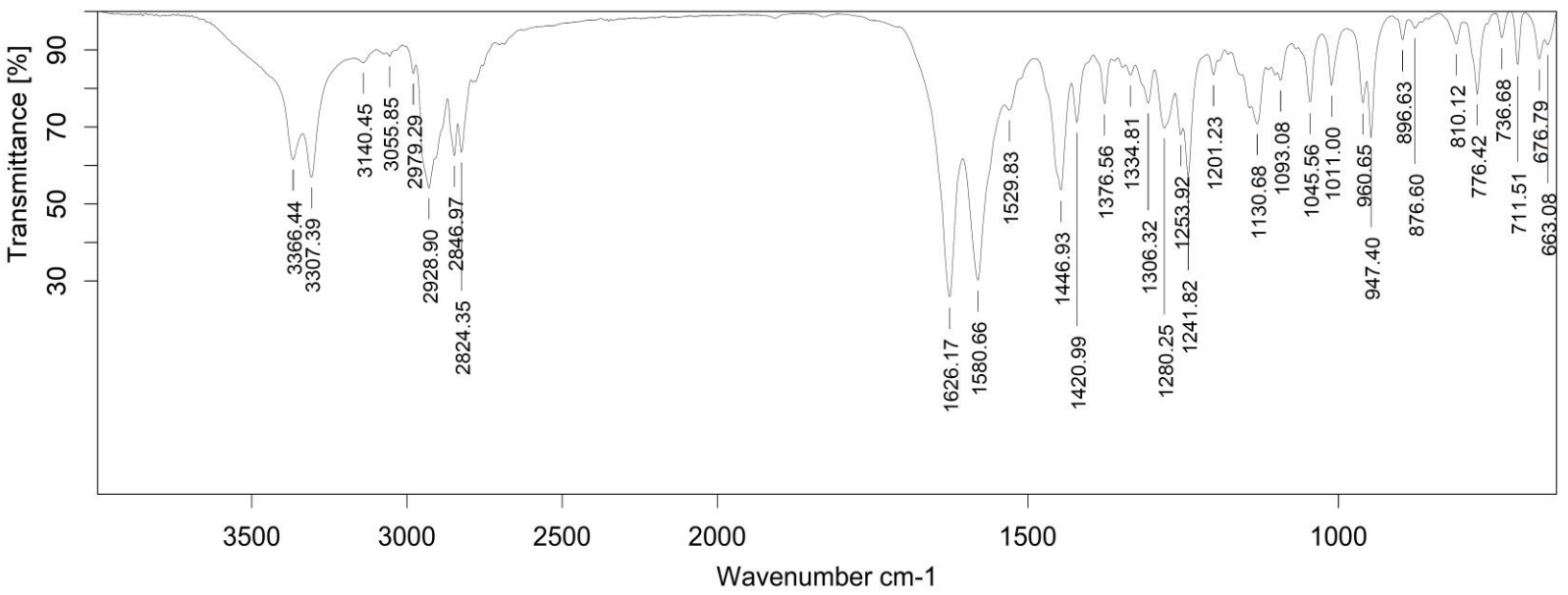
B. Methodology: N-DESMETHYL CARIPRAZINE-D8 was recorded on FT-IR Bruker Spectrometer by using KBr pellet technique. The structural assignments have been correlated with the following frequencies.

C. Results:

S. No.	Absorption peak cm-1	Specific type of bond	Corresponding Functional Group
1.	1280.25	Stretching	C-N
2.	3366.44	Stretching	N-H
3.	1626.17	Stretching	C=O
4.	776.42	Stretching	C-Cl

Instrument ID No:SATL/EQ/025

SIMSON LIFE SCIENCES PVT.LTD



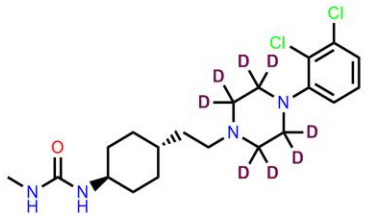
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Sample Name:N-Desmethyl Cariprazine d8

Lot No./Batch No:SL-DTR-324-160 Reg No-SLN-03725-25-26

Date & Time:10/06/2025,10:34:17

Operator Name:saimadhuriB



N-DESMETHYL CARIPRAZINE-D8

Chemical Formula: $C_{20}H_{22}D_8Cl_2N_4O$

Molecular Weight: 421.43

Experiment:Trans.XPM

Resolution:4

Sample Scans:32

Frequency Range:4000 to 650

10/06/2025 10:35:35

Page 1/1

Reviewed By: B. Sujatha

Prepared By:

V. PURITY BY HPLC:

A. Experimental:

Product name	**:** N-DESMETHYL CARIPRAZINE-D8	**Instrument Name :**	HPLC
Batch No.	**:** SL-DTR-324-160	**Instrument Model :**	Shimadz
Method	**:** Inhou	**Instrument ID :**	SATL/EQ/212

B. HPLC Method:

Column: C_{18}, (150 X 4.6mm), 5µm
Mobile phase A: 1.36gm of KH2PO4 in 1000ml of water. Adjusted pH 3.2 with diluted OPA.
Mobile phase B: acetonitrile
Elution mode: Gradient Programme

Detector (λ)	:	220nm
Column Temperature	:	30°C
Run Time	:	30min
Flow	:	1 ml/min
Diluent	:	acetonitrile, water (50:50 V/V)
Inj. Volume	:	20µl
Sample Preparation	:	1 mg/ml in Diluent.

Gradient Programme:

Time	Mobile Phase A	Mobile Phase B
0	80	20
5	80	20
15	20	80
20	20	80
25	80	20
30	80	20

C. Results: 96.07% by area normalization

Prepared By: **Reviewed By:**

HPLC Chromatogram:

Simson Life Sciences Pvt Ltd

<Sample Information>

07_06_2025_(1)_007.lcd

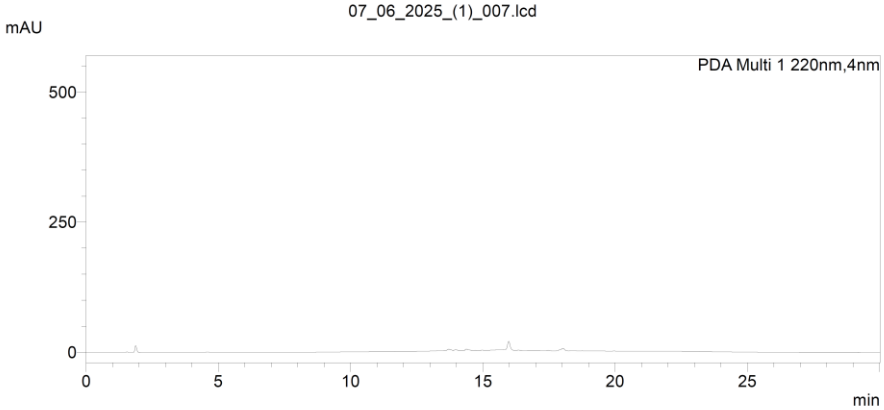
Sample Name	: N-Desmethyl Cariprazine		
Sample ID	: Blank		
Data Filename	: 07_06_2025_(1)_007.lcd		
Method Filename	: General Gradient In-House Method.lcm		
Batch Filename	: 07_06_2025_(1).lcb		
Vial #	: 2-24	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 07/06/2025 14:48:27	Acquired by	: NARESH KATIKA
Date Processed	: 07/06/2025 15:32:56	Processed by	: NARESH KATIKA
Data Description	: Reg No:CSL/02004/25-26		

Column ID:150*4.6mm,5u(C18)Hypersil BDS CLC0242
Method:General Gradient Method.
MP-A: 1.36gm of KH2PO4 in 1000ml of water.
Adjusted pH 3.2 with diluted OPA.
MP-B: ACN
Flow:1.0 ml/min
Diluent:Water:ACN(50:50)
Time Programme:

0.01 Pumps	B.Conc 20
5.00 Pumps	B.ConC20
15.00 Pumps	B.Conc 80
20.00 Pumps	B.Conc 80
25.00 Pumps	B.Conc 20
30.00 Pumps	B.Conc 20
30.01 Controller	Stop

<Chromatogram>

07_06_2025_(1)_007.lcd



<Peak Table>

07_06_2025_(1)_007.lcd

PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
Total				

SATLEQ212$CSL_JUN_2025 - 15-129-2 - 07_06_2025_(1)_007.lcd

Prepared By: **Reviewed By:**

Simson Life Sciences Pvt Ltd

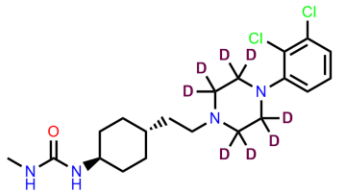
<Sample Information>

07_06_2025_(1)_003.lcd

Sample Name	: N-Desmethyl Cariprazine-d8		
Sample ID	: SL-DTR-324-160		
Data Filename	: 07_06_2025_(1)_003.lcd		
Method Filename	: General Gradient In-House Method.lcm		
Batch Filename	: 07_06_2025_(1).lcb		
Vial #	: 2-34	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 07/06/2025 10:37:33	Acquired by	: NARESH KATIKA
Date Processed	: 07/06/2025 14:35:42	Processed by	: NARESH KATIKA

Data Description : Reg No:CSL/02004/25-26
Column ID:150*4.6mm,5u(C18)Hypersil BDS CLC0242
Method:General Gradient Method.
MP-A: 1.36gm of KH2PO4 in 1000ml of water.
Adjusted pH 3.2 with diluted OPA.
MP-B: ACN
Flow:1.0 ml/min
Diluent:Water:ACN(50:50)
Time Programme:

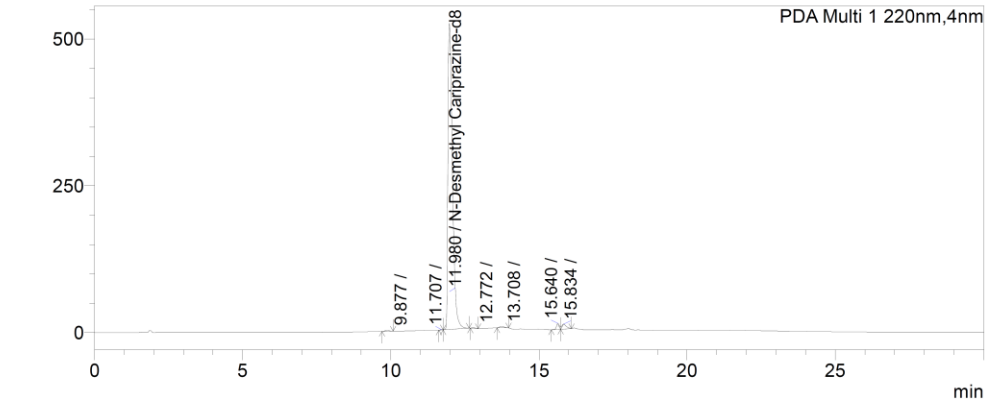
0.01 Pumps	B.Conc 20
5.00 Pumps	B.ConC20
15.00 Pumps	B.Conc 80
20.00 Pumps	B.Conc 80
25.00 Pumps	B.Conc 20
30.00 Pumps	B.Conc 20
30.01 Controller	Stop



N-DESMETHYL CARIPRAZINE-D8
Chemical Formula: $C_{20}H_{22}D_8Cl_2N_4O$
Molecular Weight: 421.43

<Chromatogram>

07_06_2025_(1)_003.lcd



<Peak Table>

07_06_2025_(1)_003.lcd

PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
1		9.877	20771	0.361
2		11.707	2557	0.044
3	N-Desmethyl Cariprazine-d8	11.980	5532957	96.069
4		12.772	9087	0.158
5		13.708	28122	0.488

SATLEQ212$CSL_JUN_2025 - 15-125-2 - 07_06_2025_(1)_003.lcd

Prepared By: **Reviewed By:**

VI. LOSS ON DRYING AND ASH CONTENT BY THERMO GRAVIMETRIC ANALYSIS (TGA):

A. Experimental:

Product name	**:** N-DESMETHYL CARIPRAZINE-D8	**Instrument Name**	**:** TGA
Batch No.	**:** SL-DTR-324-160	**Instrument Model**	**:** Perkin Elmer
Method	**:** 30ºC to 800ºC	**Instrument ID**	**:** SATL/EQ/041

B. Methodology: Sample was recorded on a TGA Analyzer as per the below conditions.

30ºC to 120ºC at 10ºC/min; Gas Flow:

120ºC to 800ºC at 40ºC/min; Gas Flow:

C. Results:

i. % of Loss Observed up to 105ºC: 2.13%

ii. % of Ash content observed: NIL

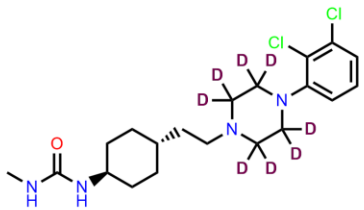
The TGA thermogram is enclosed.

Prepared By: **Reviewed By:**

Filename:	D:\SATLEQ...\N-Desmethyl Cariprazine d8.t6d
Data Collected:	10/06/2025 10:09:01
Operator ID:	Satish Kumar Raju Nadimpalli
Sample ID:	SL-DTR-324-160
Sample Weight:	1.849 mg
Comment:	SLN/03725/25-26

Simson Life Sciences PVT. Ltd

N-Desmethyl Cariprazine d8



N-DESMETHYL CARIPRAZINE-D8
Chemical Formula: $C_{20}H_{22}D_8Cl_2N_4O$
Molecular Weight: 421.43

(Weight Loss: 30° C to 105° C):2.13%
(30° to 900°, rate: 40°C/min)

10/06/2025 10:14:54

1) Hold for 1.0 min at 30.00°C
2) Heat from 30.00°C to 120.00°C at 10.00°C/min
3) Heat from 120.00°C to 900.00°C at 40.00°C/min

Reviewed By: B. Sujitha

Prepared By:

VII. ISOTOPIC PURITY:

Standard -1	10237.181	
Standard -2	10049.654	
Standard -3	10003.054	
AVG	10096.63	

N-Desmethyl Cariprazine D8
SL-DTR-324-160

Reg no:CSL/02037/25-26

D0 Content									
									In %
Preparation 1	962.388	1.43	1	1	0.1	10	98	100	0.0009
	10096.6	10	10	10	10	1.53	100		
Preparation 2	799.033	1.43	1	1	0.1	10	98	100	0.0007
	10096.6	10	10	10	10	1.54	100		
							Average		0.0008

Prepared By:

Reviewed By: B. Sujatha

VIII. DEFINED POTENCY (BY MASS BALANCE METHOD):

Potency/Content/Assay of this product has been determined by a mass balance method.

Formula:

Chromatography purity x (100-(LOD by TGA+ Ash content))/100

Purity= 96.07%
LOD by TGA: 2.13%
Ash content: 0%

Calculation:

= 96.07x (100-2.13**)**/100

Defined Potency = **94.02 %** w/w

IX. CONCLUSION: The product has been qualified by identification by ^{1}H NMR, ^{13}C NMR, Mass and HPLC, TGA.

Potency/Content/Assay has defined by mass balance method.

This product has been qualified and can be used as an analytical standard for qualitative and quantitative purpose.

Disclaimer:

The product is meant for analytical testing purpose only and not for human/animal consumption.

No patents are applicable for this product as product is manufactured in small quantities for analytical testing purpose only.

Prepared By: **Reviewed By:**