CERTIFICATE OF ANALYSIS

(Certificate No.: SPC260530 - 029 /)

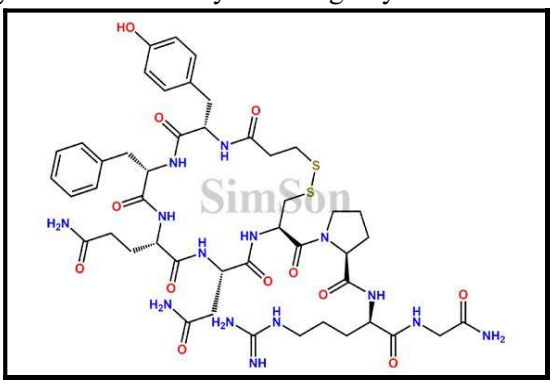
ISO 17034:2016 17025:2017 ACCAB

SimSon Pharma Limited

Reference Standards | Research Chemicals | Research Service

Analysis Date : 28/05/2026 **Re-test Date:** 27/05/2027

Product Name	**: DESMOPRESSIN EP IMPURITY D**
Chemical Name	: (S)-1-((4R,7S,10S,13S,16S)-7-(2-amino-2-oxoethyl)-10-(3-amino-3-oxopropyl)-13-benzyl-16-(4-hydroxybenzyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentaazacycloicosane-4-carbonyl)-N-((R)-1-((2-amino-2-oxoethyl)amino)-5-guanidino-1-oxopentan-2-yl
Synonyms	: [L-Arg8] Desmopressin;[8-L-Arginine]desmopressin;Mpa-Tyr-Phe-Gin-Asn-Cys-Pro-Arg-Gly-NH2
CAT No.	: D980030
Batch Number	: SR-JMP-0098-001
CAS No.	: 113-81-5
Molecular Formula	: $C_{46}H_{64}N_{14}O_{12}S_2$
Molecular Weight	: 1069.22 g/mol
Long term Storage Condition	: -20°C
Shipping Condition	: -20°C



ANALYTICAL INFORMATION:

Sr No	TESTS	RESULTS
1	**DESCRIPTION**	White Hygroscopic Solid
2	**SOLUBILITY**	Water
3	**IDENTIFICATION**	
	1. 1H-NMR	Confirms to the structure
	2. 13C-NMR	Confirms to the structure
	3. IR	Confirms to the structure
	4. MASS	Confirms to the structure
4	**PURITY (By HPLC)** (By HPLC, area Normalization)	99.89%
5	**WEIGHT LOSS (By TGA)** Weight Loss: (30°C to 105°C)rate: 20°C/min)	5.427%w/w
6	**ASH CONTENT** (105°C to 150°C , rate: 40°C/min)(150° to 900°, rate: 60°C/min)	NIL
7	**DEFINED POTENCY (By Mass Balance Method)**% = [(100-(Weight Loss by TGA +Ash content)) x HPLC Purity/100]	94.46%w/w

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

Prepared By : Hiran Darji
(Sign & Date)

Approved By : Janmay shah
(Sign & Date)

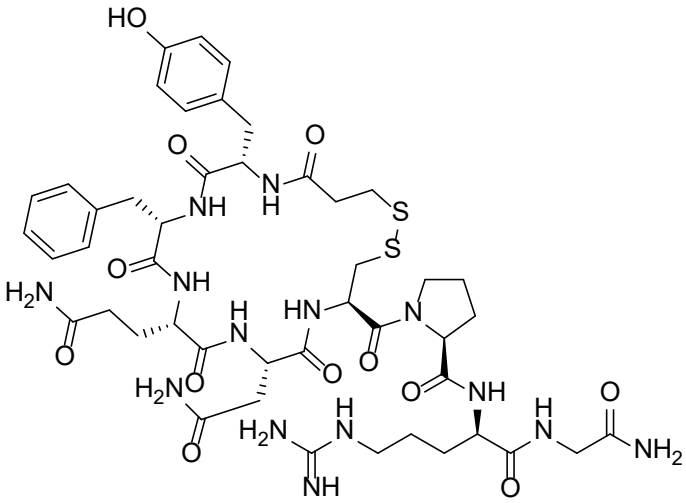
Quality Accreditations: ISO 9001:2015, ISO 17034:2016, ISO/IEC 17025:2017, GLP Certified, DSIR

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

PRODUCT TECHNICAL INFORMATION

Qualification Report Number: SR-JMP-0098-001/QR/26- 00314

Product Name	**Desmopressin EP Impurity D**
Chemical Name	(S)-1-((4R,7S,10S,13S,16S)-7-(2-amino-2-oxoethyl)-10-(3-amino-3-oxopropyl)-13-benzyl-16-(4-hydroxybenzyl)-6,9,12,15,18-pentaoxo-1,2-dithia-5,8,11,14,17-pentaazacycloicosane-4-carbonyl)-N-((R)-1-((2-amino-2-oxoethyl)amino)-5-guanidino-1-oxopentan-2-yl)pyrrolidine-2-carboxamide
Molecular Formula	$C_{46}H_{64}N_{14}O_{12}S_2$
Molecular Weight	1069.22 g/mol
Batch No.	SR-JMP-0098-001
Synonyms	[L-Arg8] Desmopressin;[8-L-Arginine]desmopressin;Mpa-Tyr-Phe-Gin-Asn-Cys-Pro-Arg-Gly-NH2
CAS No.	**113-81-5**
CAT No.	D980030



Prepared By: **Reviewed By:**

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S.No.	Description	Page. No
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I. DESCRIPTION & CHARECTERISTICS

A. Description:

Methodology **:** Visual Observation

Observation/Results **:** White Hygroscopic solid

B. Solubility:

Methodology: As per European pharmacopeia Monograph **.**

Observation/Results: water

II. IDENTIFICATION BY ^{1}HNMR SPECTROSCOPY

A. Experimental:

Product name : DESMOPRESSIN EP IMPURITY D		**Instrument Name** : FT-NMR Spectrometer	
Batch No. : SR-JMP-0098-001		**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. ^{1}H NMR Chemical shifts are reported on the δ scale in ppm in relative to TMS. The assignment of protons is given below.

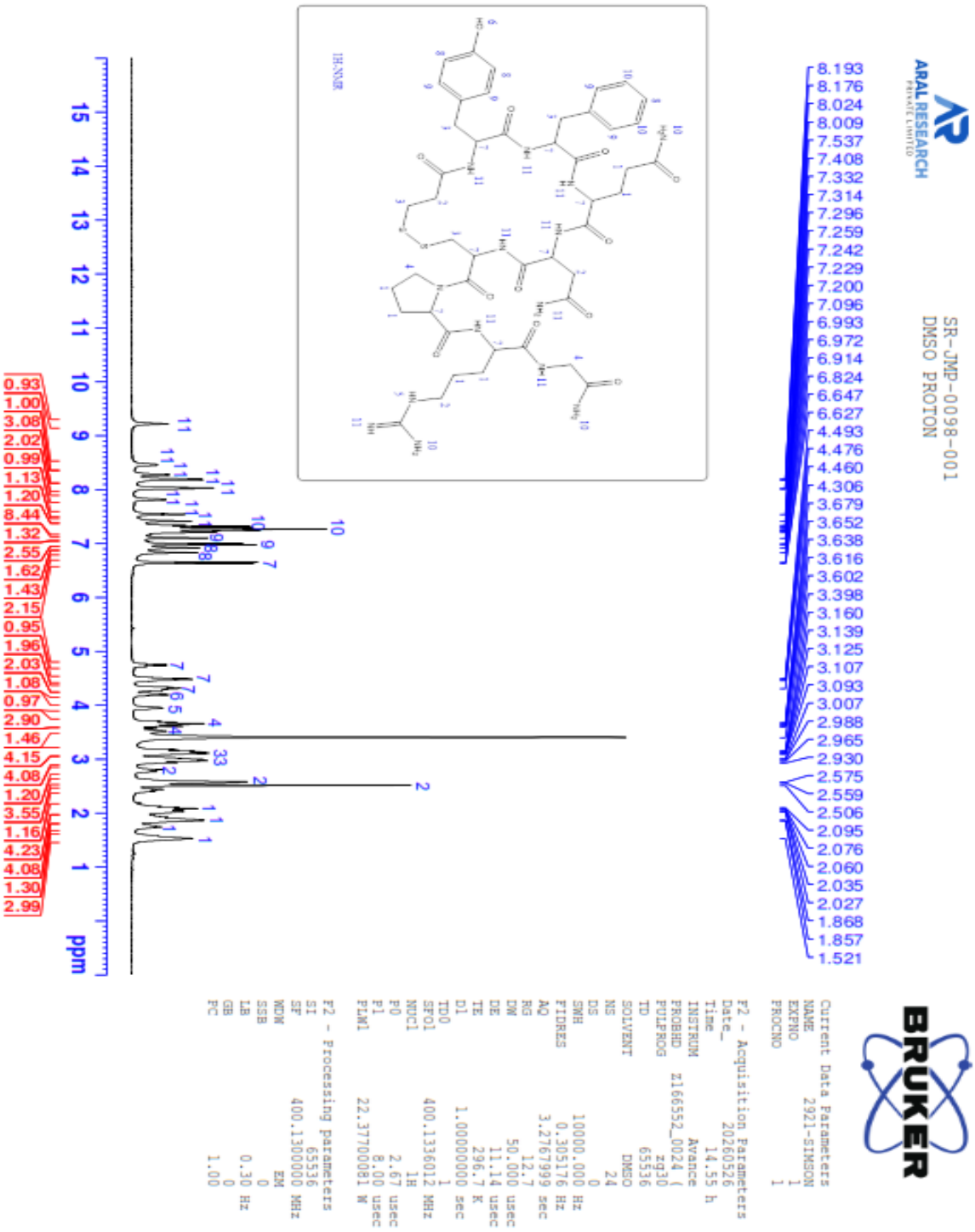
C. Results:

S. No.	Chemical Shift δ, ppm	Multiplicity	No. of protons	'J' coupling constant	Assignment of proton(s)
1.	1.521-2.116	M	12H	-	12
2.	2.432-2.797	M	6H	-	6
3.	2.930-3.173	M	8H	-	8
4.	3.511-3.694	M	4H	-	4
5.	3.942	S	1H	-	1
6.	4.185-4.201	M	1H	-	1
7.	4.269-6.647	M	7H	-	7
8.	6.824-6.914	M	3H	-	3
9.	6.972-7.160	M	4H	-	4
10.	7.200-7.314	M	8H	-	8
11.	7.332-9.215	M	10H		10
Total No. of protons			**64 H**		**64**
Remarks:-			Confirms to the structure		

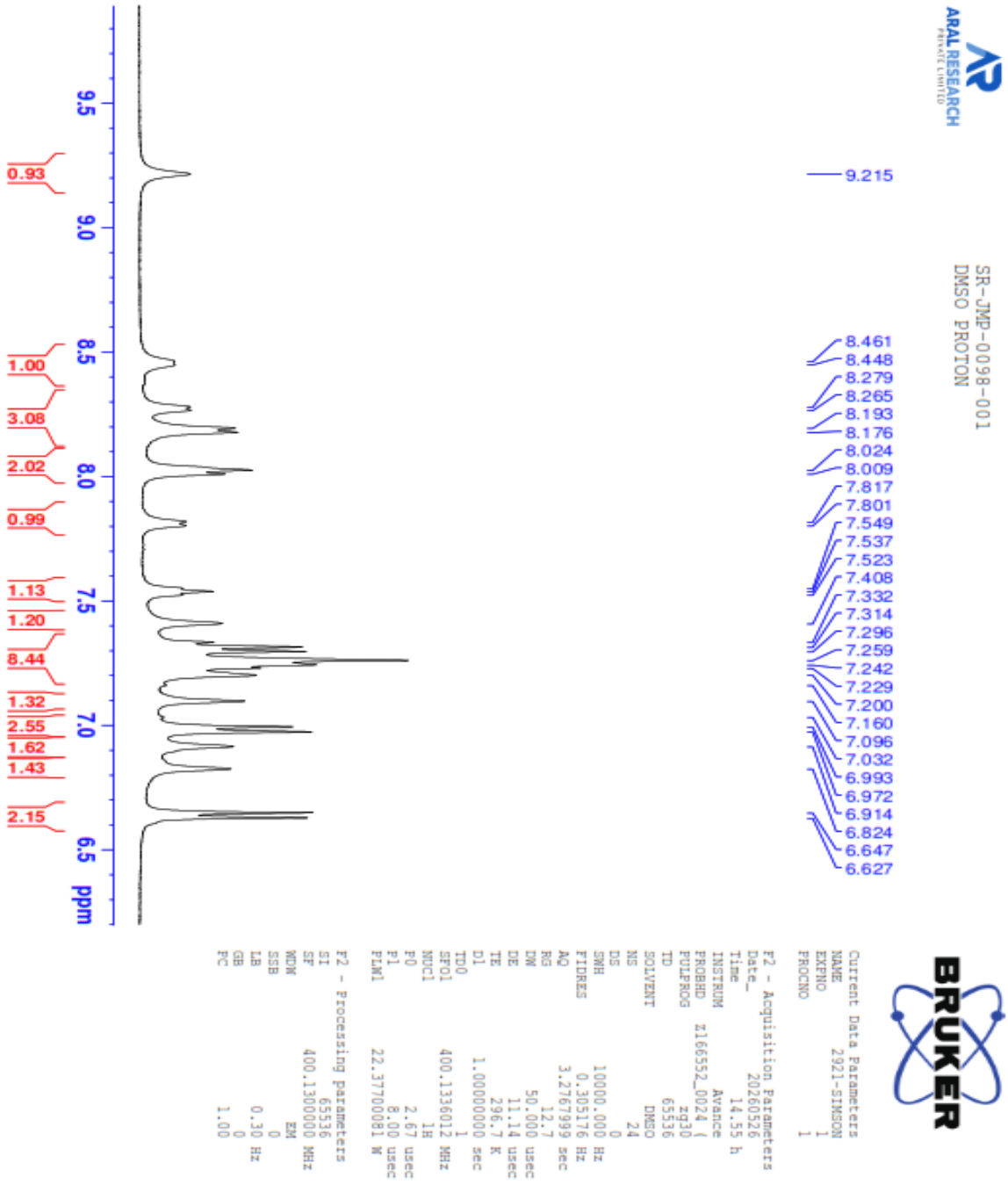
Note: The Assignments are based on chemical shifts and multiplicities

Remarks: NA

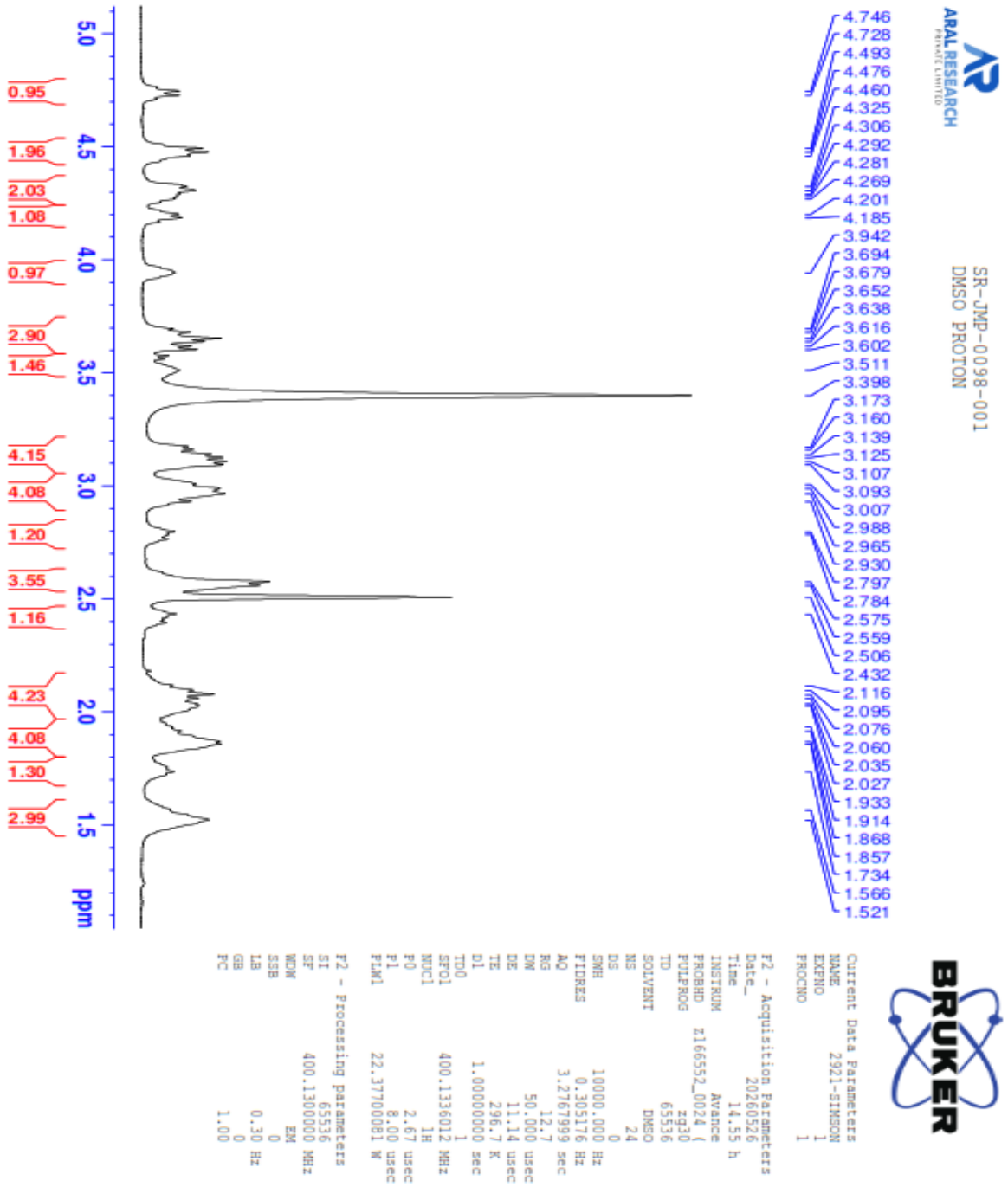
Prepared By: **Reviewed By:**



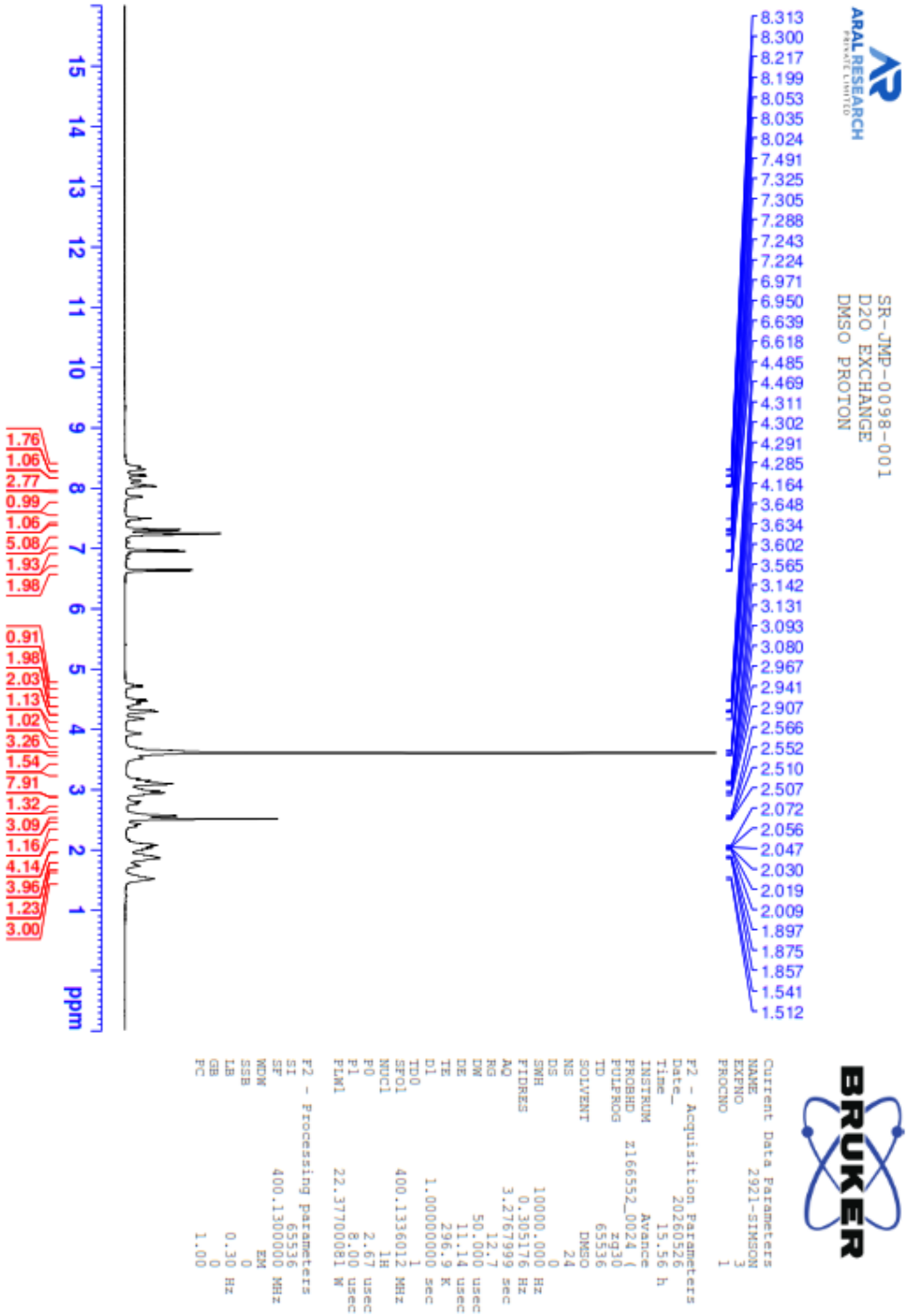
Prepared By: **Reviewed By:**



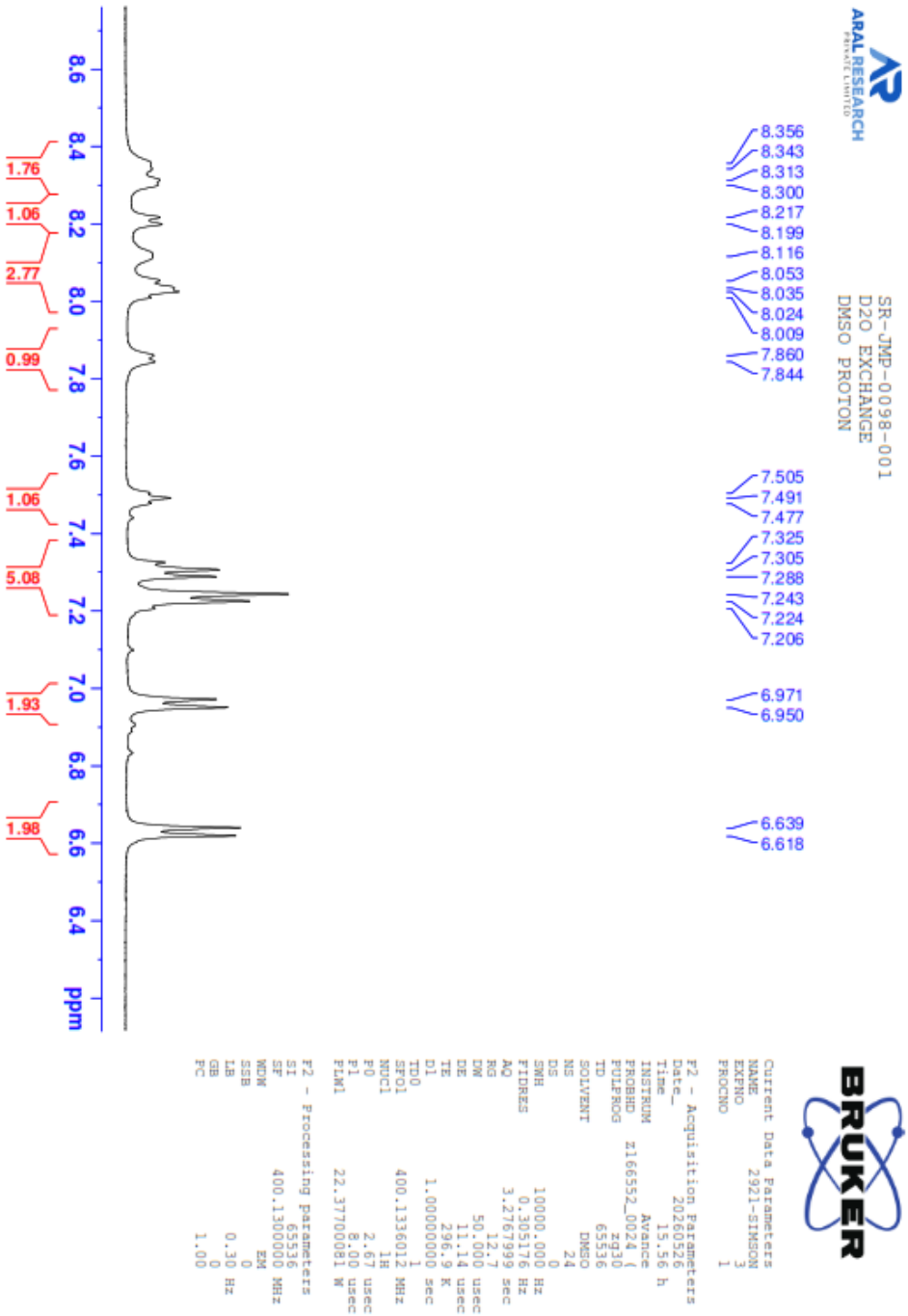
Prepared By: **Reviewed By:**



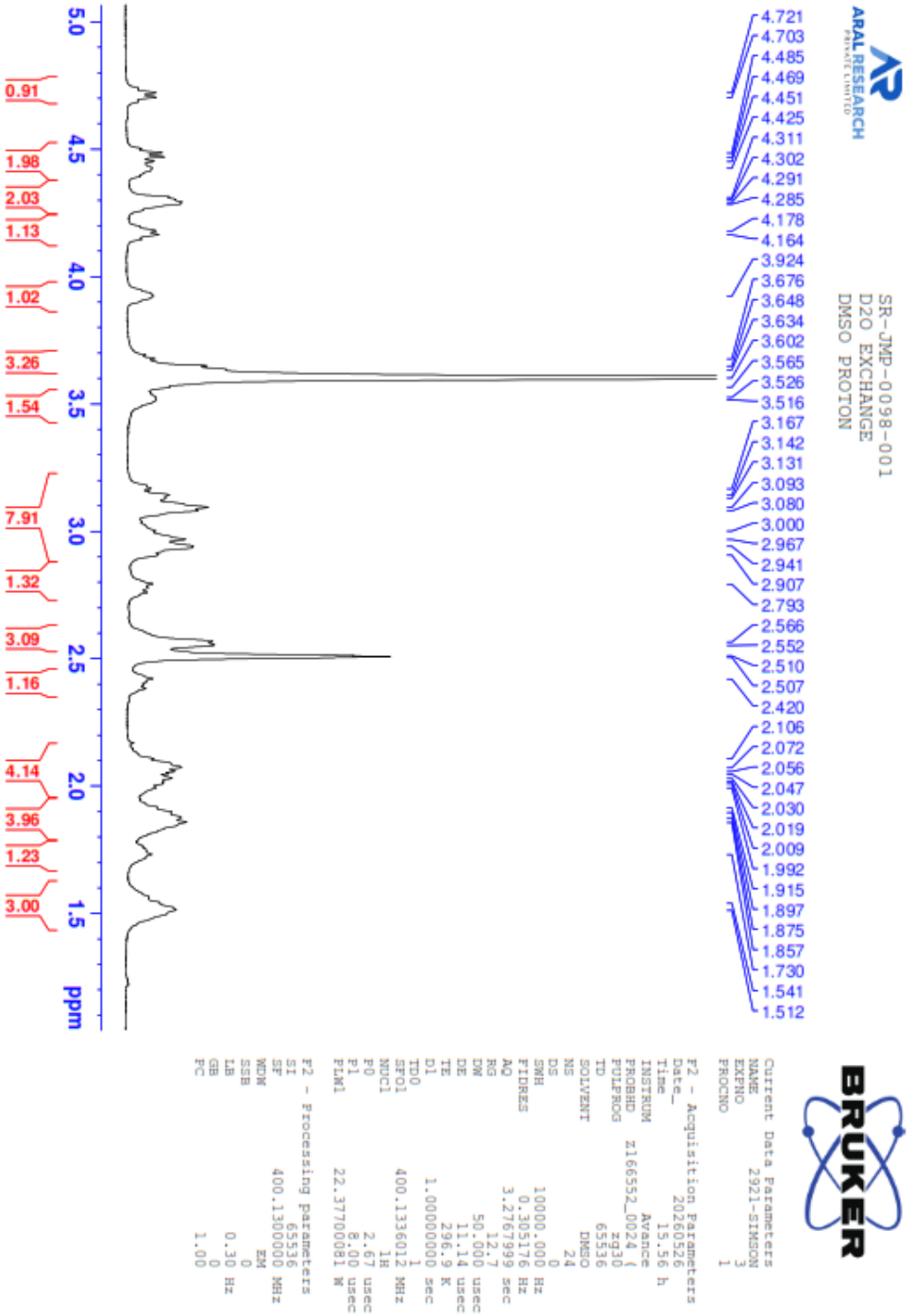
Prepared By: **Reviewed By:**



Prepared By: **Reviewed By:**



Prepared By: **Reviewed By:**



Prepared By: **Reviewed By:**

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

A. Experimental:

Product name : DESMOPRESSIN EP IMPURITY D	**Instrument Name :** FT-NMR Spectrometer
Batch No. : SR-JMP-0098-001	**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:

Prepared By: **Reviewed By:**

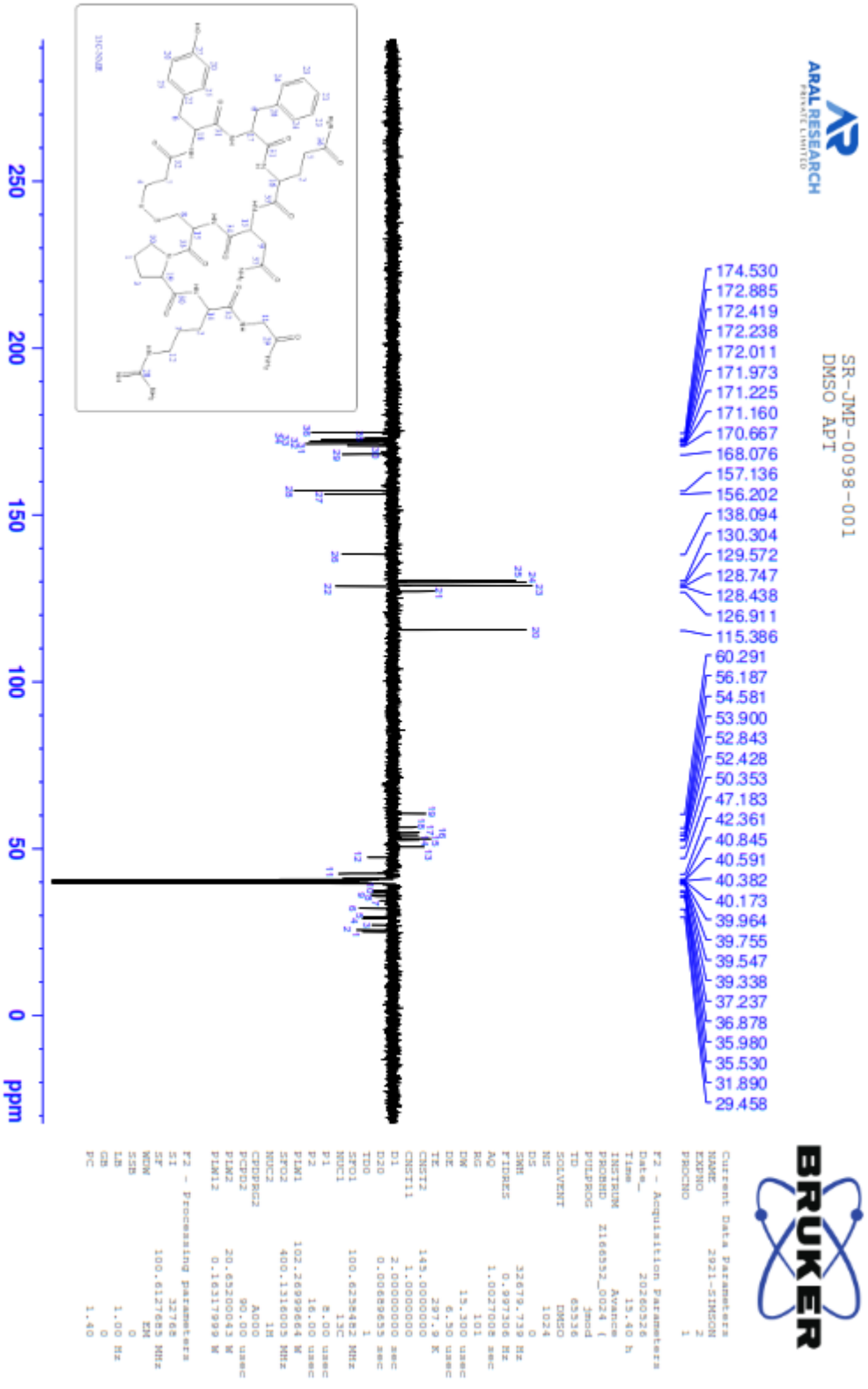
S. No.	Chemical Shift δ, ppm	Multiplicity	No. of Carbons	Assignment of Carbon(s)
1	24.923	S	2	2
2	25.048	S	2	2
3	26.957	S	1	1
4	28.935	S	1	1
5	29.458	S	1	1
6	31.890	S	2	2
7	35.530	S	1	1
8	35.980	S	1	1
9	36.878	S	1	1
10	37.237	S	1	1
11	42.361	S	1	1
12	47.183	S	1	1
13	50.353	S	1	1
14	52.428	S	1	1
15	52.843	S	1	1
16	53.900	S	1	1
17	54.581	S	1	1
18	56.187	S	1	1
19	60.291	S	1	1
20	115.386	S	2	2
21	126.911	S	1	1
22	128.438	S	1	1
23	128.747	S	2	2
24	129.572	S	2	2
25	130.304	S	2	2
26	138.094	S	1	1
27	156.202	S	1	1
28	157.136	S	1	1

29	168.076	S	1	1
30	170.667	S	1	1
31	171.160-171.225	D	2	2
32	171.973-172.011	D	2	2
33	172.238	S	2	2
34	172.419	S	1	1
35	172.885	S	1	1
36	174.530	S	1	1
Total No. of Carbons			**46**	**46**
Remarks:-			Confirms to the structure	

Note: The Assignments are based on chemical shifts and multiplicities

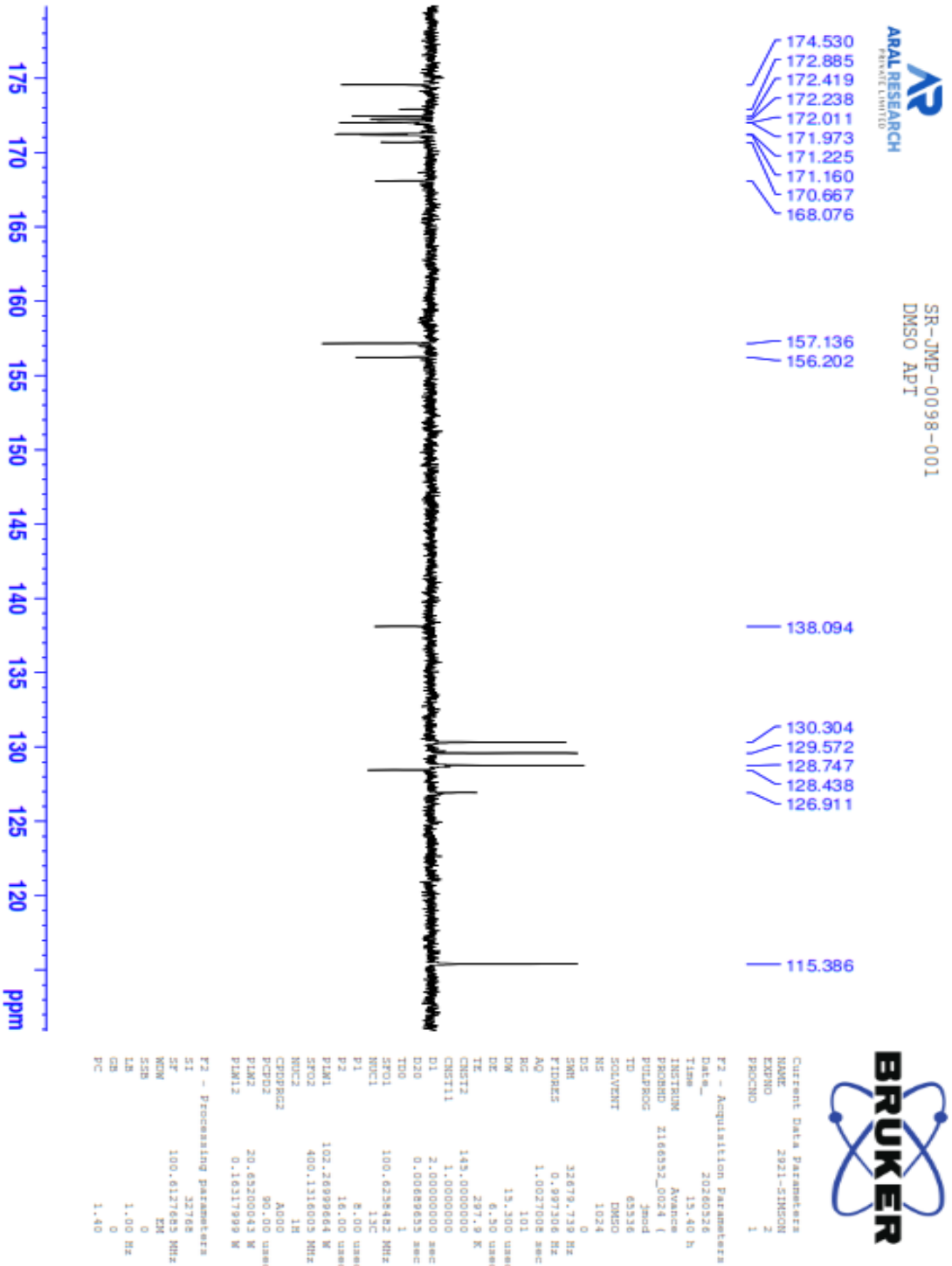
Remarks (If any):NA

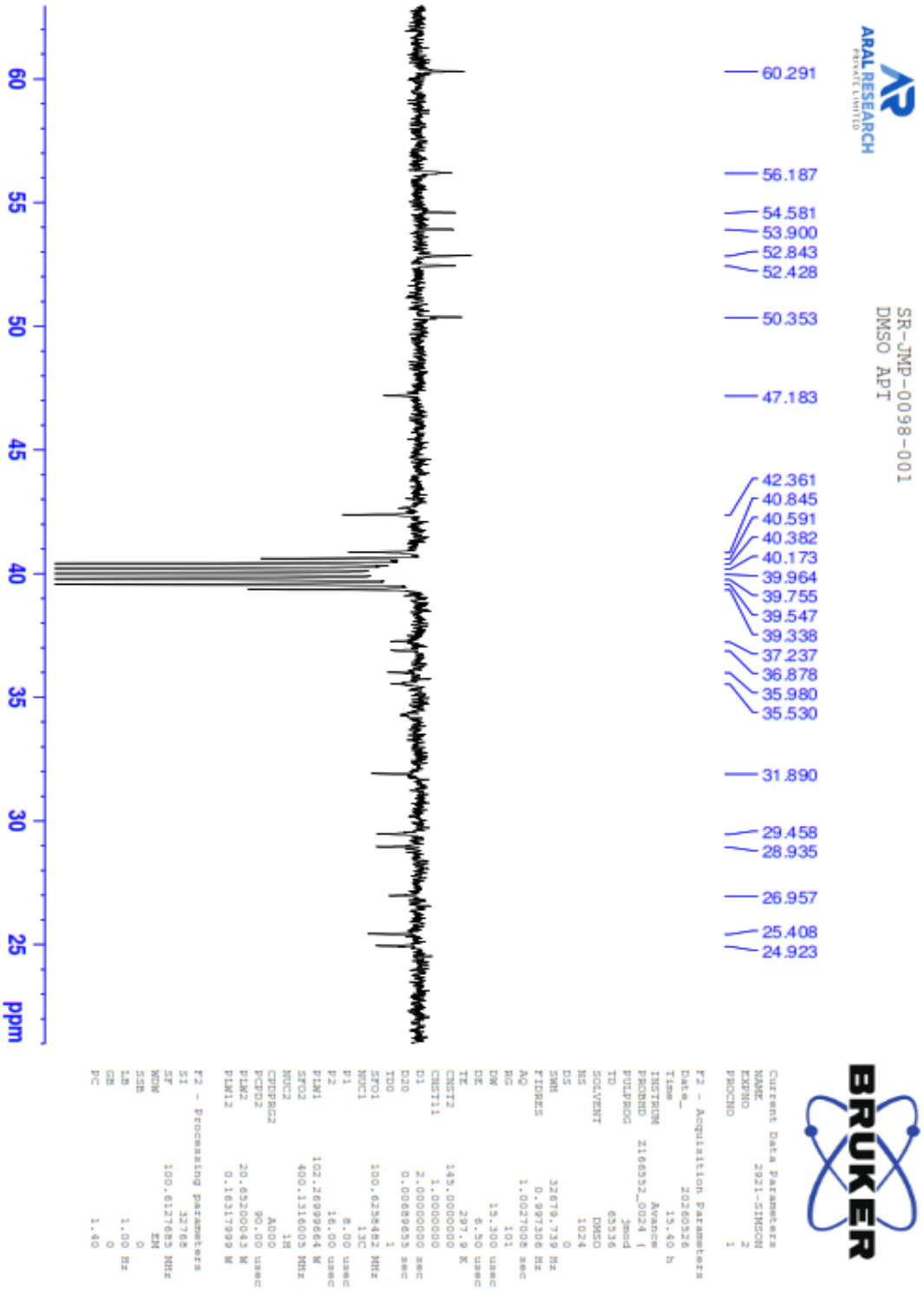
Prepared By: **Reviewed By:**



Prepared By:

Reviewed By:


ARAL RESEARCH
PRIVATE LIMITED
SR-JMP-0098-001
DMSO APT
174.530
172.885
172.419
172.238
172.011
171.973
171.225
171.160
170.667
168.076
157.136
156.202
138.094
130.304
129.572
128.747
128.438
126.911
115.386
175
170
165
160
155
150
145
140
135
130
125
120
ppm
BRUKER



Prepared By: **Reviewed By:**

IV. IDENTIFICATION BY MASS SPECTROSCOPY:

A. Experimental:

Product name	: DOLUTEGRAVIR IMPURITY D	**Instrument Name**	: Mass Spectrometer
Batch No.	: SR-JMP-0098-001	**Instrument Model**	: API 2000
Solvent used	: METHANOL	**Instrument ID**	: SRTL/EQ/014

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 1069.13 g/mol &535.20 g/mol corresponding to $[M+H]^{+}$/ $[M/2+H]^{+}$ confirms the monoisotopic mass as m/z corresponding to the Molecular formula $C_{46}H_{64}N_{14}O_{12}S_{2}$.

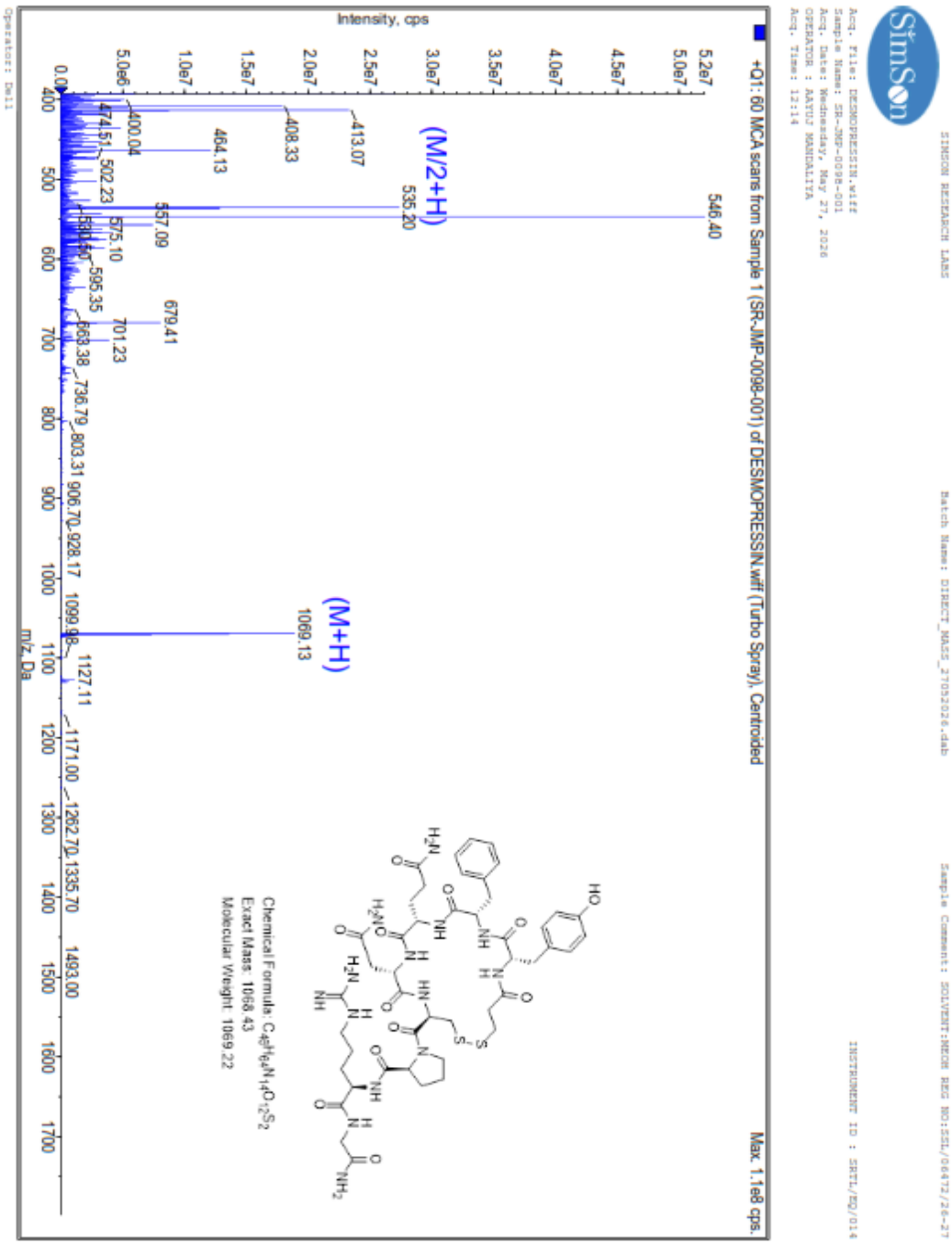
C. Results:

S. No.	Composition	Exact Mass	Molecular Weight	m/z value
1.	$C_{46}H_{64}N_{14}O_{12}S_{2}$	1068.43	1069.22	1069.13 (+ve mode)
2.	$C_{46}H_{64}N_{14}O_{12}S_{2}$	1068.43	1069.22	535.20(M/2+H) (+ve mode)

Remarks:

1. Mass peak at m/z 1069.13/535.20 corresponds to product mass peak.
2. Other peaks are unidentified peaks

Prepared By: **Reviewed By:**



Prepared By: **Reviewed By:**

V. IDENTIFICATION BY FT-IR SPECTROSCOPY:

A. Experimental:

Product name	: DOLUTEGRAVIR IMPURITY D	**Instrument Name**	: FT-IR Spectrometer
Batch No.	: SR-JMP-0098-001	**Instrument Model**	: SHIMADZU
Sample Preparation	: ATR	**Instrument ID**	: SRTL/EQ/031

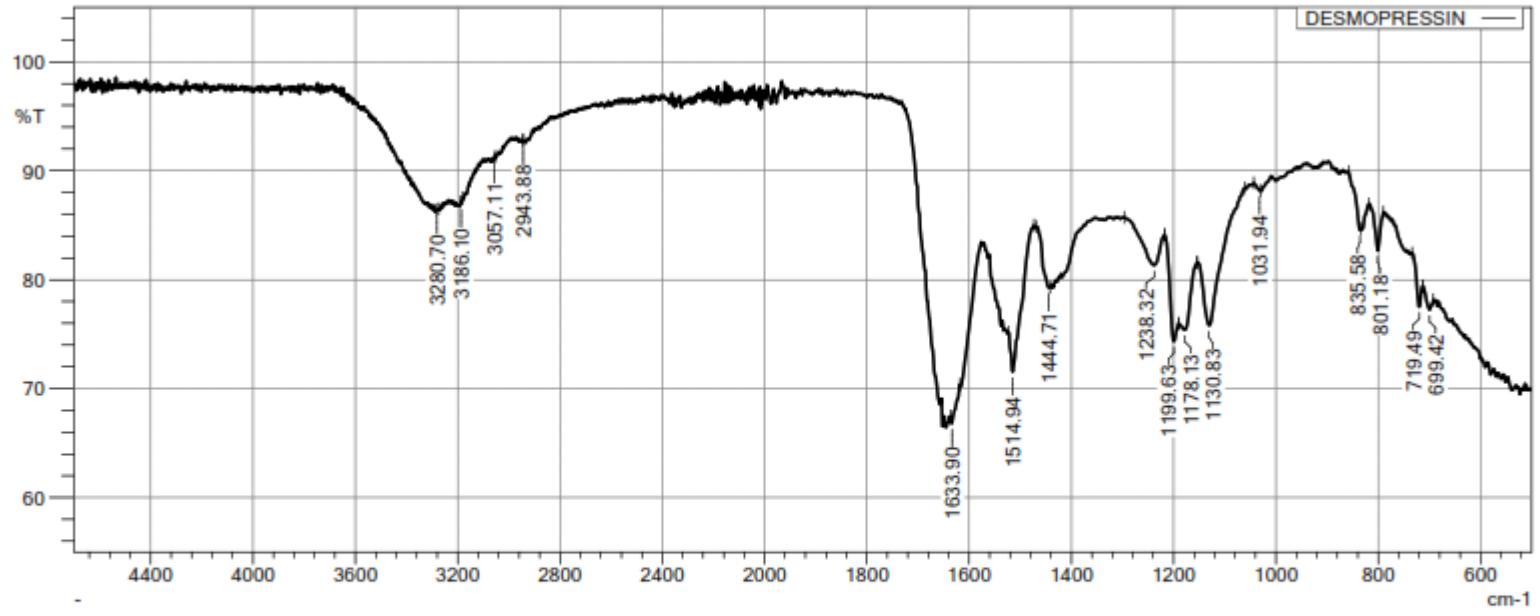
B. Methodology: DOLUTEGRAVIR IMPURITY D Compound was recorded on FT-IR Spectrometer by using ATR technique. The structural assignments have been correlated with the following frequencies.

C. Results:

S. No.	Absorption peak cm-1	Specific type of bond	Corresponding Functional group
1.	1633.90	stretching	C=O (AMIDE)
2.	3280.75	Stretching	N-H
3.	699.42	Stretching	C-S
4.	2943.88	Stretching	C-H

SIMSON RESEARCH LABS

Instrument ID No:SRTL/EQ/031



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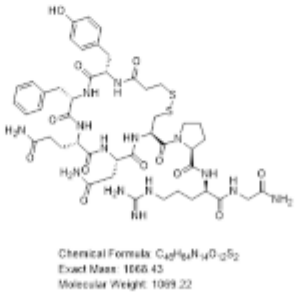
Sample Name:DESMOPRESSIN

Lot No/Batch No::SR-JMP-0098-001

Reg no. SSL/06471/26-27

Date & Time:28-05-2026 11:57:22

Operator:Megha patel



Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

Resolution:4 [cm-1]

Sample Scan:45

Frequency Range: 4000 to 400 cm-1

1 of 1

Reviewed By:

Prepared By:

Format No: SCP/002/F02-01

VI. IDENTIFICATION AND CONFIRMATION OF ISOMERISM:

A. Isomerism if any (Yes or No):Yes

If Yes, Possible isomers

S. No.	Isomers	Present or Not	Comments
1.	R and S isomer	Yes	R,S isomer present
2.	D and L isomer	No	-
3.	E and Z isomer	No	-
4.	Erythro and Threo isomer	No	-
5.	Cis and Trans	No	-
6.	Positional isomers	No	-
7.	Any diastereomers	No	-
8.	Any tautomerism	No	-
9.	Any other isomers	No	-

B. Methodology of confirmation:

C. Results and confirmation: Compound contains R,S isomer and is not a racemic mixture**.**

PURITY BY HPLC:

A. Experimental:

Product name : DESMOPRESSIN EP IMPURITY D	**Instrument Name** : HPLC
Batch No. : SR-JMP-0098-001	**Instrument Model** : Shimadzu
Method : EP	**Instrument ID** : SRTL/EQ/040

B. HPLC Method:

Method (Pharmacopoeia) : EP

Standard Testing Procedure (STP) Number for In-House method: NA

C. Pharmacopeial Information: Z

Pharmacopoeia	Availability (Yes / No)	Reported RRT	Reported RRF
EP (API)	YES	-	-
BP (API)	No	-	-
BP (Tablet, capsule etc)	No	-	-
USP (API)	No	-	-
USP (Tablet, capsule etc)	No	-	-
IP (API)	No	-	-
IP (Tablet, Formulation)	No	-	-

Prepared By: **Reviewed By:**

D. Chromatography conditions:

(Purity/RRT/RRF):

Column	SHIMADZU C18(4.6*100*5um)
Mobile phase A	0.067 M phosphate buffer solution pH 7.0 R
Mobile phase B	acetonitrile for chromatography R, mobile phase A (50:50 V/V); filter and degas.
Elution mode	Gradient Programme
Detector (λ)	220 nm
Column Temperature	30°C
Run Time	50 min
Flow	1.0 ml/min
Diluent	WATER
Inj. Volume	50 µl
Sample Preparation (for purity)	1 mg/2ml in Diluent (500 PPM)
Sample Preparation (for RRF)	1 mg/2ml in Diluent (500 PPM)

E. Gradient Programme:

Time	Mobile phase A	Mobile phase B
0.10	76	24
4.00	76	24
18.00	58	42
35.00	48	52
40.00	76	24
50.00	76	24

F. Results:

Purity: 99.895 % area by Normalization

Prepared By: **Reviewed By:**

RRT results:

Reported RRT: (as per Pharmacopeia)	Observed RRT	Observations and results (NMT±10% of reported)
-	0.95	-

RRT of the newly synthesized batch with the earlier batch (if any).

Old batch number	Old batch number RRT value	New batch number	New batch number RRT Value	Conclusion
-	-	SR-JMP-0098-001	0.95	RRT observed assigned

RRF results:

Reported RRF: (as per Pharmacopeia)	Observed RRF	Observations and results (NMT ±10% of reported)
-	1.15	-

RRF of the newly synthesized batch with the earlier batch (if any).

Old batch number	Old batch number RRF value	New batch number	New batch number RRF Value	Conclusion
-	-	SR-JMP-0098-001	1.15	Pass -RRF observed assigned

Conclusion:

Based on above observed RRT& RRF. The compound is Considered Qualified

G. Chromatograms.

a. Blank

b. Zoomed Blank

c. Sample Purity chromatogram

d. Zoomed Sample Purity chromatogram

e. Overlay chromatogram of blank and sample

f. Standard chromatogram

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g. Spiked chromatogram

h. RRT Chromatogram

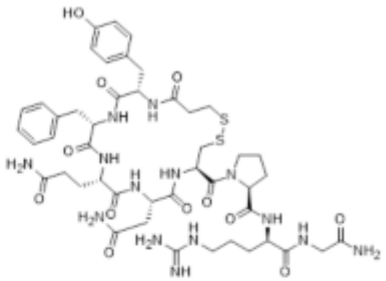
i. RRF chromatograms

Simson Research Labs

System Configuration

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Sample ID : BLANK
Data File : 2026_05_27_12.lcd
Method File : DESMOPRESSIN EP METHOD.lcm
Batch File : 2026_05_27.lcb
Vial# : 14
Injection Volume : 50
Date Acquired : 5/27/2026 5:39:51 PM
Date Processed : 5/28/2026 2:11:42 PM
Sample Type : Unknown
Option 6 :
Acquired by : dharmik_gohil
Processed by : dharmik_gohil
Comment : M.P. = AS PER EP
DILUENT = AS PER EP
COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058



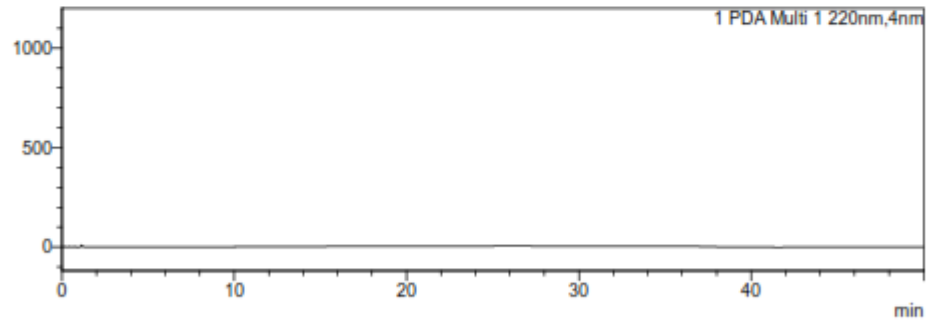
Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
0.10	Pumps	B.Conc	24	
4.00	Pumps	B.Conc	24	
18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram
mAU



Peak Table
PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
Total				

Prepared By: **Reviewed By:**

Simson Research Labs

System Configuration

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Instrument Name : SRTL_EQ_040

Sample Information 2026_05_27_12.lcd

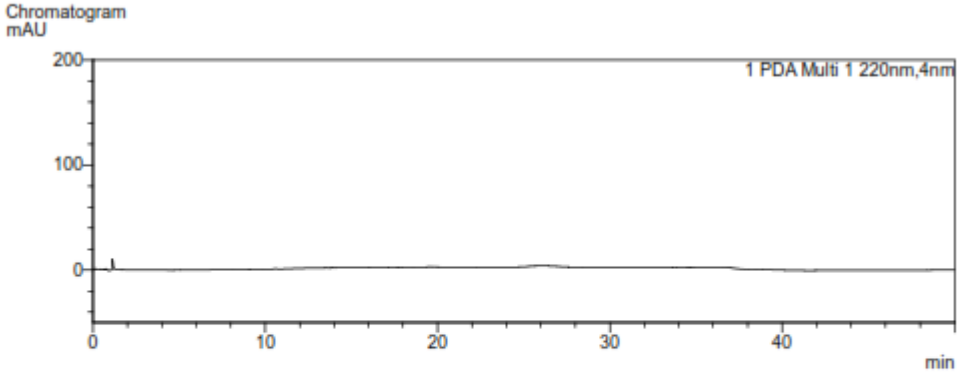
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Sample ID	: BLANK
Data File	: 2026_05_27_12.lcd
Method File	: DESMOPRESSIN EP METHOD.lcm
Batch File	: 2026_05_27.lcb
Vial#	: 14
Injection Volume	: 50
Date Acquired	: 5/27/2026 5:39:51 PM
Date Processed	: 5/28/2026 2:11:42 PM
Sample Type	: Unknown
Option 6	:
Acquired by	: dharmik_gohil
Processed by	: dharmik_gohil
Comment	: M.P. = AS PER EP DILUENT = AS PER EP COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
0.10	Pumps	B.Conc	24	
4.00	Pumps	B.Conc	24	
18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram



Peak Table
PDA Ch1 220nm

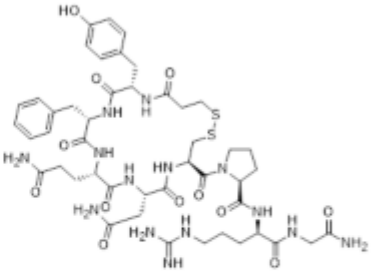
Peak#	Name	Ret. Time	Area	Area%
Total				

Prepared By: **Reviewed By:**

Simson Research Labs

System Configuration

<<Instrument>>
Instrument Name : SRTL_EQ_040



Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

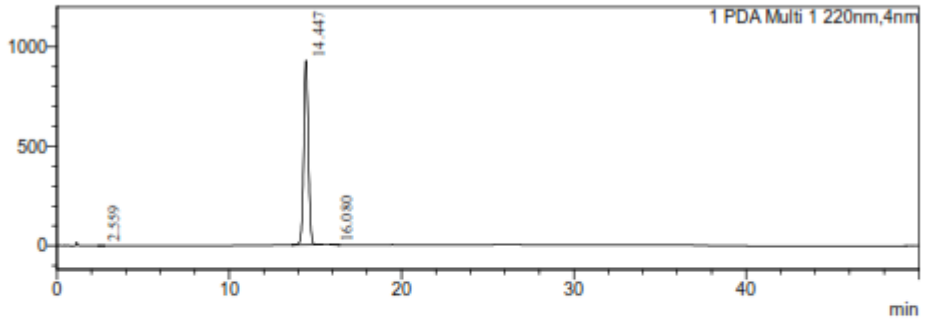
Sample Information 2026_05_27_14.lcd
Sample Name : DESMOPRESSIN EP IMPURITY D
Sample ID : SR-JMP-0098-001
Data File : 2026_05_27_14.lcd
Method File : DESMOPRESSIN EP METHOD.lcm
Batch File : 2026_05_27.lcb
Vial# : 12
Injection Volume : 50
Date Acquired : 5/27/2026 7:20:34 PM
Date Processed : 5/28/2026 2:15:30 PM
Sample Type : Unknown
Option 6 :
Acquired by : dharmik_gohil
Processed by : dharmik_gohil
Comment : M.P. = AS PER EP
DILUENT = AS PER EP
COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
0.10	Pumps	B.Conc	24	
4.00	Pumps	B.Conc	24	
18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram
mAU



Peak Table
PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
1		2.559	4764	0.025
2	DESMOPRESSIN EP IMPURITY D	14.447	17193146	99.595
3		16.080	13329	0.077
Total			17211235	100.000

Prepared By: **Reviewed By:**

Simson Research Labs

System Configuration

<<Instrument>>
Instrument Name : SRTL_EQ_040

Sample Information 2026_05_27_14.lcd

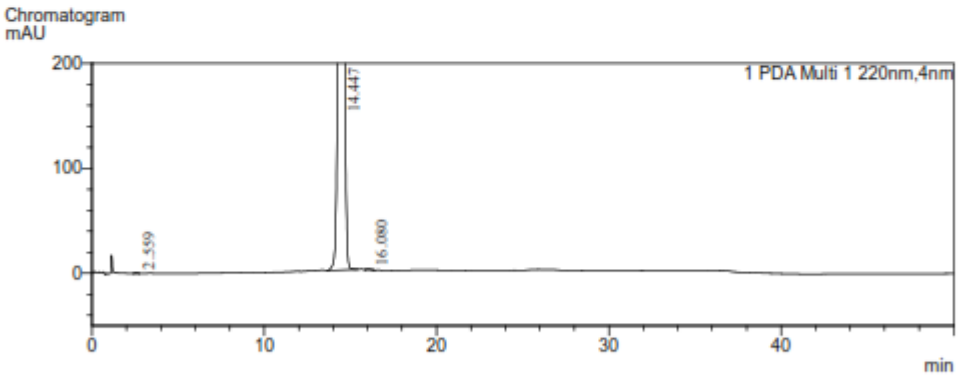
Sample Name	: DESMOPRESSIN EP IMPURITY D
Sample ID	: SR-JMP-0098-001
Data File	: 2026_05_27_14.lcd
Method File	: DESMOPRESSIN EP METHOD.lcm
Batch File	: 2026_05_27.lcb
Vial#	: 12
Injection Volume	: 50
Date Acquired	: 5/27/2026 7:20:34 PM
Date Processed	: 5/28/2026 2:15:30 PM
Sample Type	: Unknown
Option 6	:
Acquired by	: dharmik_gohil
Processed by	: dharmik_gohil
Comment	: M.P. = AS PER EP DILUENT = AS PER EP COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
0.10	Pumps	B.Conc	24	
4.00	Pumps	B.Conc	24	
18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

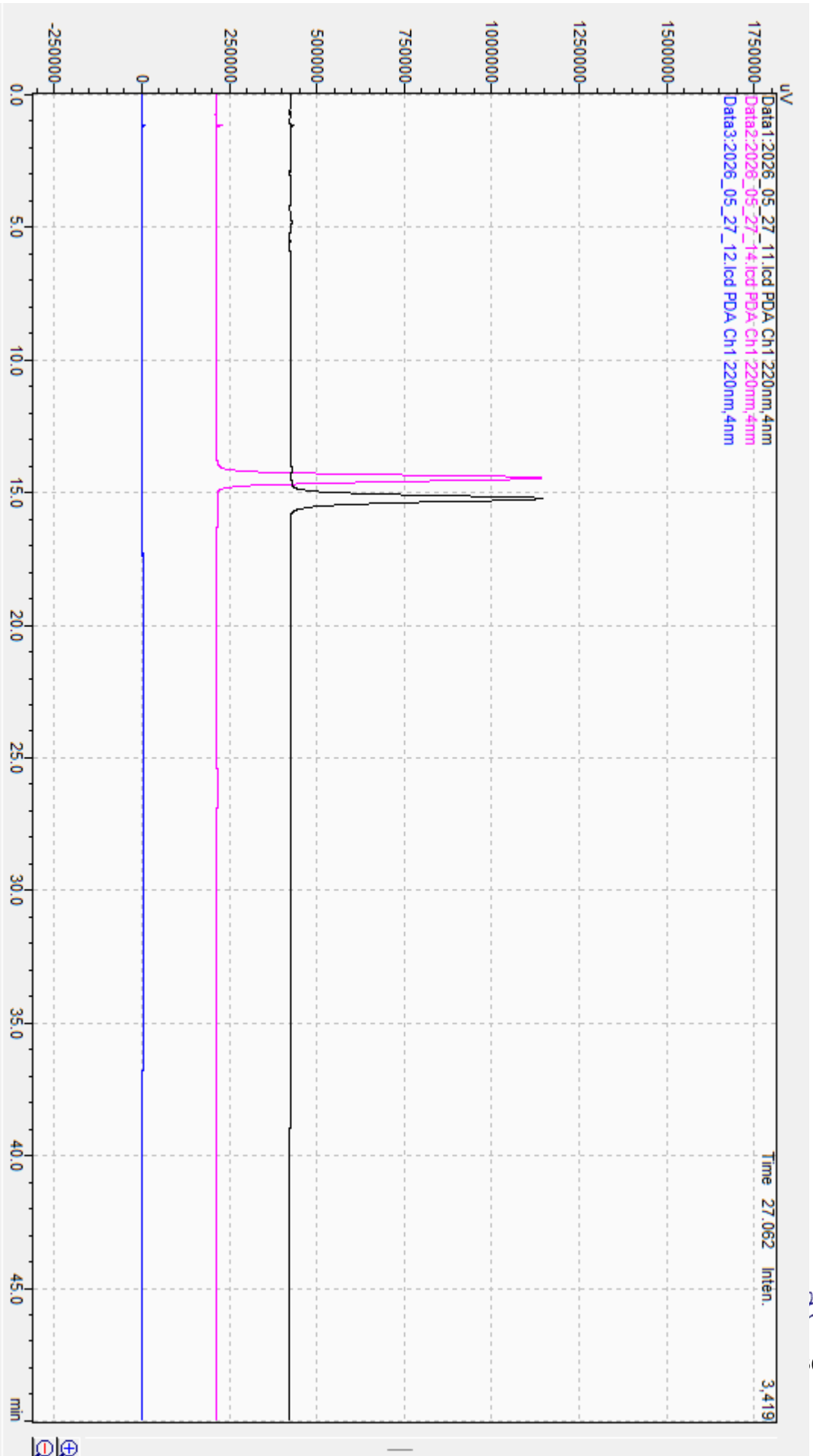
Chromatogram



Peak Table
PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
1		2.559	4764	0.025
2	DESMOPRESSIN EP IMPURITY D	14.447	17193146	99.595
3		16.050	13329	0.077
Total			17211238	100.000

Prepared By: **Reviewed By:**

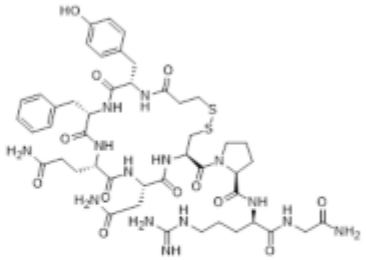

uV
-250000
0
250000
500000
750000
1000000
1250000
1500000
1750000
Data1:2026_05_27_11.lcd PDA Ch1 220nm,4nm
Data2:2026_05_27_14.lcd PDA Ch1 220nm,4nm
Data3:2026_05_27_12.lcd PDA Ch1 220nm,4nm
0.0
5.0
10.0
15.0
20.0
25.0
30.0
35.0
40.0
45.0
min
Time 27.062 Inten. 3,419

Simson Research Labs

System Configuration

<<Instrument>>
Instrument Name : SRTL_EQ_040

Sample Information 2026_05_27_11.lcd
Sample Name : DESMOPRESSIN ACETATE
Sample ID : SP-0524-191
Data File : 2026_05_27_11.lcd
Method File : DESMOPRESSIN EP METHOD.lcm
Batch File : 2026_05_28.lcb
Vial# : 16
Injection Volume : 50
Date Acquired : 5/28/2026 11:17:15 AM
Date Processed : 5/28/2026 2:13:57 PM
Sample Type : Unknown
Option 6 :
Acquired by : dharmik_gohil
Processed by : dharmik_gohil
Comment : M.P. = AS PER EP
DILUENT = AS PER EP
COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058



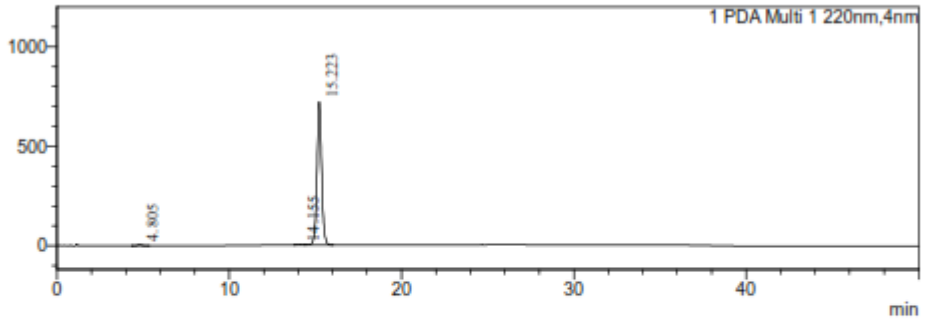
Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
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4.00	Pumps	B.Conc	24	
18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram
mAU



Peak Table
PDA Ch1 220nm

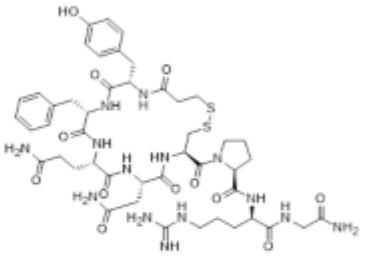
Peak#	Name	Ret. Time	Area	Area%
1		4.505	57100	0.637
2		14.155	29677	0.217
3	DESMOPRESSIN ACETATE	15.223	13547951	99.145
Total			13664727	100.000

Prepared By: **Reviewed By:**

Simson Research Labs

System Configuration

<<Instrument>>
Instrument Name : SRTL_EQ_040



Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

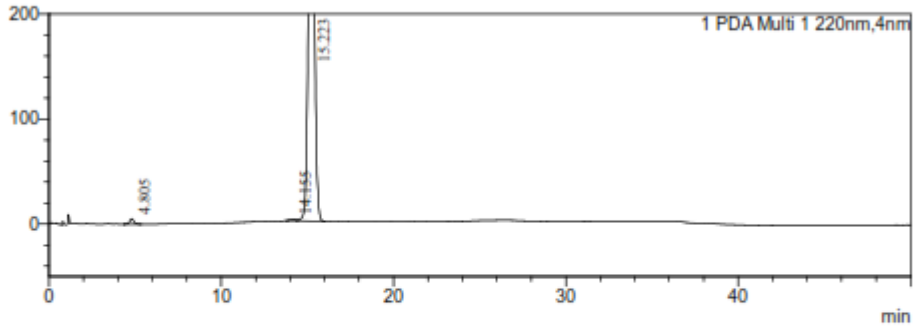
Sample Information 2026_05_27_11.lcd
Sample Name : DESMOPRESSIN ACETATE
Sample ID : SP-0524-191
Data File : 2026_05_27_11.lcd
Method File : DESMOPRESSIN EP METHOD.lcm
Batch File : 2026_05_28.lcb
Vial# : 16
Injection Volume : 50
Date Acquired : 5/28/2026 11:17:15 AM
Date Processed : 5/28/2026 2:13:57 PM
Sample Type : Unknown
Option 6 :
Acquired by : dharmik_gohil
Processed by : dharmik_gohil
Comment : M.P. = AS PER EP
DILUENT = AS PER EP
COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
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18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram
mAU



Peak Table
PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
1		4.505	57100	0.637
2		14.155	29677	0.217
3	DESMOPRESSIN ACETATE	15.223	13547951	99.145
Total			13664727	100.000

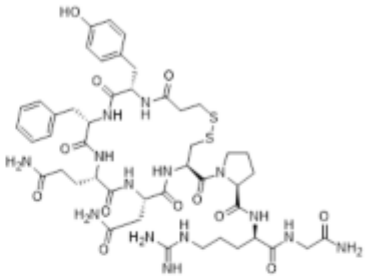
Prepared By: **Reviewed By:**

Simson Research Labs

System Configuration

<<Instrument>>
Instrument Name : SRTL_EQ_040

Sample Information 2026_05_27_13.lcd
Sample Name : DESMOPRESSIN EP IMPURITY D
Sample ID : SR-JMP-0098-001 + SP-0524-091
Data File : 2026_05_27_13.lcd
Method File : DESMOPRESSIN EP METHOD.lcm
Batch File : 2026_05_27.lcb
Vial# : 15
Injection Volume : 50
Date Acquired : 5/27/2026 6:30:12 PM
Date Processed : 5/28/2026 2:18:43 PM
Sample Type : Unknown
Option 6 :
Acquired by : dharmik_gohil
Processed by : dharmik_gohil
Comment : M.P. = AS PER EP
DILUENT = AS PER EP
COLUMN = SHIMADZU C18(4.6*100*5um)CLC/C18/0058



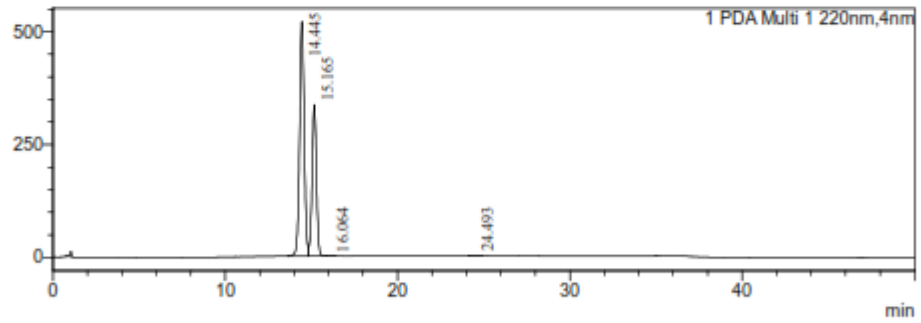
Chemical Formula: $C_{46}H_{64}N_{14}O_{12}S_2$
Exact Mass: 1068.43
Molecular Weight: 1069.22

Method

<<LC Time Program>>

Time	Module	Command	Value	Comment
0.10	Pumps	B.Conc	24	
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18.00	Pumps	B.Conc	42	
35.00	Pumps	B.Conc	52	
40.00	Pumps	B.Conc	24	
50.00	Pumps	B.Conc	24	
50.00	Controller	Stop		

Chromatogram
mAU



Peak Table
PDA Ch1 220nm

Peak#	Name	Ret. Time	Area	Area%
1	DESMOPRESSIN EP IMPURITY D	14.445	9645534	62.206
2	DESMOPRESSIN ACETATE	15.165	5825825	37.591
3		16.064	12513	0.053
4		24.493	15626	0.120
Total			15505799	100.000

Prepared By: **Reviewed By:**

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

A. Experimental:

Product name	**:** DOLUTEGRAVIR IMPURITY D	**Instrument Name**	**:** TGA
Batch No.	**:** SR-JMP-0098-001	**Instrument Model**	**:** Perkin Elmer
Method	**:** 30ºC to 900 ºC	**Instrument ID**	**:** SRTL/EQ/007

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

1) Heat from 30.00°C to 105.00°C at 20.00°C/min

2) Heat from 105.00°C to 150.00°C at 40.00°C/min

3) Heat from 150.00°C to 900.00°C at 60.00°C/mi

4) Hold for 2.0 min at 900.00°C

C. Results:

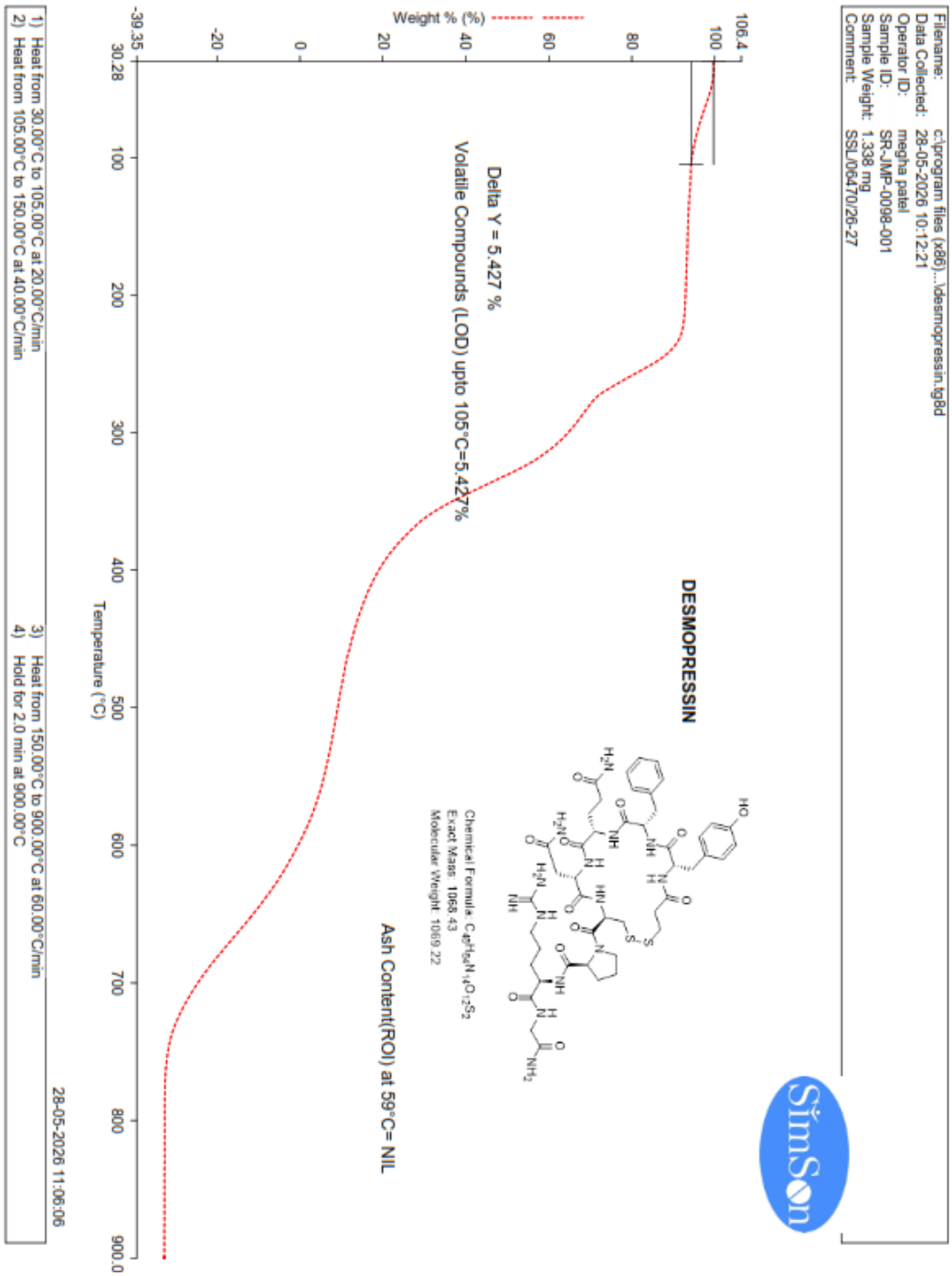
i. % of Loss Observed up to 105ºC : 5.427 %

ii. % of Ash content observed : NIL

The TGA thermogram is enclosed.

Remarks: TGA is high due to hygroscopic material.

Prepared By: **Reviewed By:**



Prepared By: **Reviewed By:**

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 : 99.89 %
LOD by TGA: 5.427%
Ash content : NIL

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

Defined Potency = 94.46 % w/w

Prepared By: **Reviewed By:**

VIII. STORAGE

A. Long term Storage:

Reference : -NA-

Methodology : Based on Structure/ Functional groups present in compound/ Synthetic experience

Conclusion : Compound is Stable at -20 °C Protect from direct sunlight.

B. Shipping Condition:

Reference : -NA-

Methodology : Based on Structure/ Functional groups present in compound/ Synthetic experience

Conclusion : Shipping is allowed at Temp -20 °C.

XI. RETEST & HANDLING INSTRUCTIONS

Reference: -NA-

Methodology: Retest date assigned based on Structure/Nature of compound /synthetic experience / Available literatures only.

Conclusion: Recommended retest date is 1 Yrs.

Handling Instruction:

- Keep the material at storage condition, ensure proper closing of container. Avoid contamination at each use.
- As the sample is liquid, keep the bottle in upright position for one to two hours.
- Colorless liquid settles at the bottom with visible quantity.
- Handle the Hygroscopic compounds under inert atmosphere.

Prepared By: **Reviewed By:**

XII. CONCLUSION: Based on the analytical interpretation, the compound is qualified/not qualified. The product has been identified & qualified by ^{1}H NMR, ^{13}C NMR, Mass, IR and HPLC.

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:**