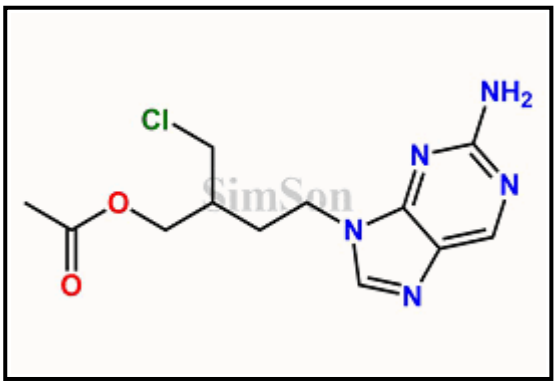
CERTIFICATE OF ANALYSIS

(Certificate No.: SPC260422 - 020 / V.01)

SimSon Pharma Limited
Reference Standards | Research Chemicals | Research Service

Analysis Date : 07/04/2026 **Re-test Date:** 06/04/2029

Product Name	**: DEOXYCHLORO FAMCICLOVIR**
Chemical Name	: 4-(2-Amino-9H-purin-9-yl)-2-(chloromethyl)butyl acetate
Synonyms	: Famciclovir Deoxy-chloro Impurity
CAT No.	: F270006
Batch Number	: SL-RJS-369-028
CAS No.	: NA
Molecular Formula	: $C_{12}H_{16}ClN_5O_2$
Molecular Weight	: 297.75 g/mol
Long term Storage Condition	: Store at 2°C to 8°C
Shipping Condition	: Ambient



ANALYTICAL INFORMATION:

Sr No	TESTS	RESULTS
1	**DESCRIPTION**	Off white 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	**PURITY (By HPLC)**	96.51%
5	**WEIGHT LOSS (By TGA)** (Weight Loss: 30°C to 120°C,rate 20°c/min)	0.52% w/w
6	**ASH CONTENT** (30°C to 120°C , rate: 20°C/min)(120°C to 850°C, rate:40°C/min)	NIL
7	**DEFINED POTENCY (By Mass Balance Method)** % =[(100-(weight Loss by TGA + Ash content by TGA))x HPLC purity/100]	96.01% w/w

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

Thatipamula

Pillai

Prepared By : (Sign & Date) Soumya Thatipamula 22/04/2026

Approved By : (Sign & Date) Sunayana Pillai 22/04/2026

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

PRODUCT TECHNICAL INFORMATION

Qualification Report Number: SL-RJS-369-028/QR/25-00032

Product Name	**DEOXYCHLORO FAMCICLOVIR**
Chemical Name	4-(2-Amino-9H-purin-9-yl)-2-(chloromethyl)butyl acetate
Molecular Formula	$C_{12}H_{16}ClN_5O_2$
Molecular Weight	297.74 g/mol
Batch No.	SL-RJS-369-028
Synonyms	Famciclovir Deoxy-chloro Impurity
CAS No.	NA
CAT No.	F270006

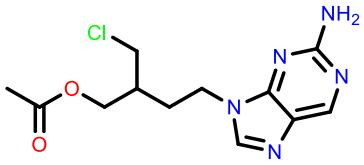


TABLE OF CONTENTS

Prepared By: **Reviewed By:**

I. IDENTIFICATION BY ^{1}HNMR SPECTROSCOPY

A. Experimental:

Product name	: DEOXYCHLORO FAMCICLOVIR	**Instrument Name**	: FT-NMR Spectrometer
Batch No.	: SL-RJS-369-028	**Instrument Model**	: BRUKER 400MHZ
Solvent	: DMSO-d6	**Instrument ID**	: SATL/EQ/197

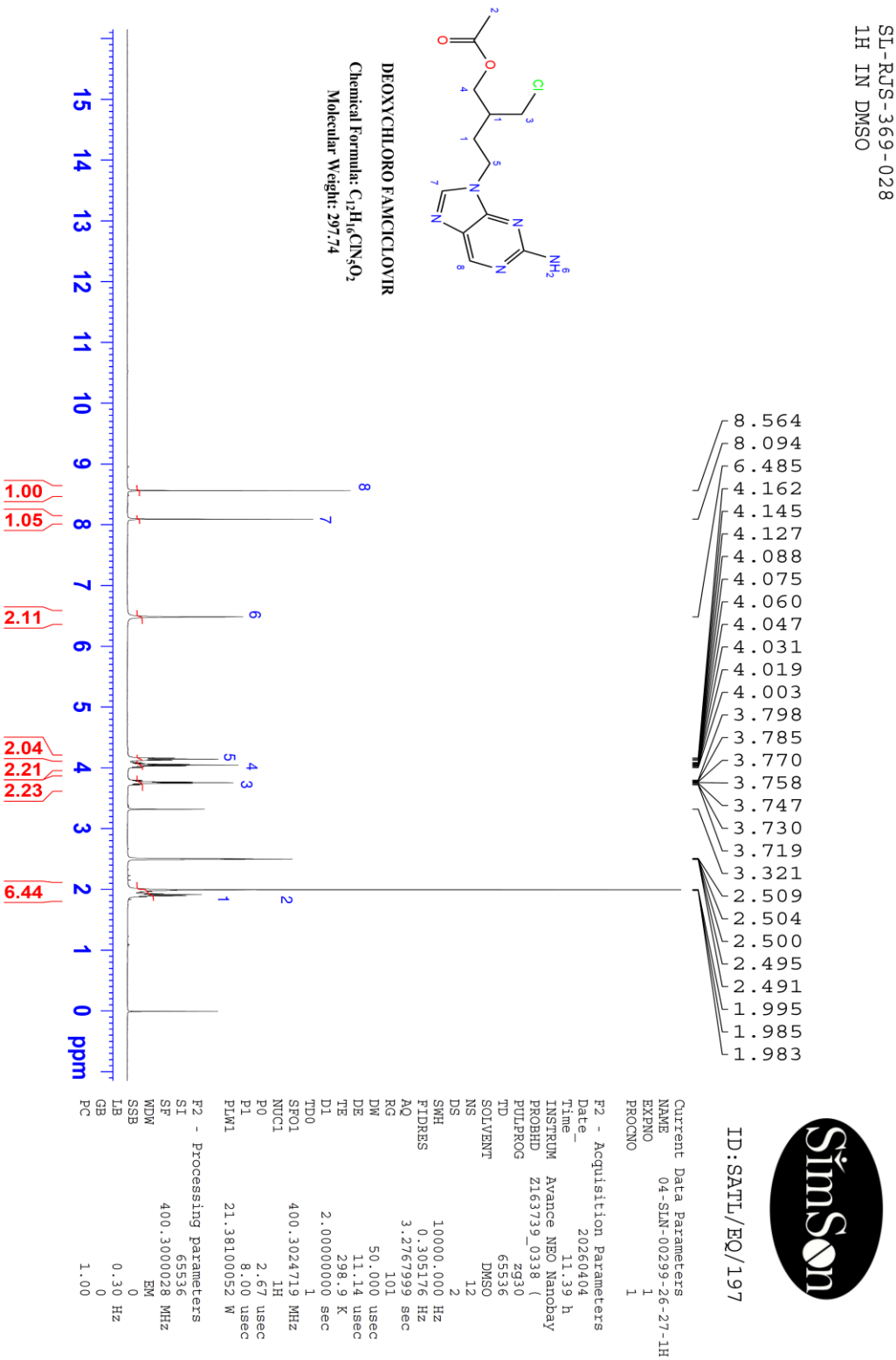
B. Methodology: The NMR experiments were performed on 400 MHZ Bruker FT-NMR Spectrometer using DMSO-d_6 Solvent. ^{1}H NMR Chemical shifts are reported on the δ scale in ppm in relative to TMS. The assignment of protons is given below.

C. Results:

S. No.	Chemical Shift δ, ppm	Multiplicity	No. of protons	'J' coupling constant	Assignment of proton (s)
1.	1.87-1.98	M	3H	-	3
2.	1.99	S	3H	-	3
3.	3.71-3.79	M	2H	-	2
4.	4.00-4.08	M	2H	-	2
5.	4.12-4.16	T	2H	-	2
6.	6.48	S	2H	-	2
7.	8.09	S	1H	-	1
8.	8.56	S	1H	-	1
Total No. of protons					**16**
Remarks:-			Confirms to the structure		

Note: The Assignments are based on chemical shifts and multiplicities

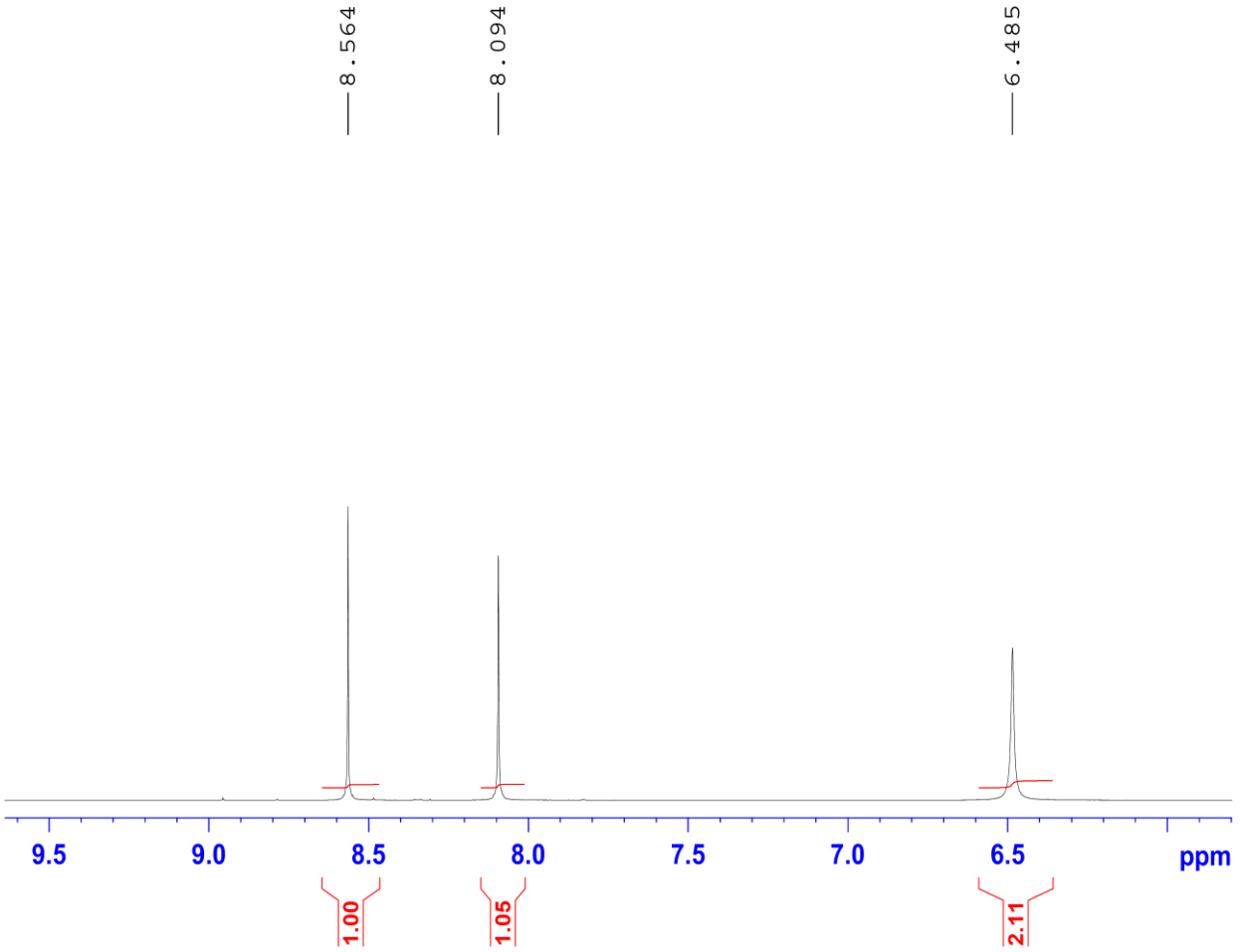
Prepared By: **Reviewed By:**



Prepared By:

Reviewed By:

SL-RJS-369-028
1H IN DMSO



ID:SATL/EQ/197

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EXPNO                1
PROCNO               1

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TD                65536
SOLVENT            DMSO
NS                   12
DS                    2
SWH           10000.000 Hz
FIDRES         0.305176 Hz
AQ            3.2767999 sec
RG                  101
DW               50.000 usec
DE               11.14 usec
TE                298.9 K
D1           2.00000000 sec
TD0                  1
SFO1        400.3024719 MHz
NUC1                 1H
P0                2.67 usec
P1                8.00 usec
PLW1        21.38100052 W

F2 - Processing parameters
SI                65536
SF          400.3000028 MHz
WDW                  EM
SSB                  0
LB                0.30 Hz
GB                   0
PC                1.00
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Reviewed By: B. Sujatha

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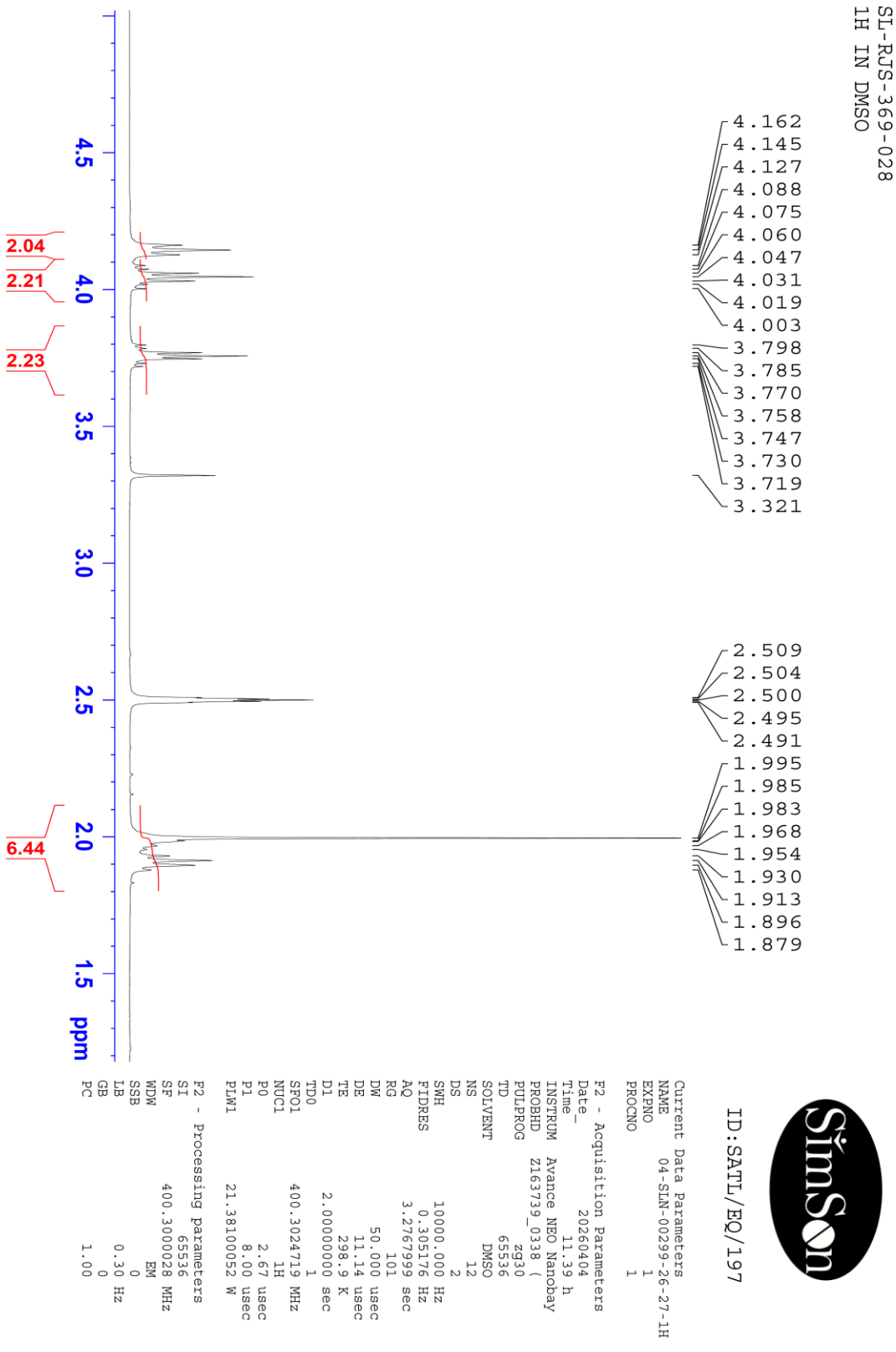
Prepared By:

Format No: SCP/002/F01-00



Prepared By:

Reviewed By: B. Sujeeth

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

A. Experimental:

Product name	: DEOXYCHLORO FAMCICLOVIR	**Instrument Name**	: FT-NMR Spectrometer
Batch No.	: SL-RJS-369-028	**Instrument Model**	: BRUKER 400MHZ
Solvent	: DMSO-d6	**Instrument ID**	: SATL/EQ/197

B. Methodology: The NMR experiments were performed on 400 MHZ Bruker FT-NMR Spectrometer using DMSO-d_6 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.

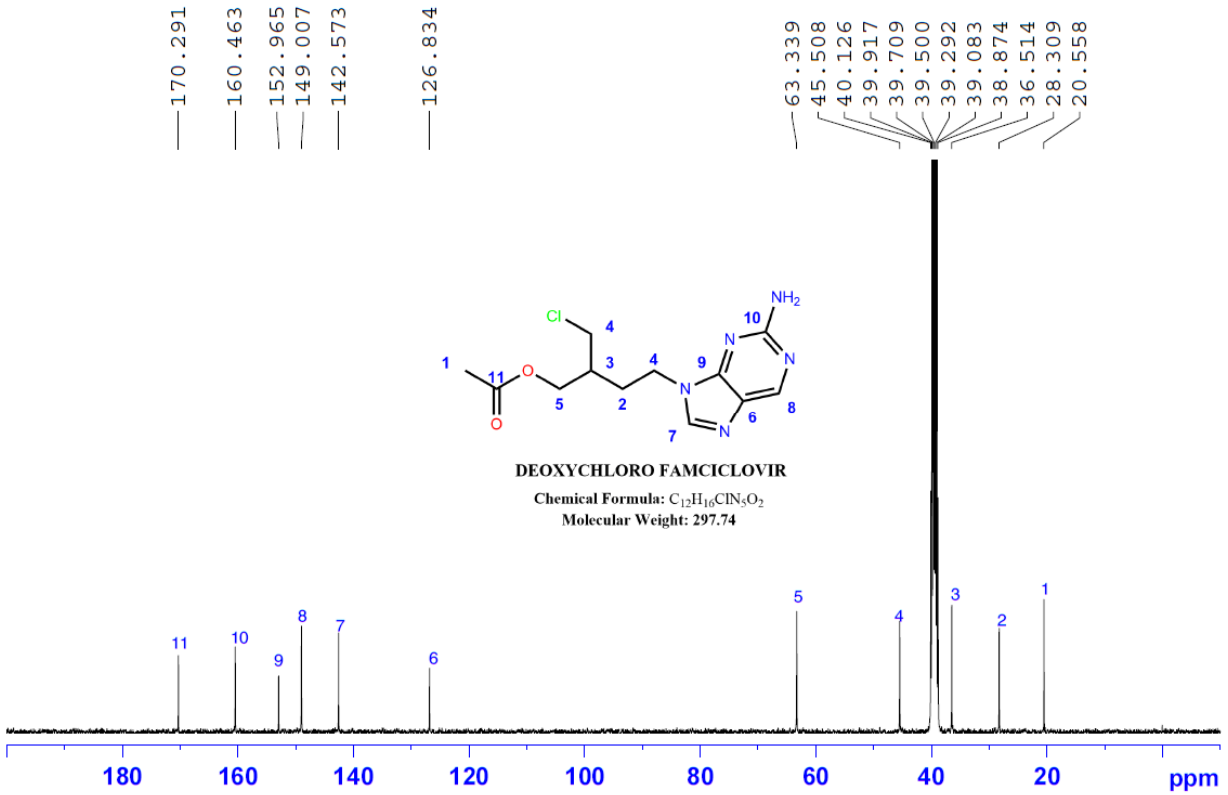
C. Results:

S. No.	Chemical Shift δ, ppm	Multiplicity	No. of Carbons	Assignment of Carbon (s)
1.	20.558	S	1C	1
2.	28.309	S	1C	1
3.	36.514	S	1C	1
4.	45.508	S	2C	2
5.	63.339	S	1C	1
6.	126.834	S	1C	1
7.	142.573	S	1C	1
8.	149.007	S	1C	1
9.	152.965	S	1C	1
10.	160.463	S	1C	1
11.	170.291	S	1C	1
Total No. of Carbons				**12**
Remarks: -			Confirms to the structure	

Note: The assignments are based on chemical shifts and multiplicities

Prepared By: **Reviewed By:**

SL-RJS-369-028
13C IN DMSO



DEOXYCHLORO FAMCICLOVIR

Chemical Formula: $C_{12}H_{16}ClN_5O_2$
Molecular Weight: 297.74

ID:SATL/EQ/197

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Current Data Parameters
NAME      04-SLN-00360-26-27-13C
EXPNO                  1
PROCNO                 1

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Time              7.23 h
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PULPROG          zgpg30
TD                65536
SOLVENT             DMSO
NS                    676
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                298.4 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        100.98000336 W
SFO2         400.3016012 MHz
NUC2                  1H
CPDPRG[2         waltz65
PCPD2             90.00 usec
PLW2         21.38100052 W
PLW12         0.16893999 W
PLW13         0.08497500 W

F2 - Processing parameters
SI                 32768
SF          100.6555647 MHz
WDW                   EM
SSB                    0
LB                  3.00 Hz
GB                     0
PC                  1.40
```

Analysed By

Supriyarao

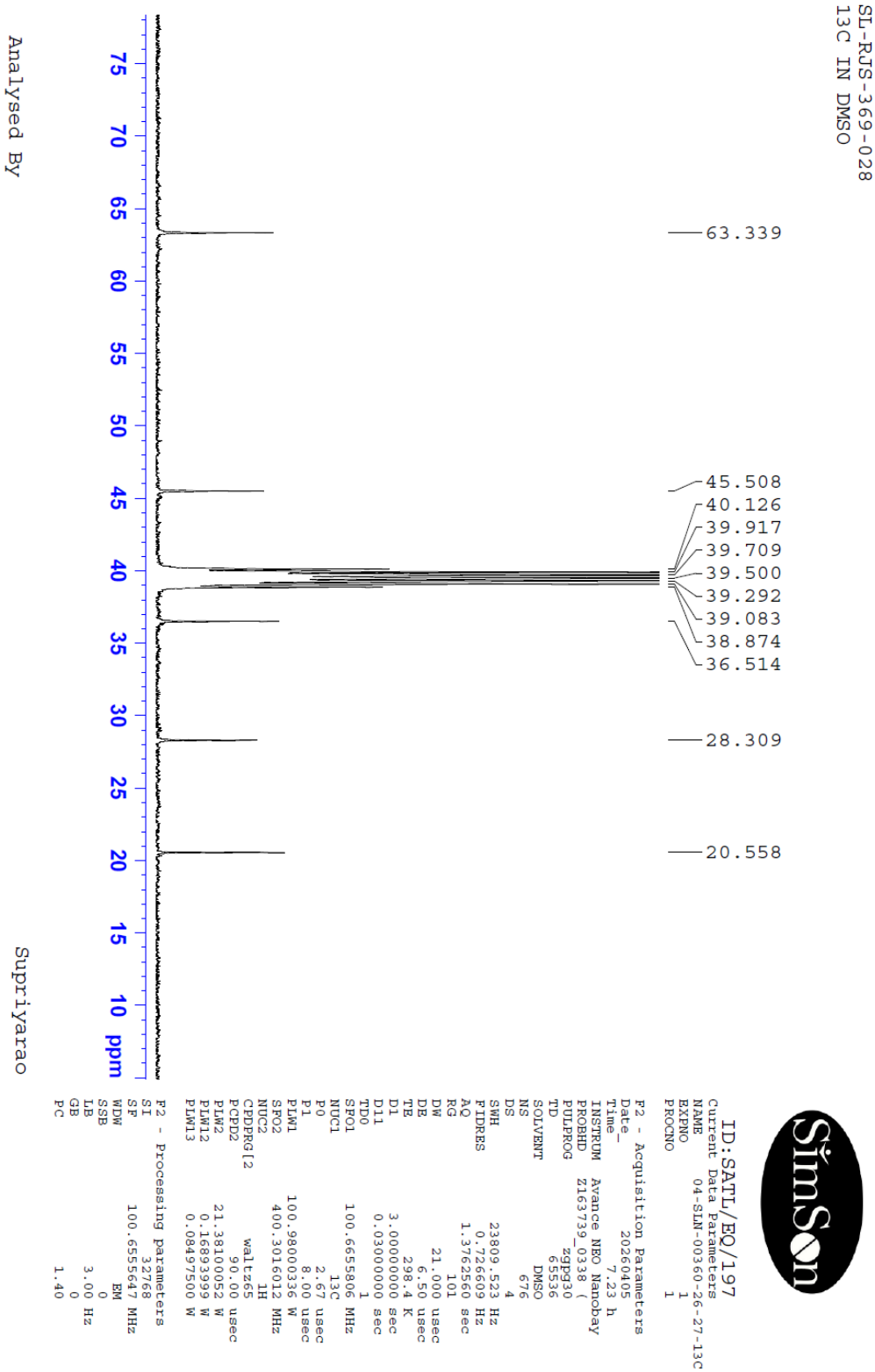
Reviewed By: B. Supriyarao

Prepared By:

Format No: SCP/002/F01-00

Prepared By:

Reviewed By:



Prepared By:

Reviewed By:

III. IDENTIFICATION BY MASS SPECTROSCOPY:

A. Experimental:

Product name	: DEOXYCHLORO FAMCICLOVIR	**Instrument Name**	: Mass Spectrometer
Batch No.	: SL-RJS-369-028	**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 298.1 g/mol corresponding to $[M+H]^+$confirms the monoisotopic mass as m/z corresponding to the Molecular formula $C_{12}H_{16}ClN_5O_2$

Solvent: methanol.

C. Results:

S. No.	Composition	Exact Mass	Molecular Weight	m/z value
1.	$C_{12}H_{16}ClN_5O_2$	297.10	297.74	298.1 (+ve mode) 299.3 (+ve mode) [M+2]

Remarks:

1. Mass peak at m/z 298.1 corresponds to product mass peak.

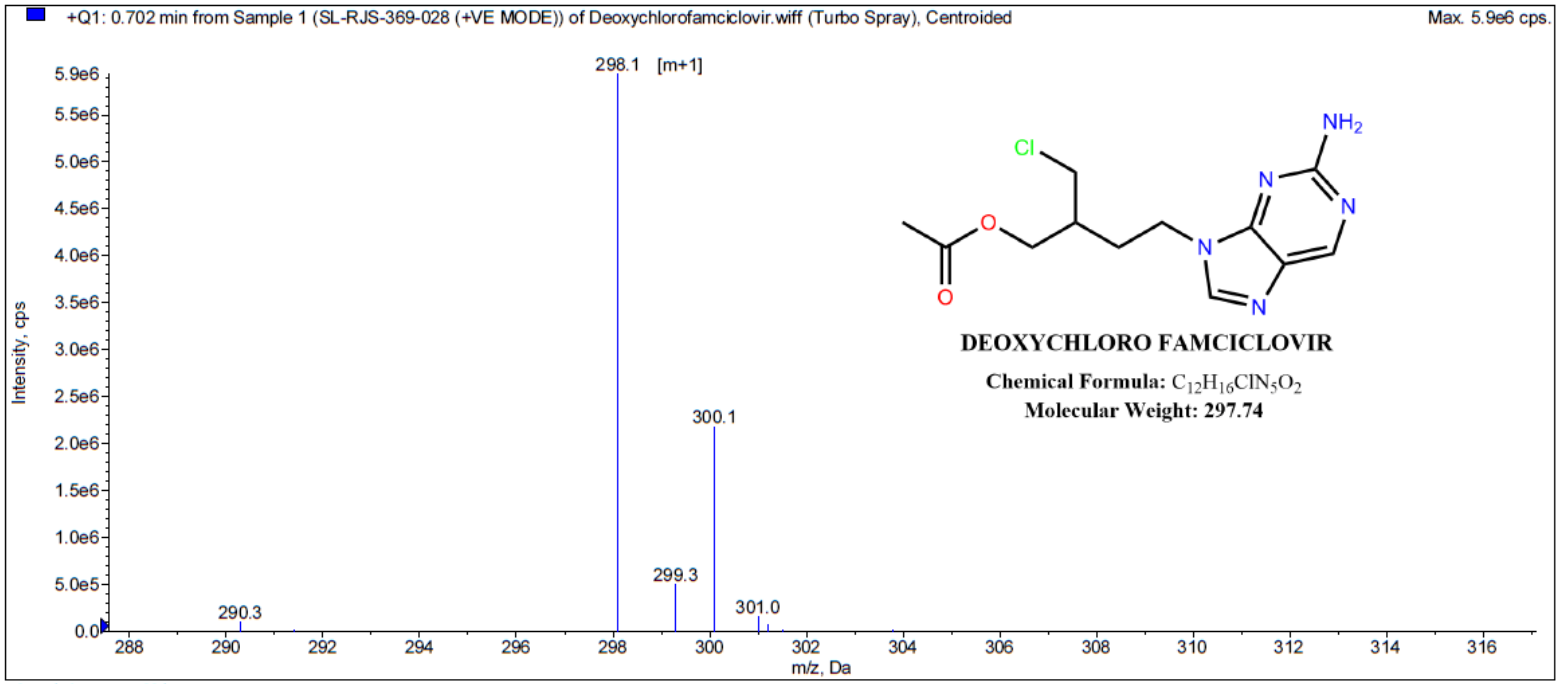
Prepared By: **Reviewed By:**

Sample Comment: Solvent:Methanol
No:SLN/00299/26-27

Reg

Acq. File: Deoxychlorofamciclovir.wiff
Sample Name: SL-RJS-369-028 (+VE MODE)
Acq. Date: Monday, April 06, 2026
Operator: Rakesh Benchiboya
Acq. Time: 12:45

InstrumentID:SATL/EQ/016



Algorithm: IntelliQuan

*Analysed By:

12:58:44
Printing Date: 06/04/2026

*Checked By:

Reviewed By:

Prepared By:

IV. IDENTIFICATION BY FT-IR SPECTROSCOPY:

A. Experimental:

Product name : DEOXYCHLORO FAMCICLOVIR	**Instrument Name** : FT-IR Spectrometer
Batch No. : SL-RJS-369-028	**Instrument Model** : BRUKER
Sample Preparation: KBr pellet	**Instrument ID** : SATL/EQ/025

B. Methodology: DEOXYCHLORO FAMCICLOVIR 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.	3310.78	Stretching	N-H
2.	1738.00	Stretching	C=O
3.	1293.17	Stretching	C-N
4.	1157.36	Stretching	C-O
5.	795.93	Stretching	C-Cl

Prepared By: **Reviewed By:**

Instrument ID No:SATL/EQ/025

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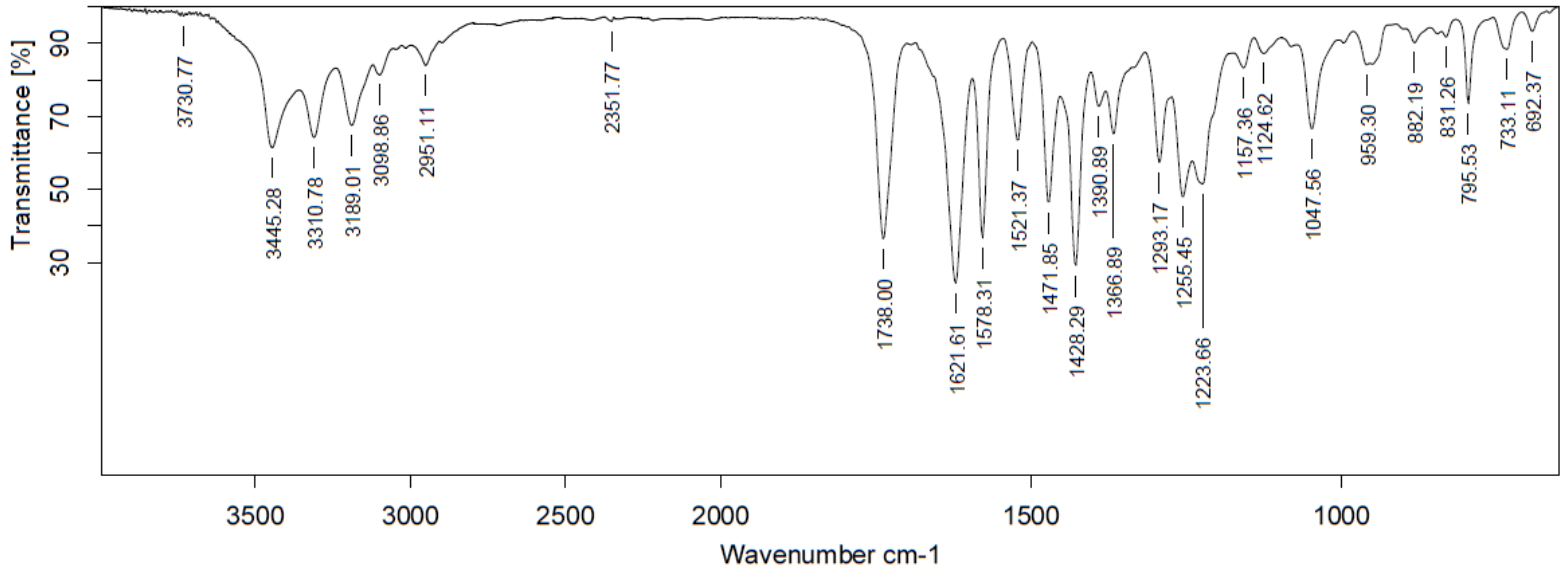

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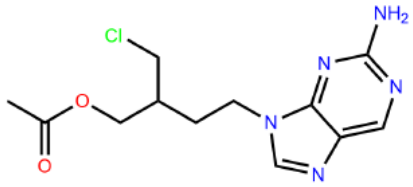
Date & Time:04/04/2026,15:57:33

Operator Name:Anjali Devi B



DEOXYCHLORO FAMCICLOVIR

Chemical Formula: $C_{12}H_{16}ClN_5O_2$

Molecular Weight: 297.74

Experiment:Trans.XPM

Resolution:4

Sample Scans:32

Frequency Range:4000 to 650

04/04/2026 16:01:09

Page 1/1

Prepared By:

Reviewed By: B. Sujatha

V. PURITY BY HPLC:

A. Experimental:

Product name	: DEOXYCHLORO FAMCICLOVIR	**Instrument Name :**	HPLC
Batch No.	: SL-RJS-369-028	**Instrument Model :**	Shimadzu
Method	: USP	**Instrument ID**	: SATL/EQ/063

B. HPLC Method:

Column: C_8, (250 X 4.6mm), 5µm

Mobile phase A: 2.72 g/L of monobasic potassium phosphate in water. Adjust with 1 M phosphoric acid to a pH of 4.0 ± 0.05.

Mobile phase B: acetonitrile

Elution mode: Gradient Programme

Detector (λ)	:	220nm
Column Temperature	:	30°C
Run Time	:	80min
Flow	:	1.0 ml/min
Diluent	:	MP-A
Inj. Volume	:	20µl
Sample Preparation	:	1 mg/ml in Diluent.

Gradient Programme:

Time	Mobile Phase A	Mobile Phase B
0	95	5
50	75	25
60	75	25
65	95	5
75	95	5
80	95	5

C. Results: 96.51% by area normalization

Prepared By: **Reviewed By:**

HPLC Chromatogram:

Simson Life Sciences Pvt Ltd

<Sample Information>

04_04_2026_(2)_006.lcd

Sample Name	: Famciclovir		
Sample ID	: Blank		
Data Filename	: 04_04_2026_(2)_006.lcd		
Method Filename	: Famciclovir Tablets_Org IMP_USP.lcm		
Batch Filename	: 04_04_2026_(2).lcb		
Vial #	: 1-50	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 04/04/2026 22:22:56	Acquired by	: Bibhu Pada Sahoo
Date Processed	: 06/04/2026 09:06:05	Processed by	: Bibhu Pada Sahoo
Data Description	: Reg No: CSL/00063/26-27 Column ID: 250*4.6 mm,5 µm Phenomenex (C8) CLC0186 Method: USP Flow: 1.0 ml/min Diluent: MP-A		

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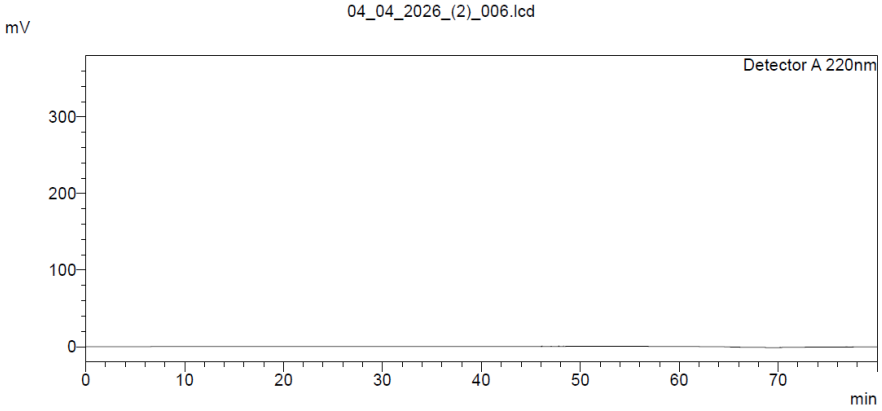
04_04_2026_(2)_006.lcd



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04_04_2026_(2)_006.lcd

Detector A 220nm

Peak#	Name	Ret. Time	Area	Area%
Total				

SATLEQ063$CSL_APR_2026 - 6-49-2 - 04_04_2026_(2)_006.lcd

Prepared By: **Reviewed By:**

Simson Life Sciences Pvt Ltd

<Sample Information>

04_04_2026_(2)_006.lcd

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Sample ID	: Blank		
Data Filename	: 04_04_2026_(2)_006.lcd		
Method Filename	: Famciclovir Tablets_Org IMP_USP.lcm		
Batch Filename	: 04_04_2026_(2).lcb		
Vial #	: 1-50	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 04/04/2026 22:22:56	Acquired by	: Bibhu Pada Sahoo
Date Processed	: 06/04/2026 09:06:05	Processed by	: Bibhu Pada Sahoo
Data Description	: Reg No: CSL/00063/26-27 Column ID: 250*4.6 mm,5 µm Phenomenex (C8) CLC0186 Method: USP Flow: 1.0 ml/min Diluent: MP-A		

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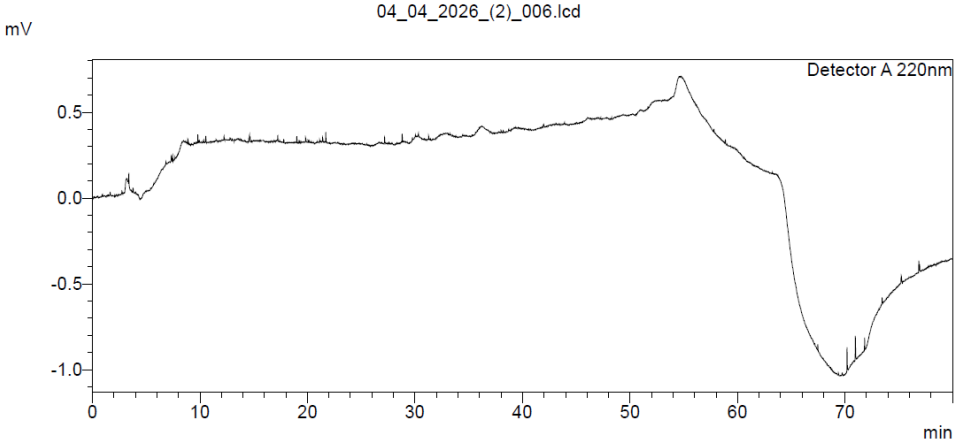
04_04_2026_(2)_006.lcd



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04_04_2026_(2)_006.lcd

Detector A 220nm

Peak#	Name	Ret. Time	Area	Area%
Total				

SATLEQ063$CSL_APR_2026 - 6-49-2 - 04_04_2026_(2)_006.lcd

Prepared By: **Reviewed By:**

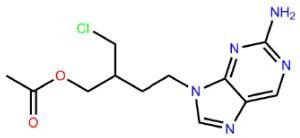
Simson Life Sciences Pvt Ltd

<Sample Information>

04_04_2026_(2)_008.lcd

Sample Name	: Deoxy ChloroFamciclovir		
Sample ID	: SL-RJS-369-028		
Data Filename	: 04_04_2026_(2)_008.lcd		
Method Filename	: Famciclovir Tablets_Org IMP_USP.lcm		
Batch Filename	: 04_04_2026_(2).lcb		
Vial #	: 1-52	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 05/04/2026 01:04:10	Acquired by	: Bibhu Pada Sahoo
Date Processed	: 06/04/2026 09:22:38	Processed by	: Rambabu Jaddu
Data Description	: Reg No: CSL/00063/26-27		

Column ID: 250*4.6 mm,5 µm Phenomenex (C8) CLC0186
Method: USP
Flow: 1.0 ml/min
Diluent: MP-A



DEOXYCHLORO FAMCICLOVIR

Chemical Formula: $C_{12}H_{16}ClN_5O_2$

Molecular Weight: 297.74

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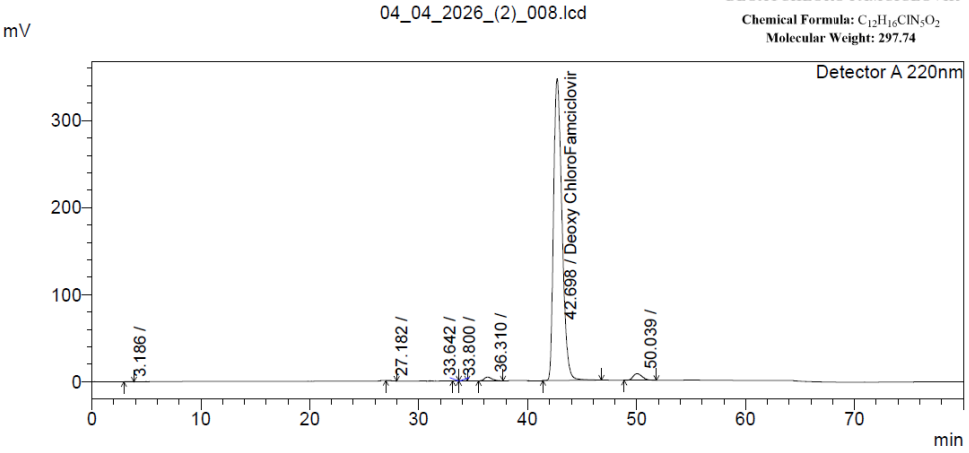

<Peak Table>

04_04_2026_(2)_008.lcd

Detector A 220nm

Peak#	Name	Ret. Time	Area	Area%
1		3.186	5502	0.029
2		27.182	4719	0.024
3		33.642	2801	0.015
4		33.800	3629	0.019
5		36.310	204081	1.058
6	Deoxy ChloroFamciclovir	42.698	18624111	96.509
7		50.039	452855	2.347
Total			19297699	100.000

SATLEQ063$CSL_APR_2026 - 6-51-2 - 04_04_2026_(2)_008.lcd

Prepared By: **Reviewed By:**

Simson Life Sciences Pvt Ltd

<Sample Information>

04_04_2026_(2)_008.lcd

Sample Name	: Deoxy ChloroFamciclovir		
Sample ID	: SL-RJS-369-028		
Data Filename	: 04_04_2026_(2)_008.lcd		
Method Filename	: Famciclovir Tablets_Org IMP_USP.lcm		
Batch Filename	: 04_04_2026_(2).lcb		
Vial #	: 1-52	Sample Type	: Unknown
Injection Volume	: 20 uL		
Date Acquired	: 05/04/2026 01:04:10	Acquired by	: Bibhu Pada Sahoo
Date Processed	: 06/04/2026 09:22:38	Processed by	: Rambabu Jaddu
Data Description	: Reg No: CSL/00063/26-27 Column ID: 250*4.6 mm,5 µm Phenomenex (C8) CLC0186 Method: USP Flow: 1.0 ml/min Diluent: MP-A		

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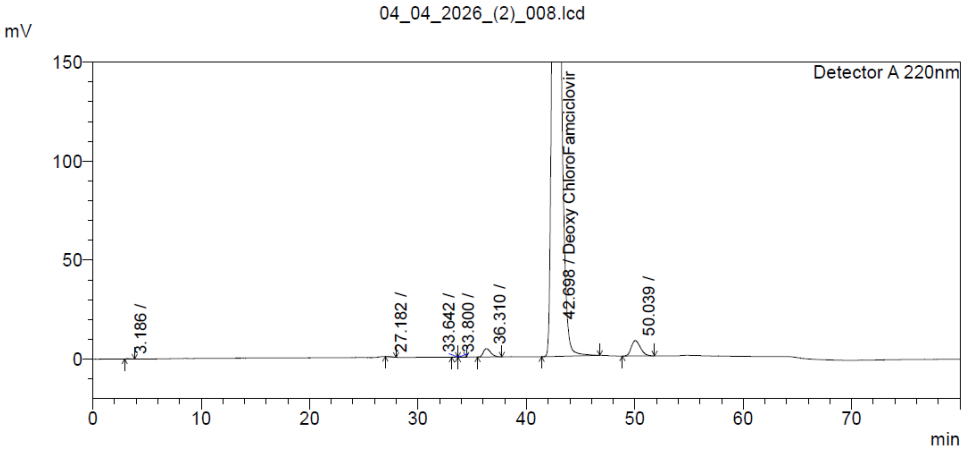


<Peak Table>

04_04_2026_(2)_008.lcd

Detector A 220nm

Peak#	Name	Ret. Time	Area	Area%
1		3.186	5502	0.029
2		27.182	4719	0.024
3		33.642	2801	0.015
4		33.800	3629	0.019
5		36.310	204081	1.058
6	Deoxy ChloroFamciclovir	42.698	18624111	96.509
7		50.039	452855	2.347
Total			19297699	100.000

SATLEQ063$CSL_APR_2026 - 6-51-2 - 04_04_2026_(2)_008.lcd

Prepared By:

Reviewed By:

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

A. Experimental:

Product name	**:** DEOXYCHLORO FAMCICLOVIR	**Instrument Name**	**:** TGA
Batch No.	**:** SL-RJS-369-028	**Instrument Model**	**:** Perkin Elmer
Method	**:** 30°C to 850°C	**Instrument ID**	**:** SATL/EQ/041

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

30°C to 120°C at 10°C/min; Gas Flow:

120°C to 850°C at 40°C/min; Gas Flow:

C. Results:

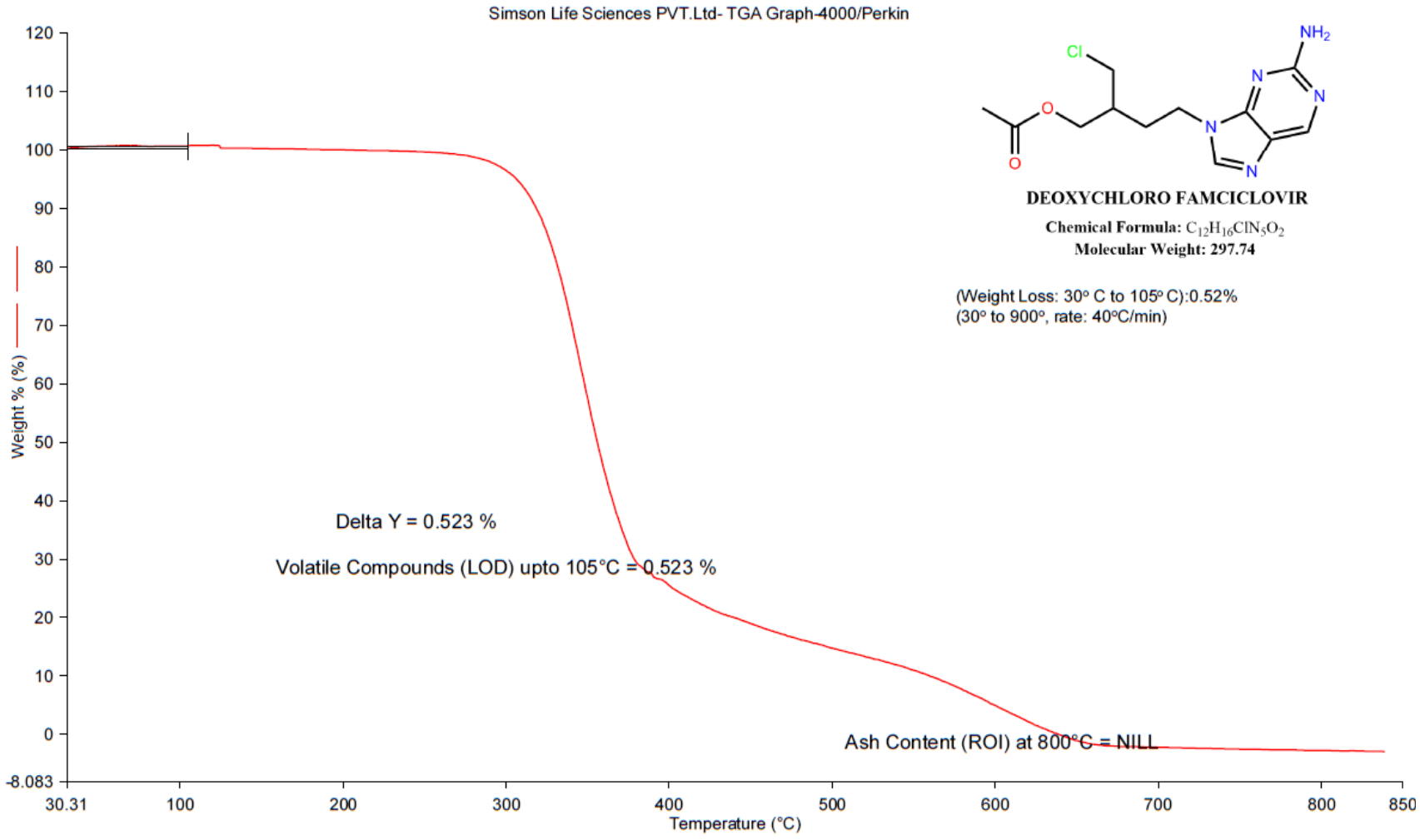
i. % of Loss Observed up to 105°C: 0.52%

ii. % of Ash content observed: NIL

The TGA thermogram is enclosed.

Prepared By: **Reviewed By:**

Filename:	D:\SATLEQ04...\Deoxy Chloro Famciclovir.t6d
Data Collected:	07/04/2026 11:17:23
Operator ID:	Karthika Alavala
Sample ID:	SLN/00360/26-27
Sample Weight:	3.881 mg
Comment:	B.No: SL-RJS-369-028



07/04/2026 11:29:46

1) Heat from 30.00°C to 120.00°C at 20.00°C/min

2) Heat from 120.00°C to 850.00°C at 40.00°C/min

Reviewed By: B. Sujitha

Prepared By:

VII. 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= 96.51%

LOD by TGA: 0.52%

Ash content: 0%

Calculation:

= 96.51x (100-0.52)/100

Defined Potency = **96.01%** w/w

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

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

This product has been qualified and can be used as an impurity 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:**