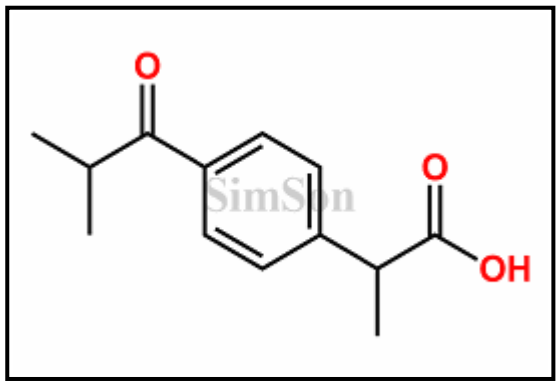
CERTIFICATE OF ANALYSIS

(Certificate No.: SPC260325 - 031 / V.01)

SimSon Pharma Limited
Reference Standards | Research Chemicals | Research Service

Analysis Date : 16/03/2026 **Re-test Date:** 15/03/2029

Product Name	**: IBUPROFEN EP IMPURITY J**
Chemical Name	: (2RS)-2-[4-(2-methylpropanoyl)phenyl]propanoic acid
Synonyms	: Methyl-4-(2-methyl-1-oxopropyl)benzeneacetic Acid
CAT No.	: I010010
Batch Number	: SL-PSK-375-004
CAS No.	: 65813-55-0
Molecular Formula	: $C_{13}H_{16}O_3$
Molecular Weight	: 220.26 g/mol
Long term Storage Condition	: Store at 2°C To 8°C
Shipping Condition	: Ambient



ANALYTICAL INFORMATION:

Sr No	TESTS	RESULTS
1	**DESCRIPTION**	Pale Yellow Solid
2	**SOLUBILITY**	Soluble in DMSO and 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)**	99.60%
5	**WEIGHT LOSS (By TGA)** Weight Loss: (30°C to 500°C , rate: 20°C/min)	0.10% w/w
6	**ASH CONTENT** (30°C to 500°C , rate: 20°C/min)(500°C to 800°C, rate: 20°C/min)	0.57% w/w
7	**DEFINED POTENCY (By Mass Balance Method)** %= [(100-(Weight Loss by TGA +Ash Content by TGA)) x HPLC Purity /100]	98.93% w/w

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

Prepared By : **Sheetal Pise**
(Sign & Date) **25/03/2026**

Approved By : **Pandharinath Varpe**
(Sign & Date) **25/03/2026**

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-PSK-375-004/QR/25-00919

Product Name	**IBUPROFEN EP IMPURITY J**
Chemical Name	(2RS)-2-[4-(2-methylpropanoyl)phenyl]propanoic acid
Molecular Formula	$C_{13}H_{16}O_3$
Molecular Weight	220.26 g/mol
Batch No.	SL-PSK-375-004
Synonyms	Methyl-4-(2-methyl-1-oxopropyl)benzeneaceticAcid
CAS No.	65813-55-0
CAT No.	I010010

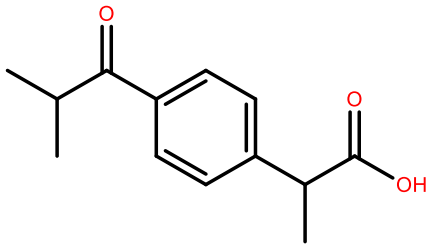


TABLE OF CONTENTS

Prepared By:

Reviewed By:

I. IDENTIFICATION BY ^{1}HNMR SPECTROSCOPY

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: FT-NMR Spectrometer
Batch No.	: SL-PSK-375-004	**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-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.	1.09-1.11	D	6H	-	6
2.	1.38-1.40	D	3H	-	3
3.	3.60-3.67	M	1H	-	1
4.	3.76-3.81	M	1H	-	1
5.	7.43-7.45	D	2H	-	2
6.	7.92-7.94	D	2H	-	2
7.	12.45	S	1H	-	1
Total No. of protons					**16**
Remarks:-			Confirms to the structure		

Note: The Assignments are based on chemical shifts and multiplicities

Remarks:

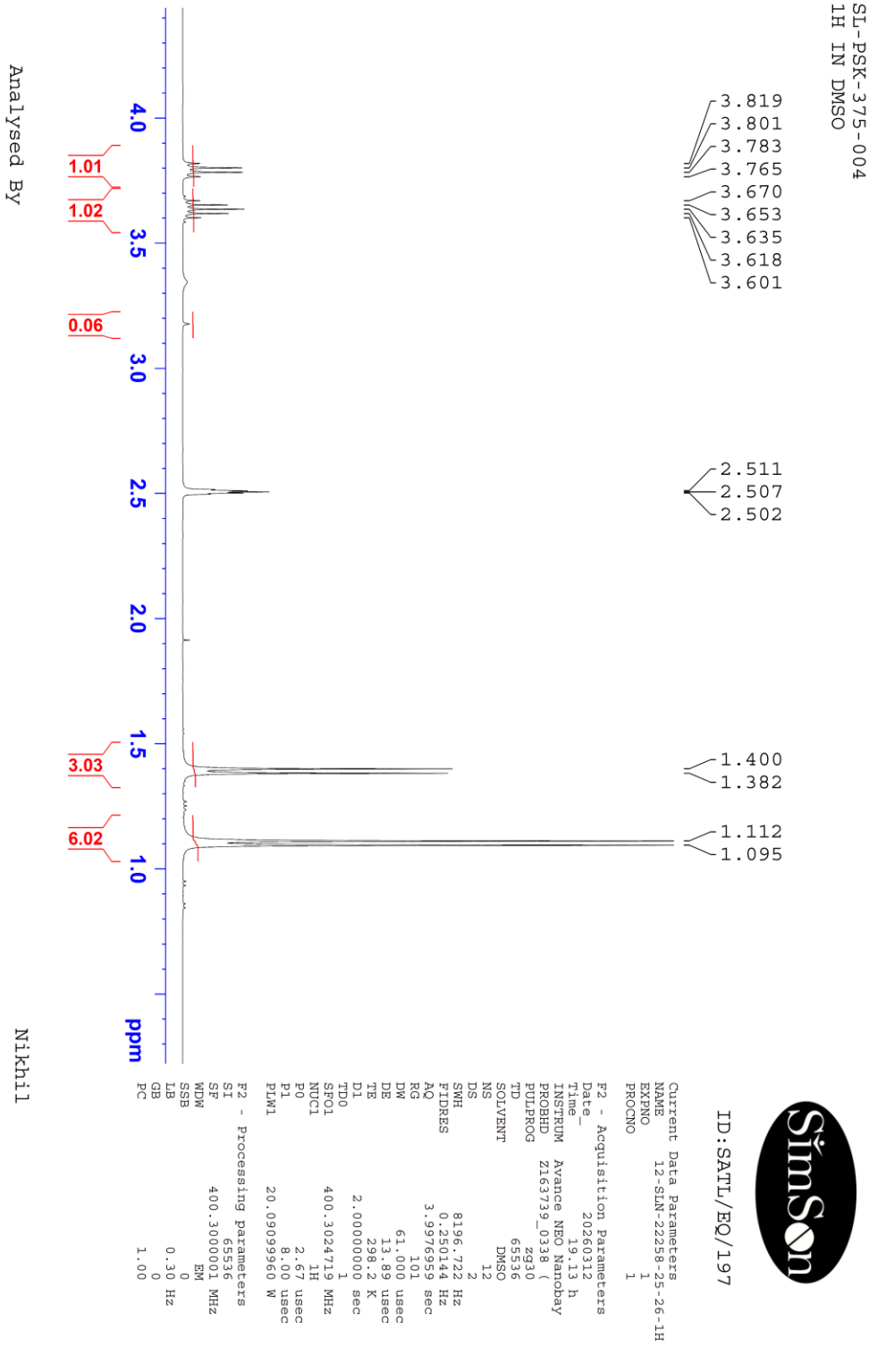
1. Solvent peaks should be mentioned

Prepared By: **Reviewed By:**

Prepared By: **Reviewed By:**

Prepared By:

Reviewed By:



Prepared By:

Reviewed By:

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

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: FT-NMR Spectrometer
Batch No.	: SL-PSK-375-004	**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-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.

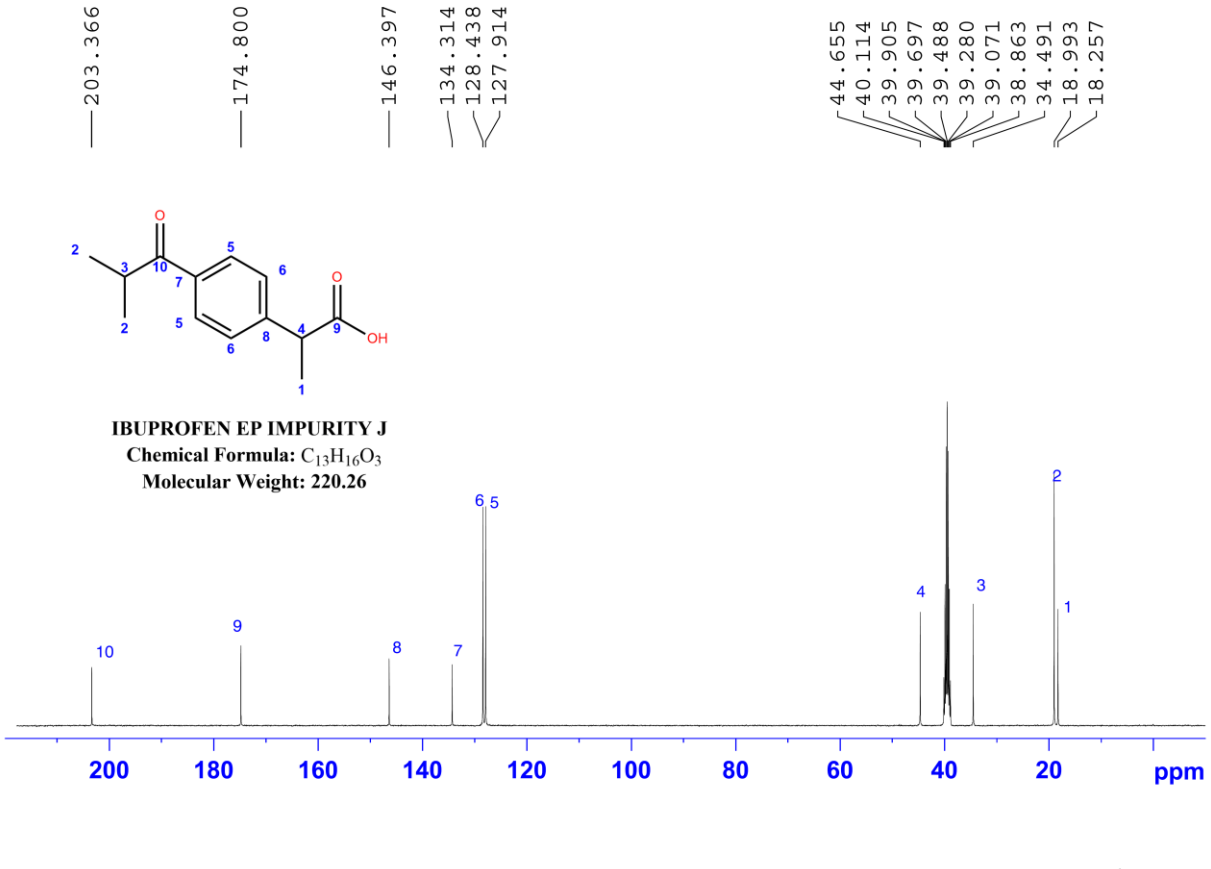
C. Results:

S. No.	Chemical Shift δ, ppm	Multiplicity	No. of Carbons	Assignment of Carbon (s)
1.	18.25	S	1C	1
2.	18.99	S	2C	2
3.	34.49	S	1C	1
4.	44.65	S	1C	1
5.	127.91	S	2C	2
6.	128.43	S	2C	2
7.	134.31	S	1C	1
8.	146.39	S	1C	1
9.	174.80	S	1C	1
10.	203.36	S	1C	1
Total No. of Carbons				**13**
Remarks:-			Confirms to the structure	

Note: The assignments are based on chemical shifts and multiplicities

Prepared By: **Reviewed By:**

SL-PSK-375-004
13C IN DMSO



ID:SATL/EQ/197

```
Current Data Parameters
NAME      14-SLN-22258-25-26-13C
EXPNO                  1
PROCNO                 1

F2 - Acquisition Parameters
Date_           20260315
Time              14.08 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG           zgpg30
TD                65536
SOLVENT             DMSO
NS                    600
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                298.0 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          100.6555618 MHz
WDW                EM
SSB                 0
LB               3.00 Hz
GB                  0
PC               1.40
```

Analysed By

Supriyarao

Reviewed By: B. Supriyarao

Prepared By:

SL-PSK-375-004
13C IN DMSO

203.366
174.800
146.397
134.314
128.438
127.914

210 200 190 180 170 160 150 140 130 ppm

Analysed By

Supriyarao

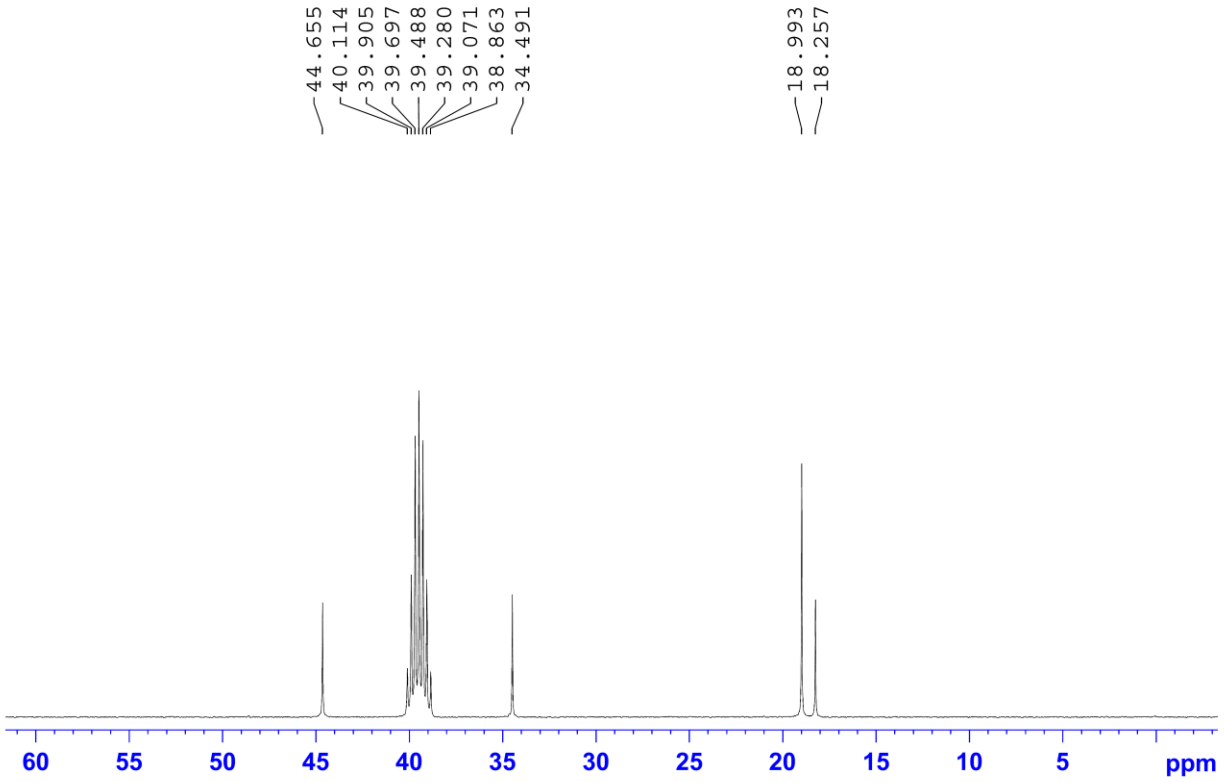
ID:SATL/EQ/197

Current Data Parameters	
NAME	14-SLN-22258-25-26-13C
EXPNO	1
PROCNO	1
F2 - Acquisition Parameters	
Date_	20260315
Time	14.08 h
INSTRUM	Avance NEO Nanobay
PROBHD	Z163739_0338 (
PULPROG	zgpg30
TD	65536
SOLVENT	DMSO
NS	600
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	298.0 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	100.6555618 MHz
WDW	EM
SSB	0
LB	3.00 Hz
GB	0
PC	1.40

Prepared By:

Reviewed By: B. Supriyarao

SL-PSK-375-004
13C IN DMSO



ID:SATL/EQ/197

```
Current Data Parameters
NAME      14-SLN-22258-25-26-13C
EXPNO                  1
PROCNO                 1

F2 - Acquisition Parameters
Date_           20260315
Time              14.08 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG           zgpg30
TD                65536
SOLVENT             DMSO
NS                    600
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                298.0 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          100.6555618 MHz
WDW                  EM
SSB                   0
LB                 3.00 Hz
GB                    0
PC                 1.40
```

Analysed By

Supriyarao

Reviewed By: B. Supriyarao

Prepared By:

III. IDENTIFICATION BY MASS SPECTROSCOPY:

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: Mass Spectrometer
Batch No.	: SL-PSK-375-004	**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 220.6 g/mol corresponding to $[M+H]^+$confirms the monoisotopic mass as m/z corresponding to the Molecular formula $C_{13}H_{16}O_3$

Solvent: methanol.

C. Results:

S. No.	Composition	Exact Mass	Molecular Weight	m/z value
1.	$C_{13}H_{16}O_3$	220.11	220.26	220.6 (+ve mode)

Remarks:

1. Mass peak at m/z 220.6 corresponds to product mass peak.
2. Other peaks are unidentified peaks

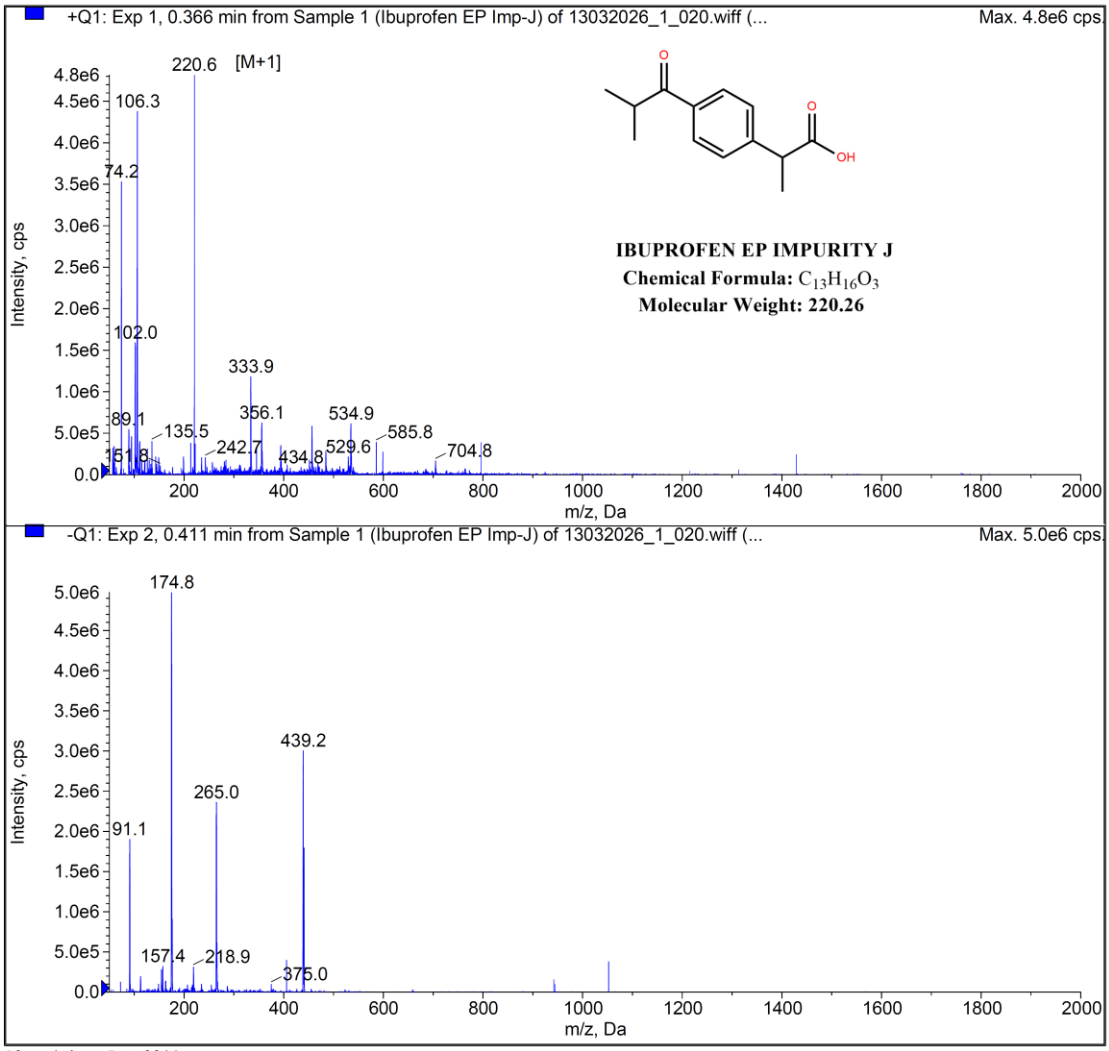
Prepared By: **Reviewed By:**

Batch Name: 13032026_1.dab

Sample Comment: Reg no:SLN/22258/25-26
MP-A:0.1%Formic acid in water
MP-B:ACN:Water(90:10)

Acq. File: 13032026_1_020.wiff
Acq. Date: Friday, March 13, 2026
Sample Name: Ibuprofen EP Imp-J
Sample ID: SL-PSK-375-004
Operator: Vijay Sai Raghav Pillarisetti
Acq. Time: 13:07

InstrumentID:SATL/EQ/271



Algorithm: IntelliQuan

*Analysed By:

*Checked By:

Prepared By:

Reviewed By:

IV. IDENTIFICATION BY FT-IR SPECTROSCOPY:

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: FT-IR Spectrometer
Batch No.	: SL-PSK-375-004	**Instrument Model**	: BRUKER
Sample Preparation	: KBr pellet	**Instrument ID**	: SATL/EQ/025

B. Methodology: IBUPROFEN EP IMPURITY J 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.	3341.07	Stretching	O-H
2.	1705.14	Stretching	C=O

Prepared By:

Reviewed By: B. Sujatha

V. PURITY BY HPLC:

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: HPLC
Batch No.	: SL-PSK-375-004	**Instrument Model**	: Shimadzu
Method	: EP	**Instrument ID**	: SATL/EQ/014

B. HPLC Method:

Column: C_{18}, (100 X 4.6mm), 5µm

Mobile phase A: 1.36gm of KH2PO4 in 1000ml of water. Adjusted pH 3.2 with diluted OPA mix 0.5 volumes of phosphoric acid, 340 volumes of acetonitrile and 600 volumes of water for chromatography; allow to equilibrate and dilute to 1000 volumes with water for chromatography;.

Mobile phase B: acetonitrile

Elution mode: Gradient Programme

Detector (λ) : 214nm
Column Temperature : 30°C
Run Time : 82min
Flow : 1.2 ml/min
Diluent : ACN: MP-A (10:90)
Inj. Volume : 20µl
Sample Preparation : 1 mg/ml in Diluent.

Gradient Programme:

Time	Mobile Phase A	Mobile Phase B
0	100	0
25	100	0
55	15	85

C. Results: 99.60% by area normalization

Prepared By: **Reviewed By:**

HPLC Chromatogram:

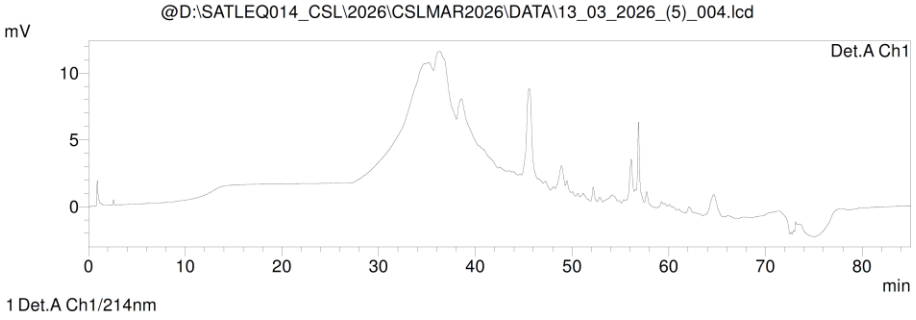
SIMSON LIFE SCIENCES

@D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd

Acquired by	: Prasad Kulkarni
Sample Name	: Ibuprofen
Sample ID	: Blank
Tray#	: 2
Vail #	: 46
Injection Volume	: 20 uL
Data File Name	: 13_03_2026_(5)_004.lcd
Method File Name	: Ibuprofen_RS_EP.lcm
Batch File Name	: 13_03_2026_(5).lcb
Report File Name	: Simsonlifesciences_Purity_Ch1 V-1.0.lcr
Data Acquired	: 13/03/2026 21:27:02
Data Processed	: 14/03/2026 09:13:47
Data Description	: Reg NO: CSL/07201/25-26

Column: 100*4.6 mm,5µm Waters XTerra MS C18 CLC0275
Method: EP
Flow: 1.2 ml/min
Diluent : ACN : MP-A (10:90)

<Chromatogram>



PeakTable @D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd
Detector A Ch1 214nm

Prepared By: **Reviewed By:**

SIMSON LIFE SCIENCES

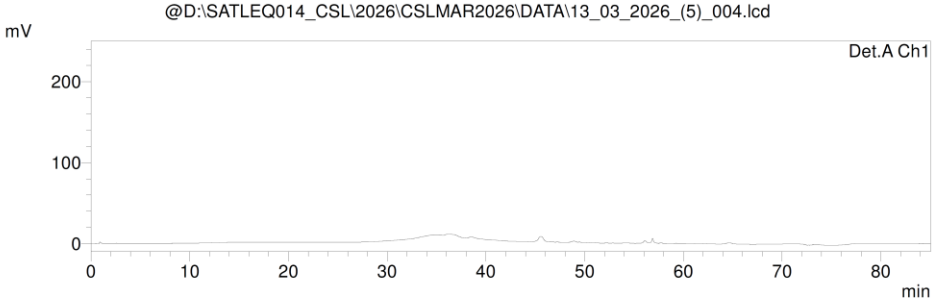
@D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd

Acquired by	: Prasad Kulkarni
Sample Name	: Ibuprofen
Sample ID	: Blank
Tray#	: 2
Vail #	: 46
Injection Volume	: 20 uL
Data File Name	: 13_03_2026_(5)_004.lcd
Method File Name	: Ibuprofen_RS_EP.lcm
Batch File Name	: 13_03_2026_(5).lcb
Report File Name	: Simsonlifesciences_Purity_Ch1 V-1.0.lcr
Data Acquired	: 13/03/2026 21:27:02
Data Processed	: 14/03/2026 09:13:47
Data Description	: Reg NO: CSL/07201/25-26

Column: 100*4.6 mm,5µm Waters XTerra MS C18 CLC0275
Method: EP
Flow: 1.2 ml/min
Diluent : ACN : MP-A (10:90)

<Chromatogram>

@D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd



1 Det.A Ch1/214nm

PeakTable @D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd
Detector A Ch1 214nm

D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_004.lcd

Prepared By:

Reviewed By:

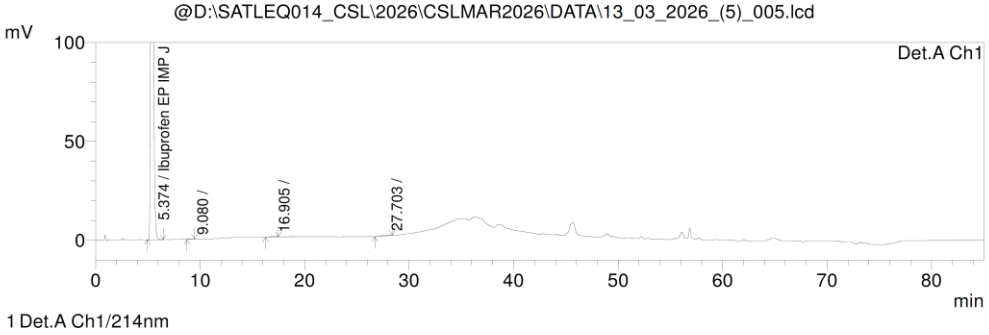
SIMSON LIFE SCIENCES

@D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd

Acquired by	: Prasad Kulkarni
Sample Name	: Ibuprofen EP IMP J
Sample ID	: SL-PSK-375-004
Tray#	: 2
Vail #	: 47
Injection Volume	: 20 uL
Data File Name	: 13_03_2026_(5)_005.lcd
Method File Name	: Ibuprofen_RS_EP.lcm
Batch File Name	: 13_03_2026_(5).lcb
Report File Name	: Simsonlifesciences_Purity_Ch1 V-1.0.lcr
Data Acquired	: 13/03/2026 22:52:43
Data Processed	: 14/03/2026 09:26:40
Data Description	: Reg NO: CSL/07201/25-26

Column: 100*4.6 mm,5µm Waters XTerra MS C18 CLC0275
Method: EP
Flow: 1.2 ml/min
Diluent : ACN : MP-A (10:90)

<Chromatogram>



PeakTable @D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd

Detector A Ch1 214nm

Peak#	Name	Ret. Time	Area	Area %
1	Ibuprofen EP IMP J	5.374	7509830	99.601
2		9.080	5036	0.067
3		16.905	5028	0.067
4		27.703	19995	0.265
Total			7539889	100.000

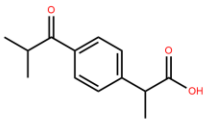
D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd

Prepared By: **Reviewed By:**

SIMSON LIFE SCIENCES

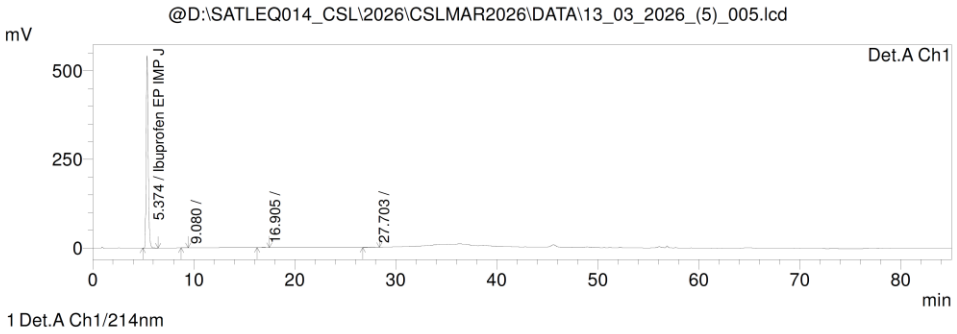
@D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd

Acquired by : Prasad Kulkarni
Sample Name : Ibuprofen EP IMP J
Sample ID : SL-PSK-375-004
Tray# : 2
Vail # : 47
Injection Volume : 20 uL
Data File Name : 13_03_2026_(5)_005.lcd
Method File Name : Ibuprofen_RS_EP.lcm
Batch File Name : 13_03_2026_(5).lcb
Report File Name : Simsonlifesciences_Purity_Ch1 V-1.0.lcr
Data Acquired : 13/03/2026 22:52:43
Data Processed : 14/03/2026 09:26:40
Data Description : Reg NO: CSL/07201/25-26
Column: 100*4.6 mm,5µm Waters XTerra MS C18 CLC0275
Method: EP
Flow: 1.2 ml/min
Diluent : ACN : MP-A (10:90)



IBUPROFEN EP IMPURITY J
Chemical Formula: $C_{13}H_{16}O_3$
Molecular Weight: 220.26

<Chromatogram>



PeakTable @D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd
Detector A Ch1 214nm

Peak#	Name	Ret. Time	Area	Area %
1	Ibuprofen EP IMP J	5.374	7509830	99.601
2		9.080	5036	0.067
3		16.905	5028	0.067
4		27.703	19995	0.265
Total			7539889	100.000

D:\SATLEQ014_CSL\2026\CSLMAR2026\DATA\13_03_2026_(5)_005.lcd

Prepared By: **Reviewed By:**

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

A. Experimental:

Product name	: IBUPROFEN EP IMPURITY J	**Instrument Name**	: TGA
Batch No.	: SL-PSK-375-004	**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 500ºC at 20ºC/min; Gas Flow:

500ºC to 800ºC at 20ºC/min; Gas Flow:

C. Results:

i. % of Loss Observed up to 105ºC: 0.10%

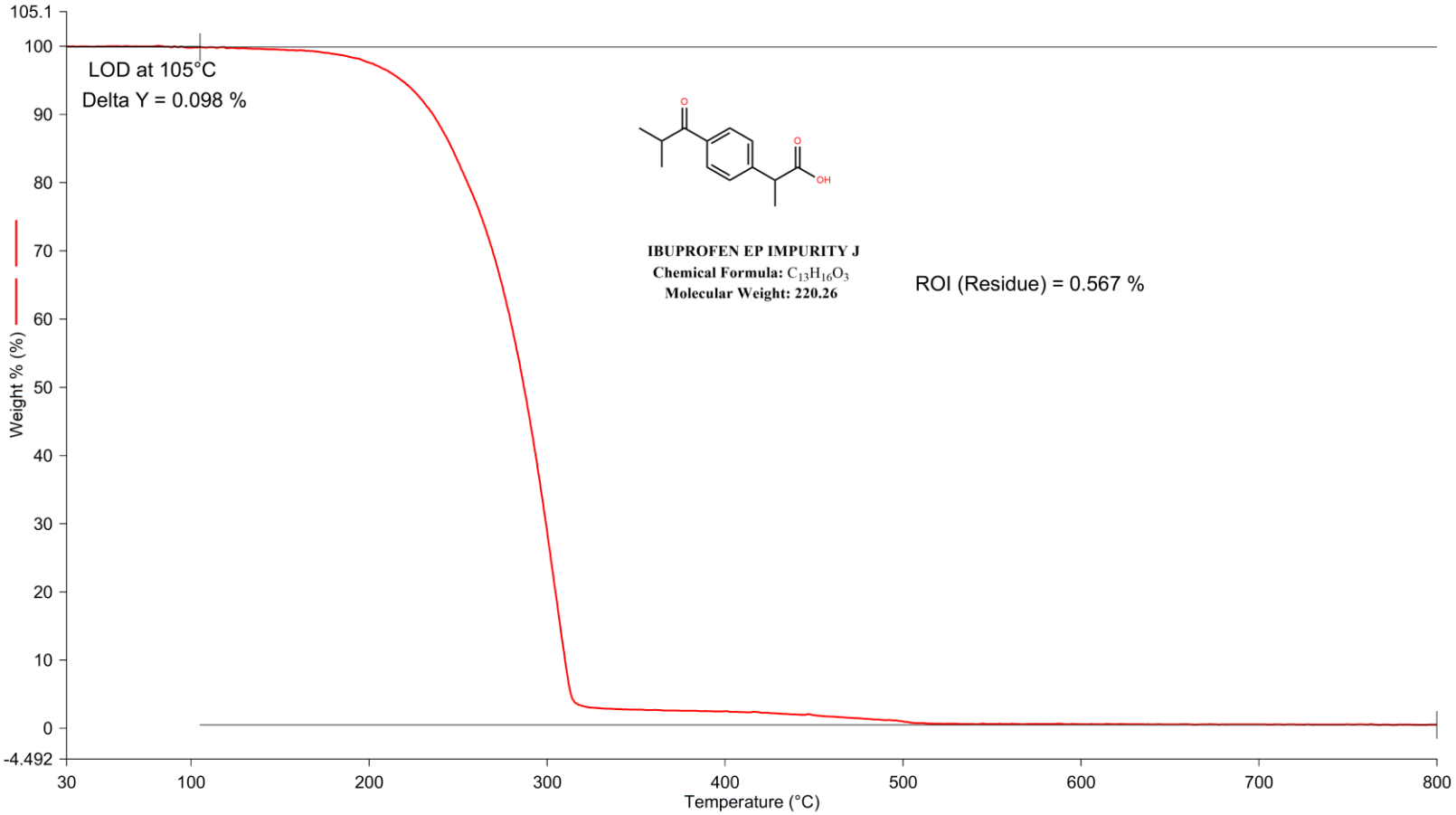
ii. % of Ash content observed:0.57%

The TGA thermogram is enclosed.

Prepared By: **Reviewed By:**

Filename:	D:\YEAR-2026\Mar-2026...\SL-PSK-375-004.t6d
Data Collected:	16-Mar-2026 23:55:13
Operator ID:	Sumanth
Sample ID:	SL-PSK-375-004
Sample Weight:	6.316 mg
Comment:	012419

Abani Labs Private Limited



16-Mar-2026 23:59:37

1) Heat from 30.00°C to 500.00°C at 20.00°C/min
2) Heat from 500.00°C to 800.00°C at 20.00°C/min
3) Hold for 1.0 min at 800.00°C

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= 99.60%
LOD by TGA: 0.10%
Ash content: 0.57%

Calculation:

= 99.60x (100-(0.10+0.57))/100

Defined Potency = **98.93 %** w/w

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