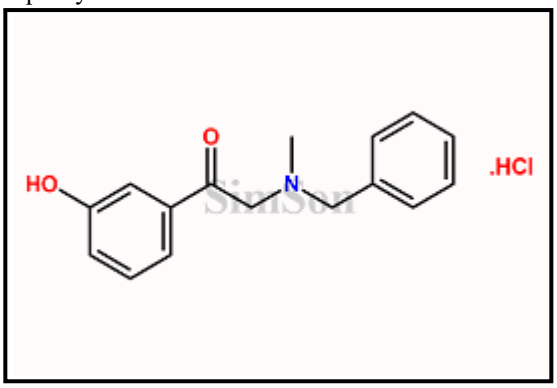
CERTIFICATE OF ANALYSIS

(Certificate No.: SPC230127 - 023 / V.01)

SimSon Pharma Limited
Reference Standards | Research Chemicals | Research Services

Analysis Date : 24/01/2023 **Re-test Date:** 23/01/2026

Product Name	:	PHENYLEPHRINE RELATED COMPOUND E (HYDROCHLORIDE SALT)
Chemical Name	:	2-(benzyl(methyl)amino)-1-(3-hydroxyphenyl)ethanone hydrochloride
Synonyms	:	Benzyl Phenylephrone Hydrochloride ;Phenylephrine EP Impurity E
CAT No.	:	P510002A
Batch Number	:	SL-RJS-269-026
CAS No.	:	71786-67-9
Molecular Formula	:	$C_{16}H_{18}ClNO_2$
Molecular Weight	:	291.77 g/mol; 255.31 g/mol (As base)
Storage Condition	:	Store at 2°C to 8°C (Inert atmosphere)
Shipping condition	:	Ambient



ANALYTICAL INFORMATION:

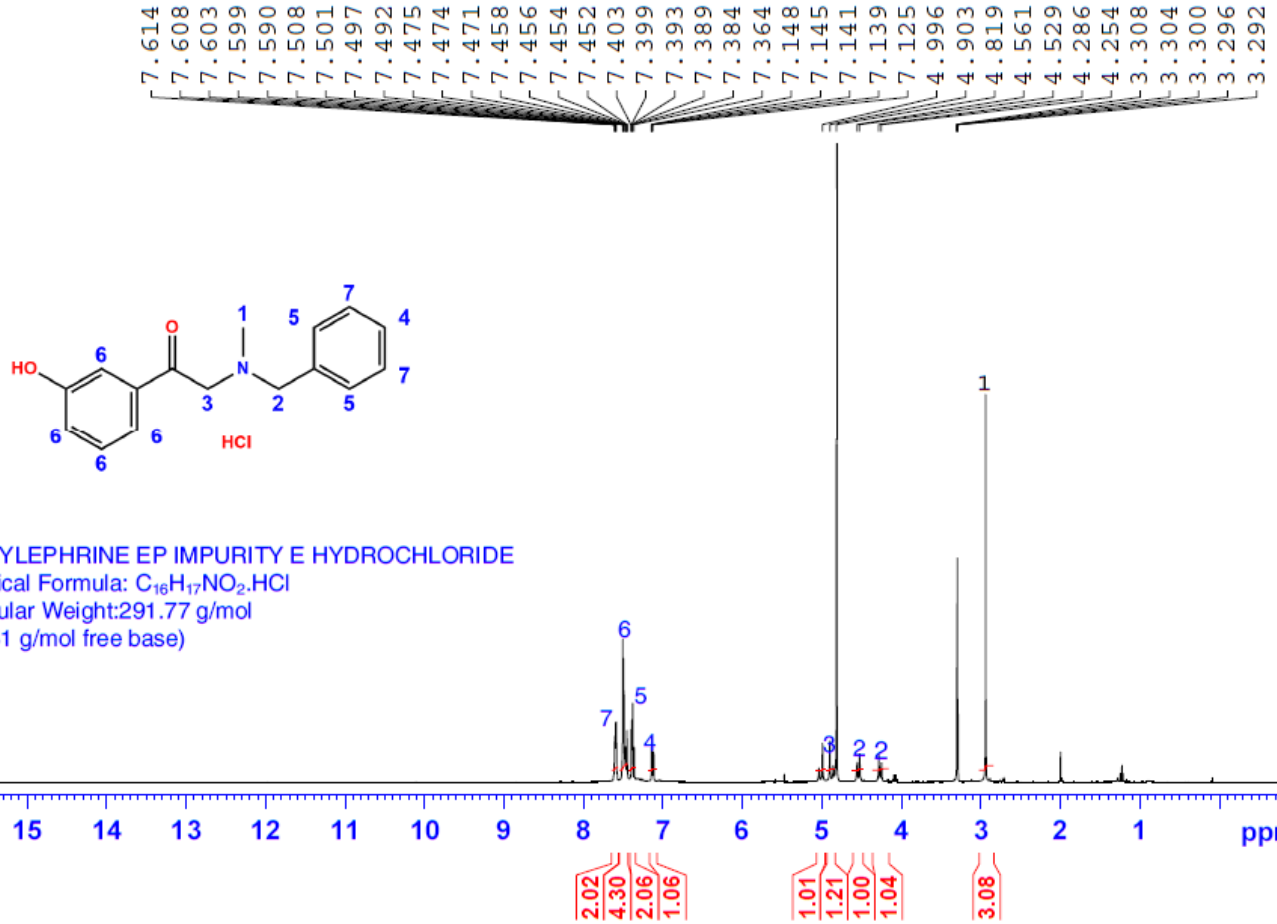
Sr No	TESTS	RESULTS
1	**DESCRIPTION**	Beige solid
2	**IDENTIFICATION** 1. 1H-NMR 2. MASS 3. IR	 Conforms to the structure Conforms to the structure Conforms to the structure
3	**CHROMATOGRAPHIC PURITY** (By HPLC, area Normalization)	94.07 %
4	**TGA** (weight Loss: 30° to 105°C) (30° to 450°, rate 20°C/min)	0.83 %w/w
5	**DEFINED POTENCY (By Mass Balance Method)** [(100-TGA) X HPLC Purity/100]	93.29 %w/w

Prepared By : **Mrunali Mohite**
(Sign & Date) **25/01/2023**

Approved By : **Nehal Sonavadia**
(Sign & Date) **25/01/2023**

Quality Accreditations: ISO 9001:2015, ISO 17034:2016, ISO/IEC 17025:2017, GLP Certified, DSIR (Series - SP & SC)
Not for Human or Animal Consumption. Only for Analytical Testing Purpose
Office : B-307, Sarita Building, Prabhat Indl. Estate. Nr. Dahisar Toll Naka, Dahisar (East), Mumbai - 400068.

SL-RJS-269-026
1H IN CD3OD



ID:SATL/EQ/197

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Current Data Parameters
NAME      19-CSL-07445-22-23-1H
EXPNO                1
PROCNO               1

F2 - Acquisition Parameters
Date_          20230119
Time              13.51 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG           zg30
TD               65536
SOLVENT           MeOD
NS                  16
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              300.9 K
D1             2.00000000 sec
TD0                  1
SFO1         400.3024719 MHz
NUC1                 1H
P0               2.67 usec
P1               8.00 usec
PLW1         18.79700089 W

F2 - Processing parameters
SI               65536
SF           400.3000117 MHz
WDW                 EM
SSB                  0
LB              0.30 Hz
GB                   0
PC                1.00
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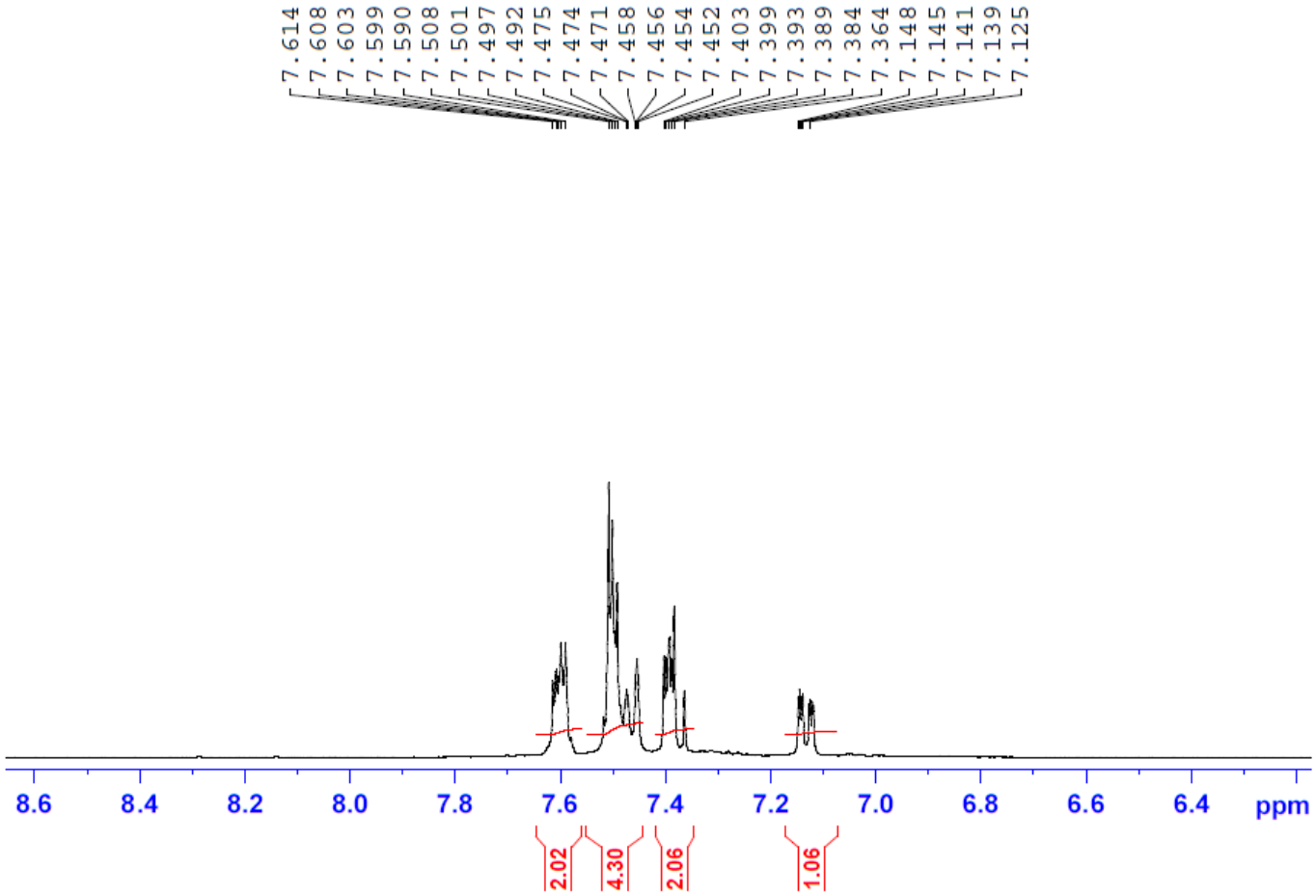
SL-RJS-269-026
1H IN CD3OD



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EXPNO                        1
PROCNO                       1

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Time                 13.51 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG                zg30
TD                    65536
SOLVENT                MeOD
NS                       16
DS                        2
SWH                8196.722 Hz
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AQ                3.9976959 sec
RG                      101
DW                 61.000 usec
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SFO1           400.3024719 MHz
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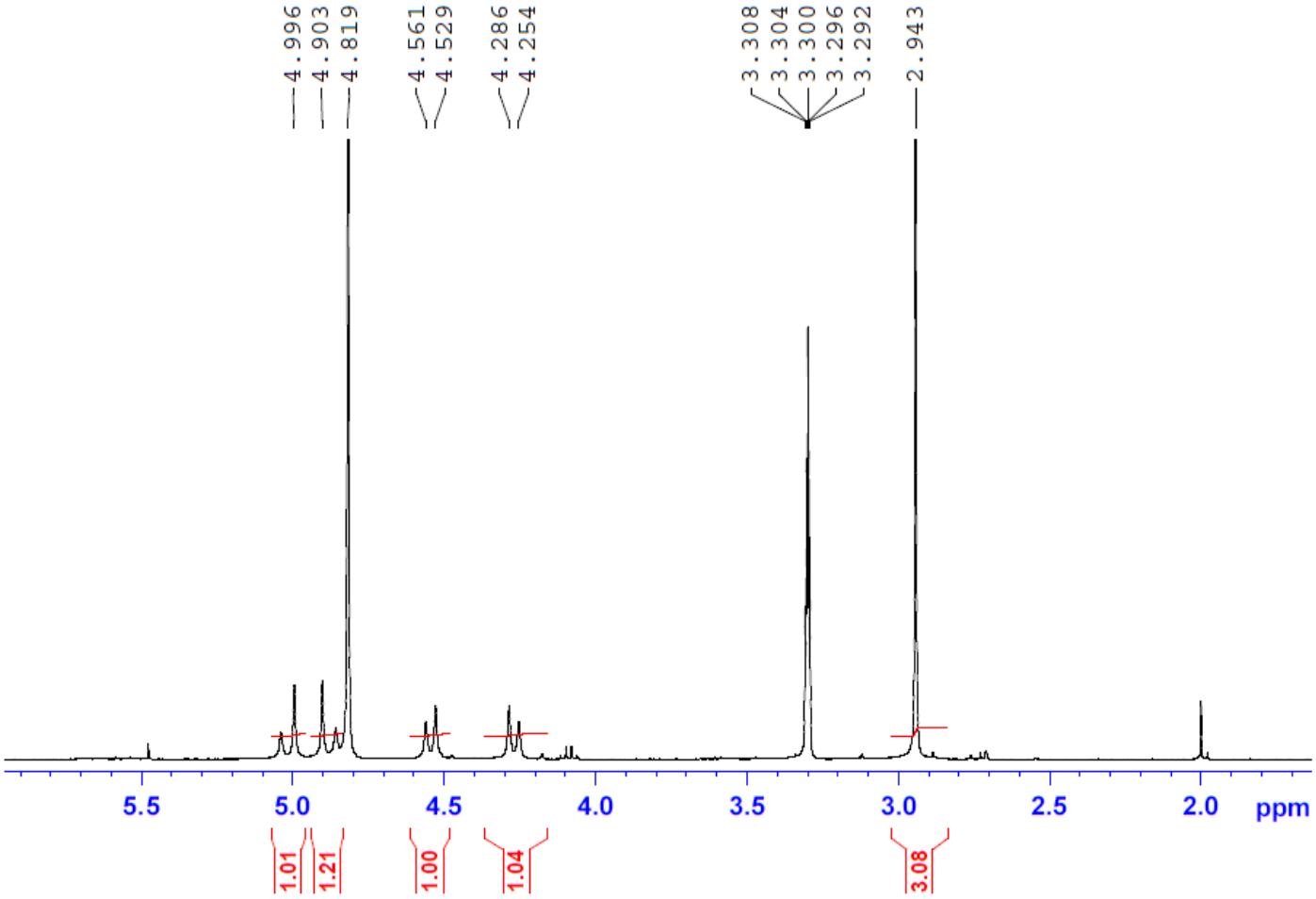
SF             400.3000117 MHz
WDW                      EM
SSB                       0
LB                 0.30 Hz
GB                        0
PC                     1.00
```

SL-RJS-269-026
1H IN CD3OD



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EXPNO                        1
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F2 - Acquisition Parameters
Date_              20230119
Time                 13.51 h
INSTRUM  Avance NEO Nanobay
PROBHD   Z163739_0338 (
PULPROG                 zg30
TD                     65536
SOLVENT                 MeOD
NS                        16
DS                         2
SWH                 8196.722 Hz
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AQ                3.9976959 sec
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DW                  61.000 usec
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TD0                        1
SFO1           400.3024719 MHz
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PLW1           18.79700089 W

F2 - Processing parameters
SI                     65536
SF             400.3000117 MHz
WDW                       EM
SSB                        0
LB                   0.30 Hz
GB                         0
PC                      1.00
```

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

S.No.	**Chemical Shift δ, ppm**	*Multiplicity*	*No. of protons*	*'J' coupling constant*	*Assignment of proton(s)*
1.	2.94	S	3H	-	3
2.	4.25- 4.56	D	2H	-	2
3.	4.90- 4.99	D	2H	-	2
4.	7.12- 7.14	M	1H	-	1
5.	7.36- 7.40	M	2H	-	2
6.	7.45- 7.50	M	4H	-	4
7.	7.59- 7.61	M	2H	-	2
Total No. of protons					16
Remark :-			Confirms to the structure		

Note: The assignments are based on chemical shifts and multiplicities

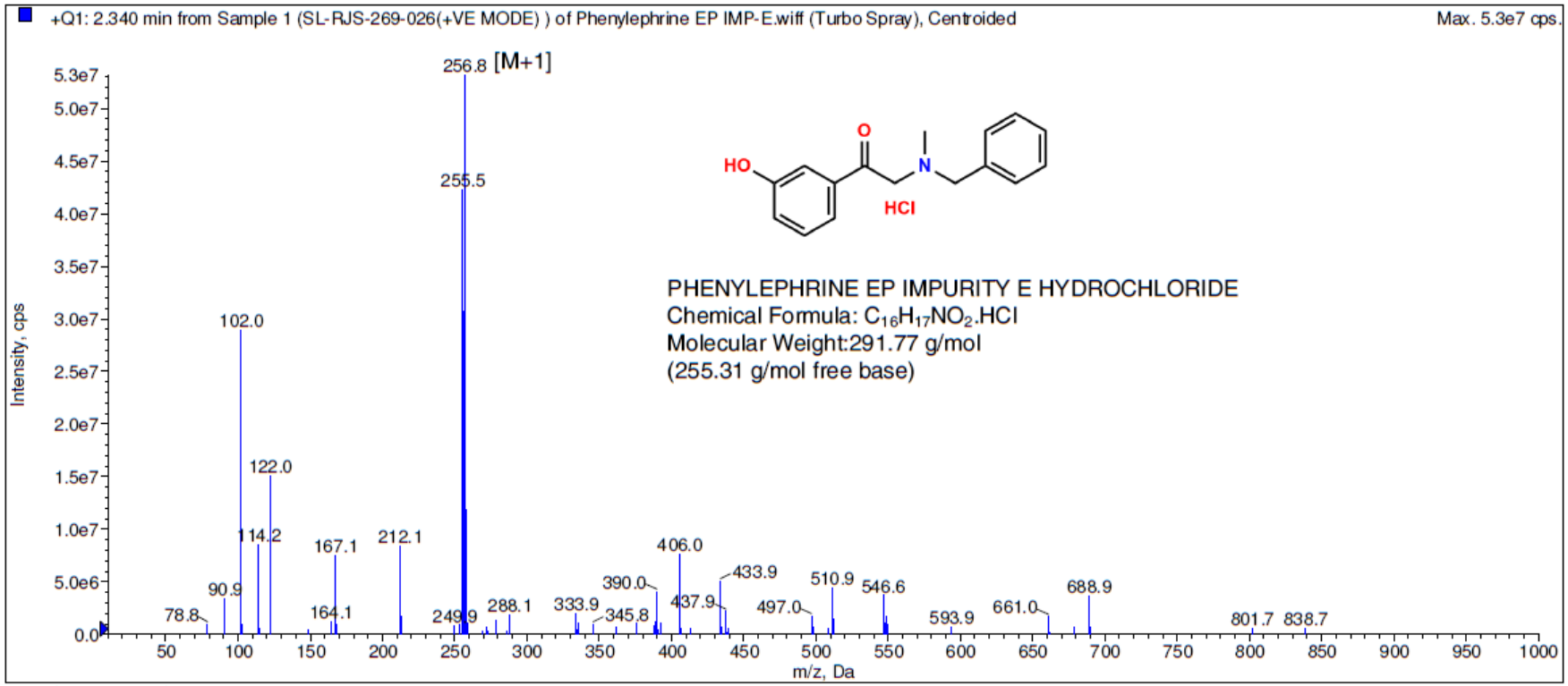
Batch Name: ManualTune.bat

Sample Comment: Solvent:-Methanol
Reg.No:CSL/07421/22-23

Acq. File: Phenylephrine EP IMP-E.wiff
Sample Name: SL-RJS-269-026(+VE MODE)
Acq. Date: Wednesday, January 18, 2023
Operator: Indu Kosuri
Acq. Time: 15:55

Sample ID: TuneSampleID

InstrumentID:SATL/EQ/178



Algorithm: IntelliQuan

*Analysed By:

*Checked By:

SS DATA: The mass spectroscopy studies were performed on API 2000 mass spectrometer triple quadrupole. The mass spectrum in positive mode displayed a protonated molecular ion at

M/Z 256.8 g/mol corresponding to $[M+H]^+$confirms the monoisotopic mass as m/z corresponding to the Molecular formula $C_{16}H_{17}NO_2$

Solvent: methanol.

S.No	Composition	Exact Mass	Molecular Weight	m/z value
1.	$C_{16}H_{17}NO_2$	255.13	255.31	256.8(+ve mode)

Instrument ID No:SATL/EQ/025

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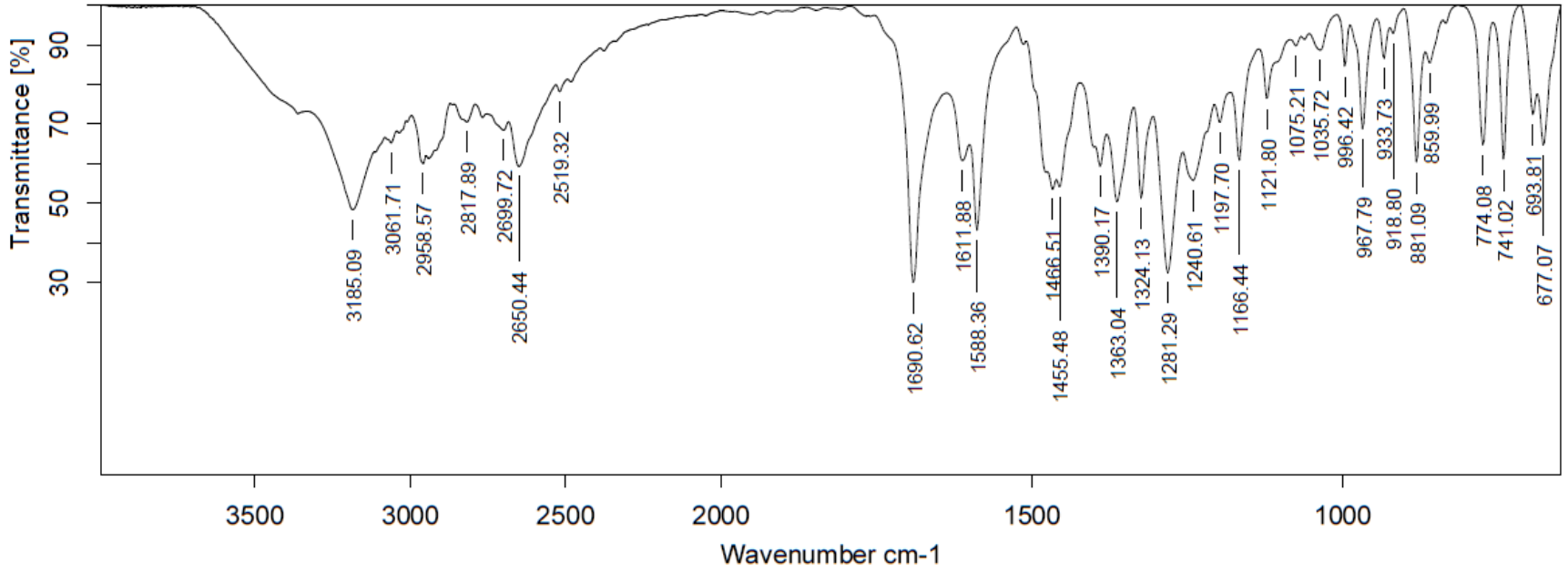


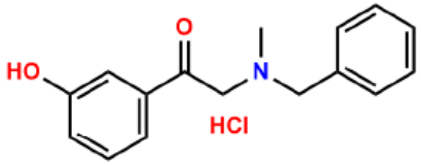
Path/File Name:D:\SATLEQ025_CSL\2023\CSLJAN2023\DATA/Phenylephrine EP impurity -E SL-RJS-269-026 Reg No- CSL-07445-22-23.0

Sample Name:Phenylephrine EP impurity -E

Lot No./Batch No:SL-RJS-269-026 Reg No- CSL-07445-22-23

Date & Time:19/01/2023,15:03:36

Operator Name:Shameena Dudekula



PHENYLEPHRINE EP IMPURITY E HYDROCHLORIDE
Chemical Formula: $C_{16}H_{17}NO_2.HCl$
Molecular Weight:291.77 g/mol
(255.31 g/mol free base)

Experiment:Trans.XPM

Resolution:4

Sample Scans:32

Frequency Range:4000 to 650

FTIR DATA: The FTIR spectrum was recorded in the solid-state KBr pellet using Bruker spectrophotometer. The IR data is tabulated below.

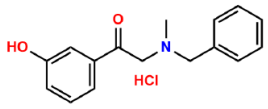
S.No	Type of bond	Specific type of bond	Absorption peak cm-1
1.	C=O	Stretching	1690.62
2.	C-N	Stretching	1281.29

HPLC REPORT:

SIMSON LIFE SCIENCES

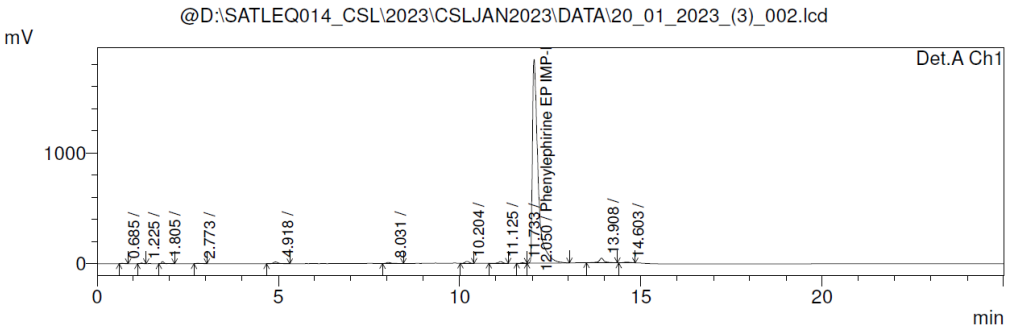
@D:\SATLEQ014_CSL\2023\CSLJAN2023\DATA\20_01_2023_(3)_002.lcd

Acquired by : Venkata Rao Jonnalagadda
Sample Name : PhenylephirineEP IMP-E
Sample ID : SL-RJS-269-026
Tray# : 2
Vail # : 41
Injection Volume : 10 uL
Data File Name : 20_01_2023_(3)_002.lcd
Method File Name : Phenylephirine_BP.lcm
Batch File Name : 20_01_2023_(3).lcb
Report File Name : Simsonlifesciences_Purity_Ch1 V-1.0.lcr
Data Acquired : 20/01/2023 19:02:27
Data Processed : 21/01/2023 09:30:53
Data Description : Reg No:-CSL/07445/22-23
Column ID:- (C18) 100*3.6.*3µ CLC0158
Method : BP
Flow : 1.5mL/min
Diluent : MP-A



PHENYLEPHRINE EP IMPURITY E HYDROCHLORIDE
Chemical Formula: $C_{16}H_{17}NO_2.HCl$
Molecular Weight:291.77 g/mol
(255.31 g/mol free base)

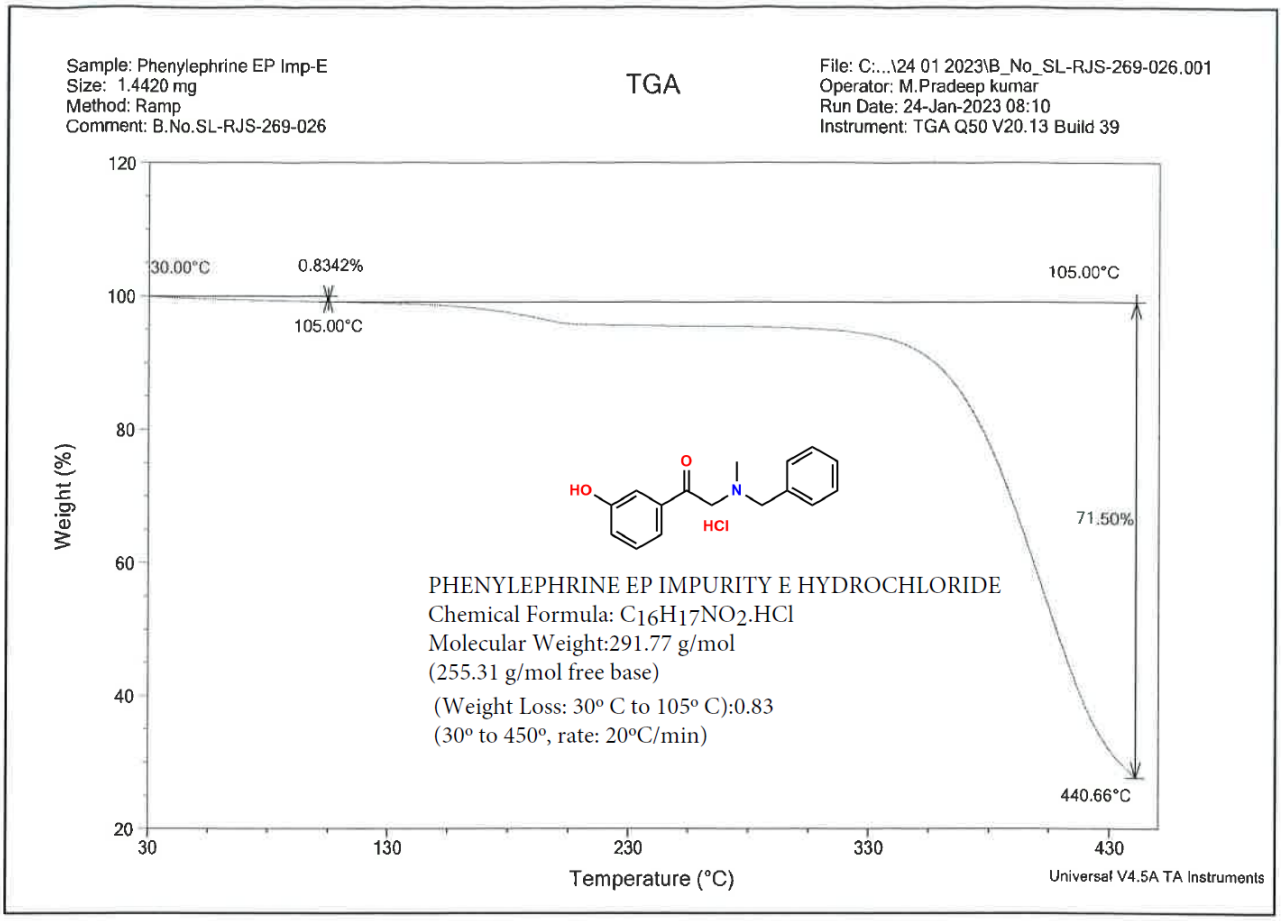
<Chromatogram>



1 Det.A Ch1/215nm

PeakTable @D:\SATLEQ014_CSL\2023\CSLJAN2023\DATA\20_01_2023_(3)_002.lcd
Detector A Ch1 215nm

Peak#	Name	Ret. Time	Area	Area %
1		0.685	32843	0.157
2		1.225	32371	0.154
3		1.805	110196	0.526
4		2.773	45682	0.218
5		4.918	151094	0.721
6		8.031	73449	0.350
7		10.204	132724	0.633
8		11.125	123739	0.590
9		11.733	29374	0.140
10	Phenylephirine EP IMP-E	12.050	19715721	94.069
11		13.908	430637	2.055
12		14.603	81030	0.387
Total			20958859	100.000



Method Log:

1: Ramp 20.00°C/min to 450.00°C

2: End of method

ANALYSED BY : 24/01/2023

CHECKED BY : 24/01/2023