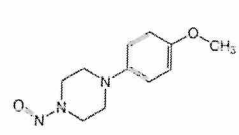
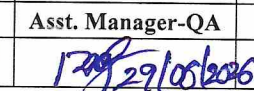
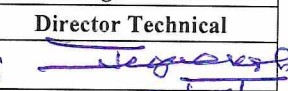




CERTIFICATE OF ANALYSIS

Name		N-Nitroso Itraconazole Impurity 1		
Chemical Name		1-(4-Methoxyphenyl)-4-nitrosopiperazine		
Molecular Formula		C ₁₁ H ₁₅ N ₃ O ₂		
Molecular Weight		221.26 g/mol		
Batch No.		SK-PS-26-3228		
CAS No.		75051-59-1	Retest / Lot01	
Analysis Date		Aug-2026	Retest DateJul-2028	
Next Retest date		NA		
S.No.	Test	Specification	Result	
1	Description	White to off-white solid	Off-white solid	
2	Solubility	Soluble in methanol and DMSO	Complies	
3	Identification by IR	Confirms to the structure	Confirms	
4	Identification by Mass	Confirms to the desired mass	Confirms	
5	Identification by ¹ HNMR	Confirms to the structure	Confirms	
6	Purity by HPLC	Not less than 90.0%	98.1%	
7	Weight loss by TGA	Not more than 2.0%	0.702%	
8	Potency(Purity by HPLC-TGA)	Not less than 90.0%	97.4%	
9	Long term storage condition	Preserve in tight, light resistant containers, and store at 2 to 8°C.		
10	Handling & Transit Condition	Controlled room temperature.		
Remarks: The material complies with the above specifications.				
Revision History				
Revision No. 00 (New document)			Released on 29 Aug 2026	

	Prepared by	Reviewed by (AD/CRD/QA)			Approved by(QA)
Name	V. Tejeswara Rao	B. Ram Mohan	Dr. Meenakshi Sharma	J. Raghu	Dr. K. Jagadeswara Rao
Designation	Sr. Executive -AD	Deputy Manager-AD	General Manager-CRD	Asst. Manager-QA	Director Technical
Sign and Date	 29/08/2026	 29/08/2026	 29/08/2026	 29/08/2026	 29/08/2026

QA-018-F004-00

Page No.: 1 of 1

Annexure - I (IR)

Laboratory Note Book

 SKPHARMA

Name of the Product :- N-Nitroso Phaconazole impurity-1
 Batch No :- SK-PS-26-3228
 A.R NO :- SK-AR-26-555
 Test :- FTIR.
 Instrument used :- SKP-INS-FTIR-005

Sample Preparation:-

weighed 2-3 mg of sample approximately
 in to the FTIR Pan and scanned at 4000-600 cm^{-1}

Result:- Complies
 (Refer the attached FTIR spectrum)

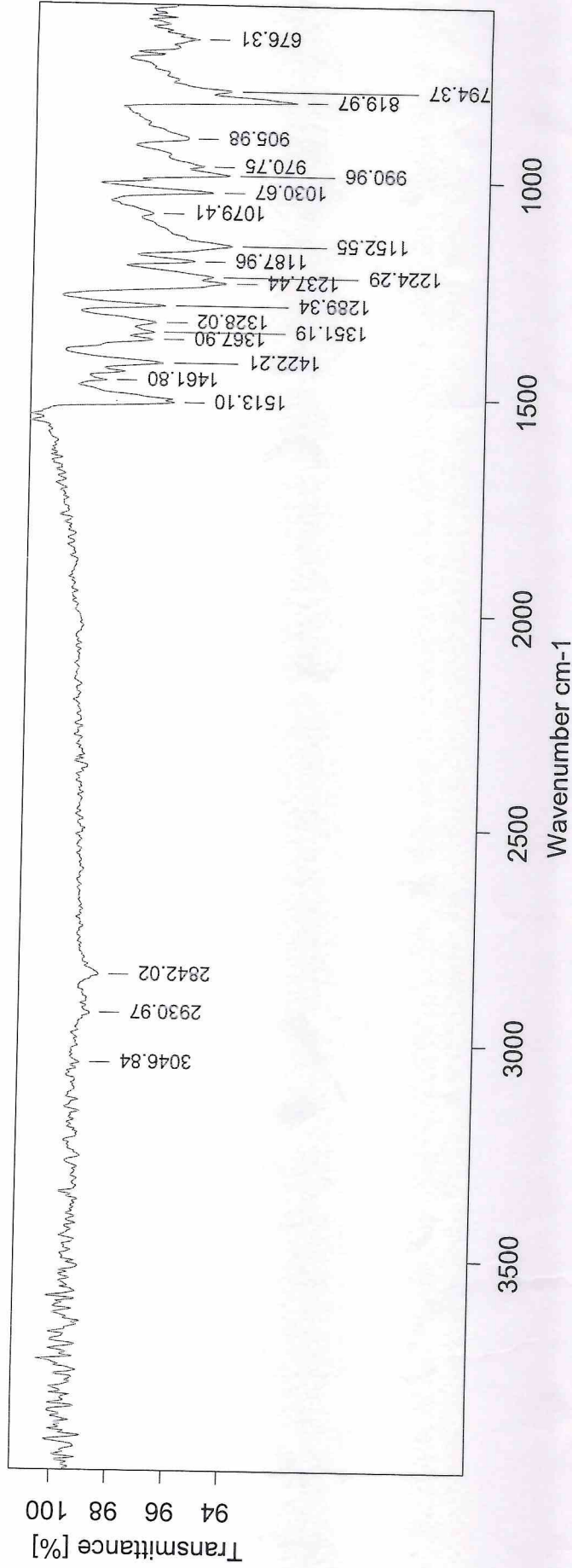
Description :- off white solid
 solubility :- soluble in methanol.



Analyzed by (Sign and date)	Reviewed by (Sign and date)
 27/08/2026.	 27/08/2026.

Instrument ID No: SKP-INS-IR-005

SK PharmaTech Solutions Pvt Ltd



Path/File Name: C:\Users\pcl\Documents\Bruker\OPUS_8.7.4\DATA\MEAS\N-Nitroso itraconazole impurity-1.0

Sample Name: N-Nitroso itraconazole impurity-1

Lot No./Batch No: SK-PS-26-3228

Date & Time: 27-08-2026, 09:48:16

Operator Name: lab lab

Experiment: ATR_ZNSE.XPM

Resolution: 4

Sample Scans: 24

Frequency Range: 4000 to 600



Page No. :- 2 of 4.

Analysed by:
Date: 27/08/2026

Page 1 of 1
Printed on: 27-08-2026 09:57:58

Checked by:
Date: 27/08/2026

Annexure -I (IR)

"C:\Users\pc\Documents\Bruker\OPUS_8.7.41\DATA\MEAS\N-Nitroso itraconazole impurity-1.0"

Peak Table TR

Peak Picking

Peak Picking

Method: Standard

Searched for minima: Yes

Number of peaks: 30

Sensitivity > [%]: 0.000000

From: 3115.618109

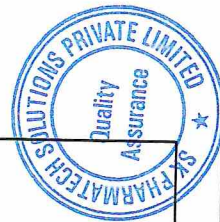
to: 607.249434

Absolute peak height > 0.000000

Relative peak height < [%] 0.000000

Absolute peak height < 0.000000

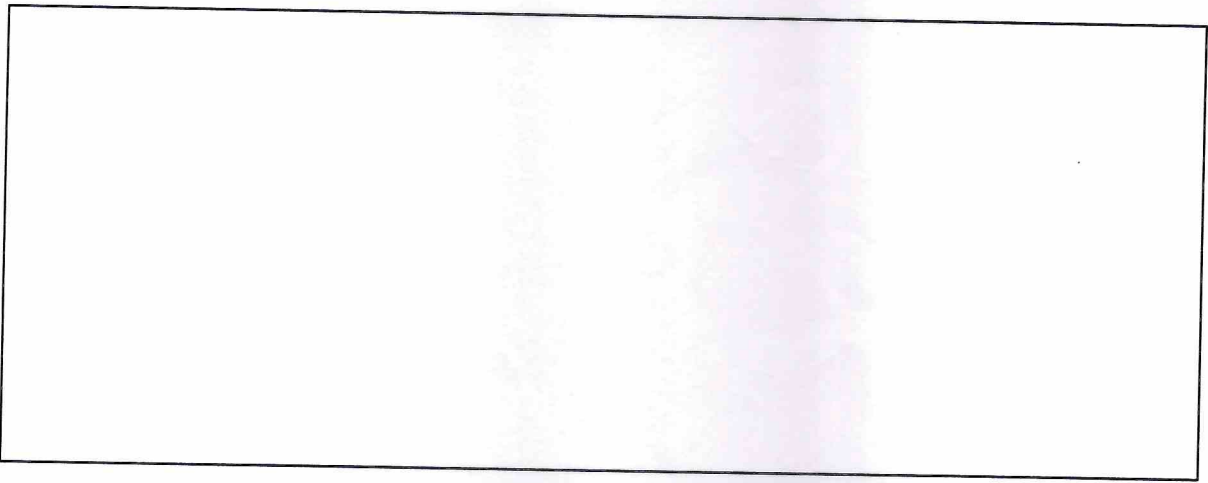
Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold < Shoulder
2842.0217	0.986	0.023	1238.9313	268.730255
3046.8407	0.992	0.004	9.6595	76.911385
1422.2140	0.967	0.034	17.7283	88.358467
1367.8978	0.970	0.014	310.6476	24.394630
1351.1925	0.970	0.013	378.2320	20.469051
1328.0232	0.970	0.029	61.4415	62.277885
1289.3420	0.966	0.037	14.3551	60.620396
1237.4414	0.945	0.040	41.6654	62.039249
1187.9636	0.956	0.023	13.2896	41.277180
1152.5522	0.943	0.054	71.2602	126.663162
1079.4091	0.972	0.007	1449.6866	8.981794
1030.6748	0.950	0.039	14.5689	80.296822
1030.6748	0.950	0.039	14.5689	80.296822
990.9597	0.944	0.046	62.1920	84.590958
970.7494	0.954	0.007	7.6308	12.718536
970.7494	0.954	0.007	7.6308	12.718536
905.9752	0.960	0.020	29.7167	65.273750
905.9752	0.960	0.020	29.7167	65.273750
819.9654	0.921	0.064	37.3896	96.595047
819.9654	0.921	0.064	37.3896	96.595047
794.3743	0.944	0.009	34.7487	10.395816



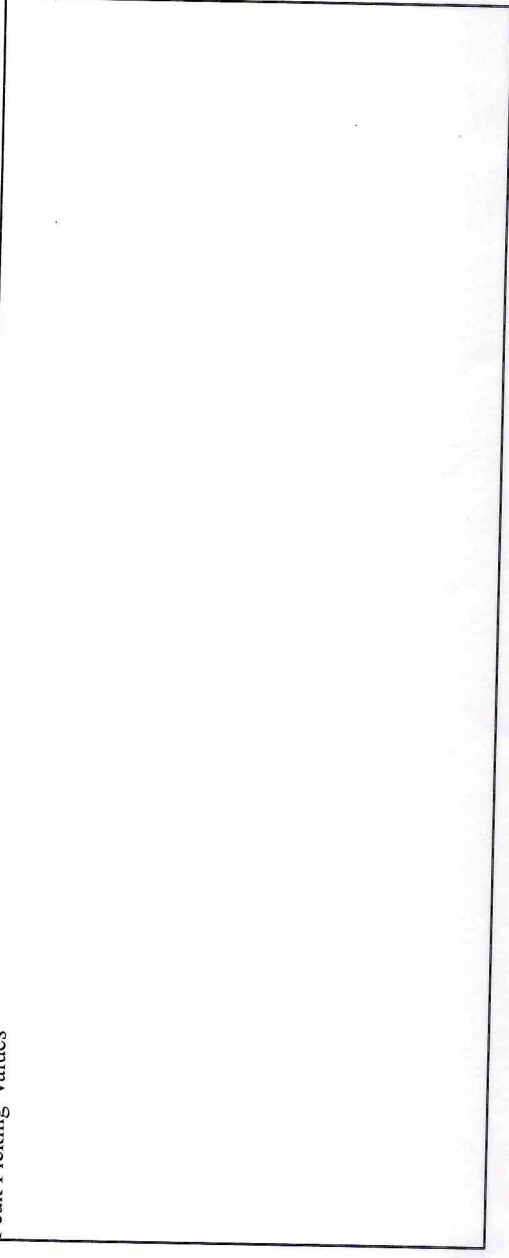
C:\Users\pc\Documents\Bruker\OPUS_8.7.41\DATA\MEAS\N-Nitroso itraconazole impurity-1.0 N-Nitroso itraconazole

27/08/2026

27/08/2026



Peak Picking Values

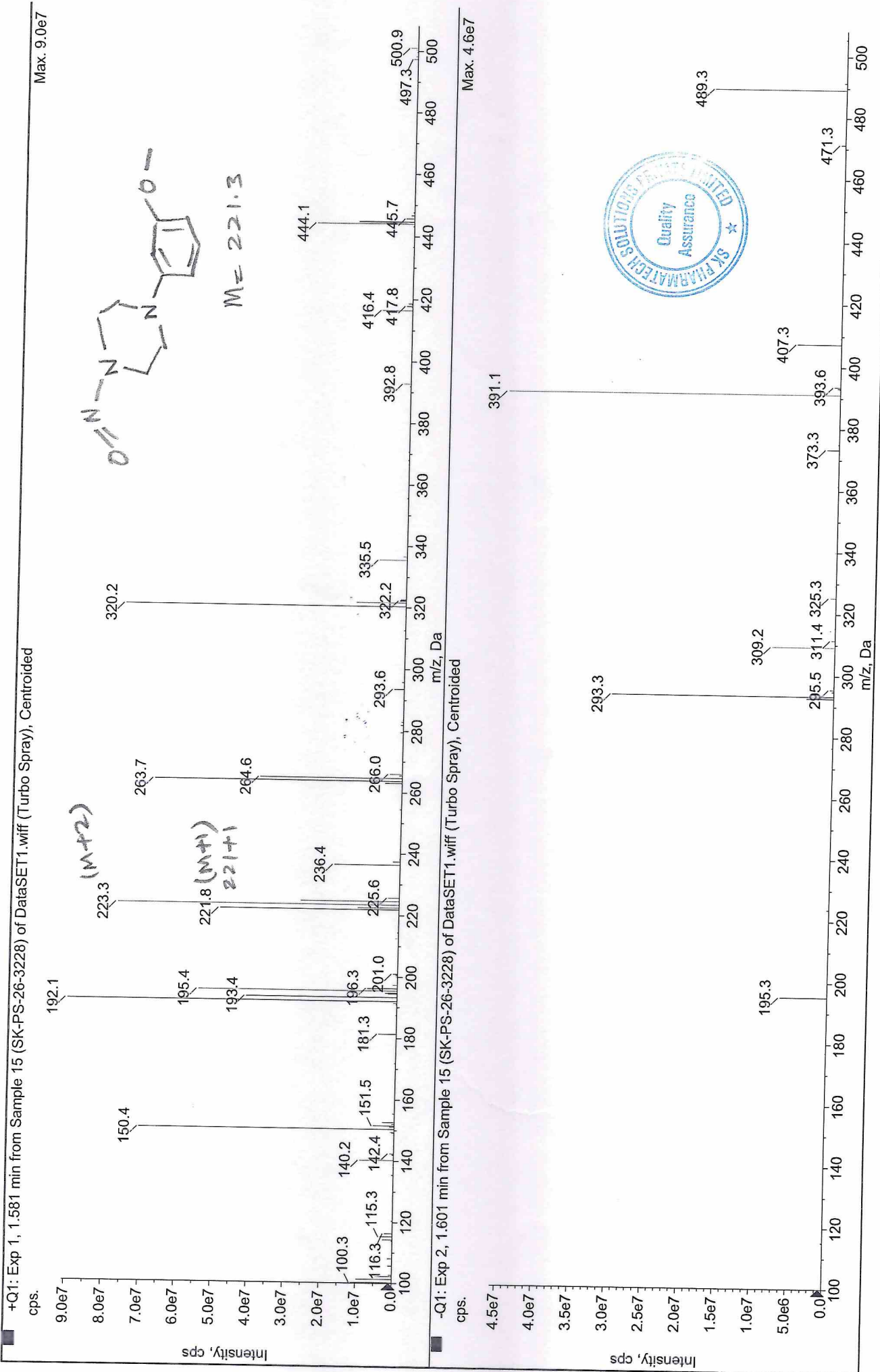


Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold < Shoulder
794.3743	0.944	0.009	34.7487	10.395816
676.3134	0.956	0.022	45.5799	77.989868
676.3134	0.956	0.022	45.5799	77.989868
1513.0972	0.963	0.050	33.7020	79.560066
1513.0972	0.963	0.050	33.7020	79.560066
1461.7954	0.987	0.008	11.7768	13.585682
1461.7954	0.987	0.008	11.7768	13.585682
1224.2904	0.949	0.009	33.2535	7.272636
2930.9675	0.989	0.005	18.1325	66.914864

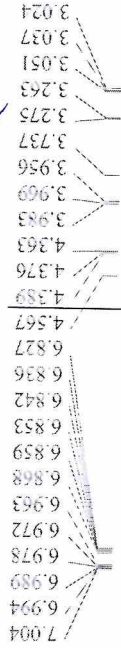


21/08/2016

21/08/2016

Printing Date: Wednesday, August 26,
2026 Acq. Time: 15:29

Annexure - III (HNMR)



```

---- PROCESSING PARAMETERS ----
sexp( 0.27483[Hz], 0.0[s] )
trapezoid( 0[%], 0[%], 80[%], 100[%] )
zerofill( 2, TRUE )
fft( 1, TRUE, TRUE )
machinephase
ppm
auto_reference( 5[%], TRUE )
reference( 3.20975[ppm], 3.3[ppm] )
thresh( 0.23816[%], 1 )

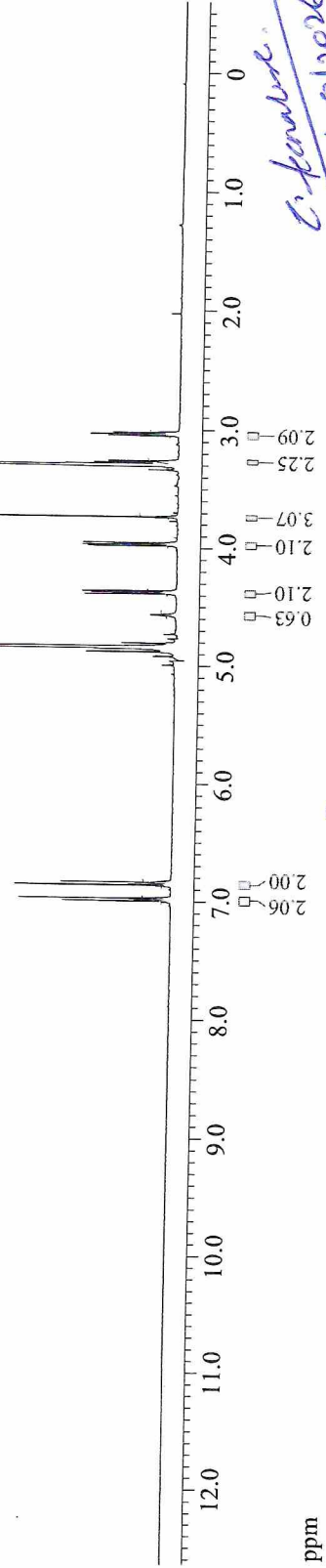
```

Derived from: SK-PS-26-3228_Proton-1-1.jdf

```

Creation Time      = 27-AUG-2026 16:32:42
Instrument         = NMR-400MHz (JEOL)
Spectrometer      = NM-70010S4L1
Instrument id     = ABNL/QC/NMR-01
Author           = 1059
Reviewed by      = RMG
Solvent          = METHANOL-D4
Acquisition Parameters
Experiment       = proton.jxp
X_Offset        = 7[ppm]
X_Sweep         = 9.00576369[kHz]
Relaxation_Delay = 2[s]
Scans           = 16

```



Confirmed
27/08/2026

Annexure - III (1H NMR)

7.004
6.994
6.989
6.978
6.972
6.963

6.868
6.859
6.853
6.842
6.836
6.827

```

----- PROCESSING PARAMETERS -----
sexp( 0.27483[Hz], 0.0[s] )
trapezoid( 0[%], 0[%], 80[%], 100[%] )
zerofill( 2, TRUE )
fft( 1, TRUE, TRUE )
machinephase
ppm
auto_reference( 5[%], TRUE )
reference( 3.20975[ppm], 3.3[ppm] )
thresh( 0.23816[%], 1 )

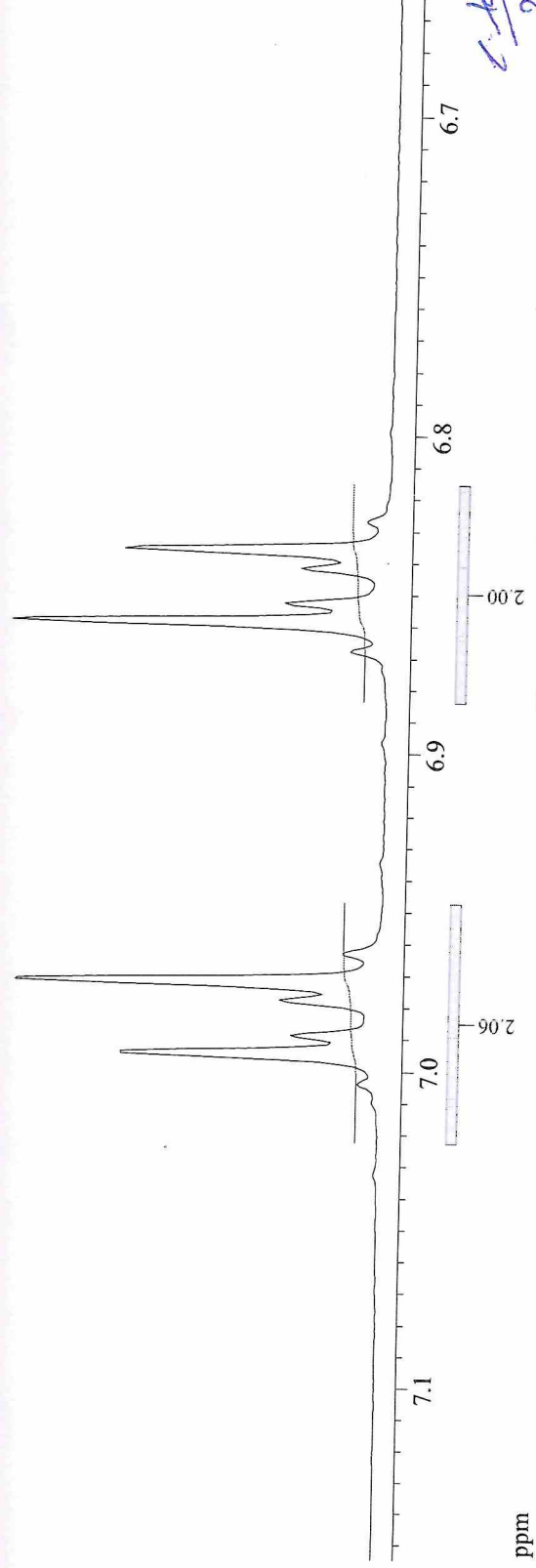
```

Derived from: SK-PS-26-3228_Proton-1-1.jdf

```

Creation Time      = 27-AUG-2026 16:32:42
Instrument         = NMR-400MHz (JEOL)
Spectrometer      = NM-70010S4L1
Instrument id      = ABNL/QC/NMR-01
Author            = 1059
Reviewed by       = RMG
Solvent           = METHANOL-D4
Acquisition Parameters
Experiment        = proton.jxp
X_Offset          = 7[ppm]
X_Sweep           = 9.00576369[kHz]
Relaxation_Delay  = 2[s]
Scans             = 16

```



ppm



L. K. Kulkarni
27/08/2026

Annexure -III (1H NMR)

SK-PS-26-3228_Proton-1-2.jdf
037601

4.567
4.389
4.376
4.363

3.983
3.969
3.956

3.737

3.275
3.263

3.051
3.037
3.024

```

---- PROCESSING PARAMETERS ----
sexp( 0.27483[Hz], 0.0[s] )
trapezoid( 0[%], 0[%], 80[%], 100[%] )
zerofill( 2, TRUE )
fft( 1, TRUE, TRUE )
machinephase
ppm
auto_reference( 5[%], TRUE )
reference( 3.20975[ppm], 3.3[ppm] )
thresh( 0.23816[%], 1 )

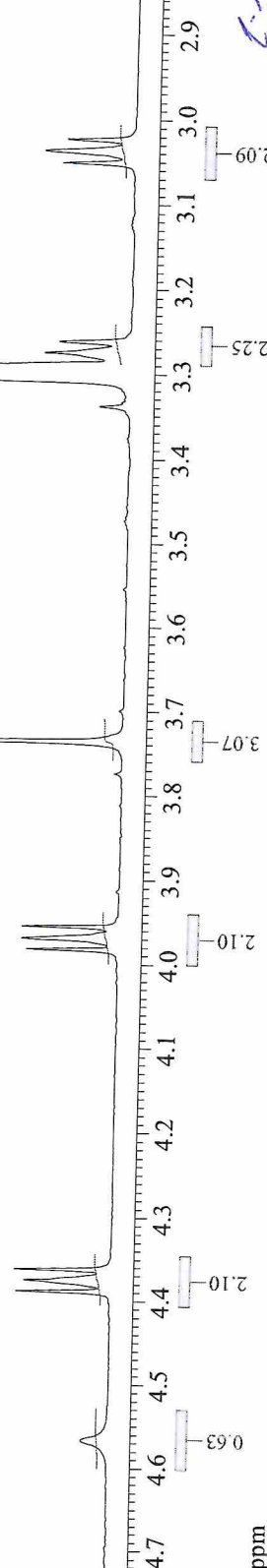
```

Derived from: SK-PS-26-3228_Proton-1-1.jdf

```

Creation Time      = 27-AUG-2026 16:32:42
Instrument         = NMR-400MHz (JEOL)
Spectrometer      = NM-70010S4L1
Instrument id     = ABNL/QC/NMR-01
Author           = 1059
Reviewed by      = RMG
Solvent          = METHANOL-D4
Acquisition Parameters
Experiment       = proton.jxp
X_Offset        = 7[ppm]
X_Sweep         = 9.00576369[kHz]
Relaxation_Delay = 2[s]
Scans           = 16

```



C. Anand
27/08/2026

Annexure -III- ('HNMR)

J-Coupling Analysis Report

Path = \\ABNL-01\Share folder\NMR Raw Data\Aug-2026\27-Aug-2026\SK-PS-26-3228_Proton-1-2.jdf

Position	Integral	Pattern	J	
6.98 [ppm]	2	td	J1 = 6.321 [Hz],	J2 = 4.031 [Hz]
6.85 [ppm]	2	td	J1 = 6.390 [Hz],	J2 = 3.939 [Hz]
4.57 [ppm]	1	s		
4.38 [ppm]	2	t	J1 = 5.222 [Hz]	
3.97 [ppm]	2	t	J1 = 5.359 [Hz]	
3.74 [ppm]	3	s		
3.27 [ppm]	2	d	J1 = 4.947 [Hz]	
3.04 [ppm]	2	t	J1 = 5.497 [Hz]	



C. K. Kulkarni
27/08/2026

Product name :- N-nitroso itraconazole Impurity - I

Batch no :- SK-PS-26-3228

A.R NO :- SK-AR-26-555

Test :- TGA.

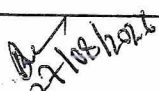
Instrument used :- SKP-INS-TGA-026.

weighed 1.255 mg of sample into a ceramic Pan and heated at the temperature 350° at the rate of $15^{\circ}\text{C}/\text{min}$

Result = $\Delta Y = 0.702\%$

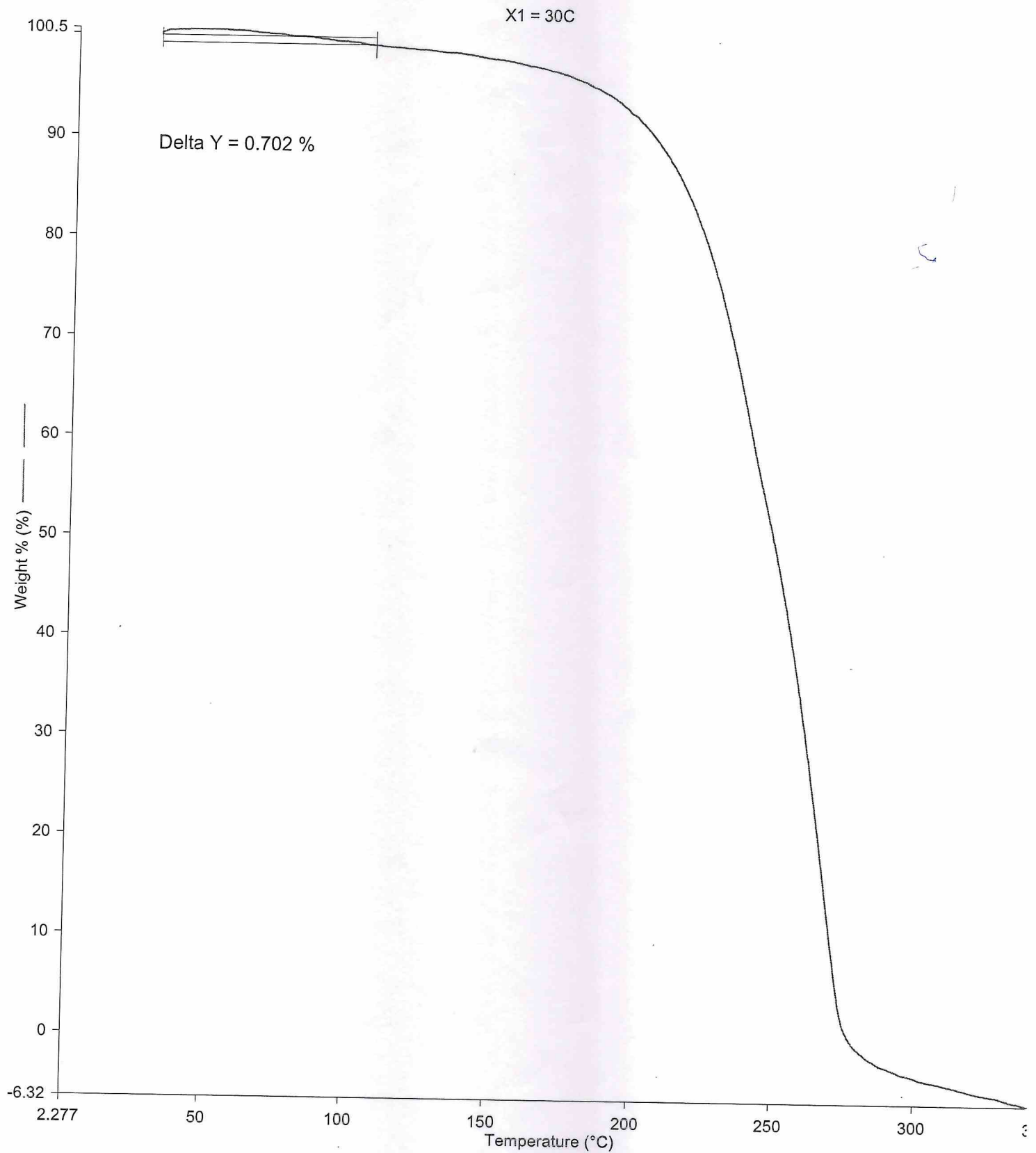
(Refer attached the TGA Report)



Analyzed by (Sign and date)	Reviewed by (Sign and date)
 27/08/2026	 27/08/2026

Annexure - IV (TGA)

Filename: C:\Program Files (x86)\P...\27082026_01.t6d
Operator ID: lalitha
Sample ID: SK-PS-26-3228
Sample Weight: 1.255 mg
Comment: N-Nitroso itraconazole impurity-1



1) Heat from 30.00°C to 350.00°C at 15.00°C/min

27-08-2026 11:50:12

MS
27/08/2026

Page No. 2 of 2.



Re
27/08/2026

SAMPLE INFORMATION

Sample Name:	BLANK	Acquired By:	M.siva
Sample Type:	Unknown	Sample Set Name:	27082026 HPLC 40
Vial:	1	Acq. Method Set:	HPLC 24_MIN
Injection #:	1	Processing Method:	LC PQ
Injection Volume:	100.00 ul	Channel Name:	260.0nm
Run Time:	24.0 Minutes	Proc. Chnl. Descr.:	2998 PDA 260.0 nm (2998
Date Acquired:	08-27-2026 16:38:47 PM IST		
Date Processed:	08-27-2026 19:39:15 PM IST		

METHOD INFORMATION:

BUFFER:

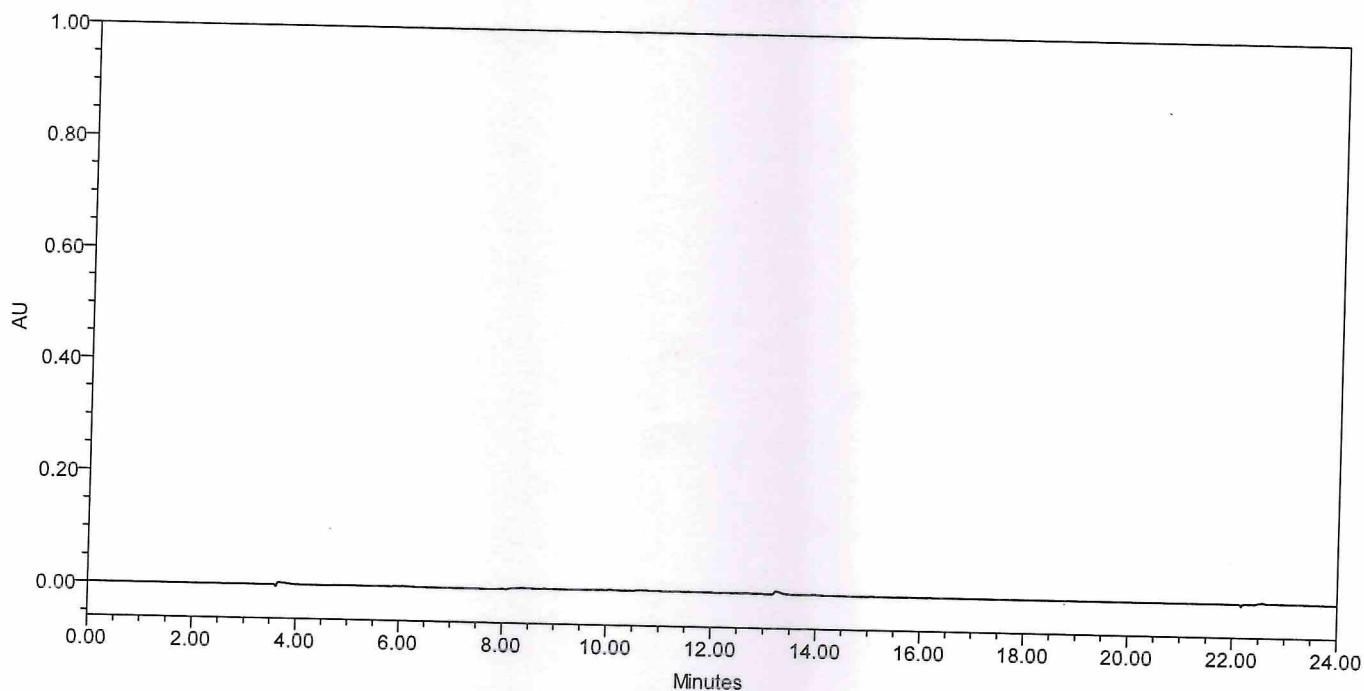
MP A 0.1% TFA IN 1000ML WATER

MP B: ACN:WATER(90:10)V/V

COLUMN: LUNA C18 (250MM*4.6*5um)

GRADIENT PRO: 0/10, 3/10, 10/100, 19/100, 19.5/10, 24/10

FLOW: 1.0ML/MIN



1

Reported by User: M.Siva
Report Method: HPLC 40 REPORT
Report Method ID: 4640
Page: 1 of 1

Project Name: AUGUST-2026

Date Printed:

08-27-2026

19:52:10 Asia/Kolkata



Page No:- 1 of 2

22/08/2026

MS
22/08/2026

SAMPLE INFORMATION

Sample Name: SK-PS-26-3228
 Sample Type: Unknown
 Vial: 2
 Injection #: 1
 Injection Volume: 4.00 ul
 Run Time: 24.0 Minutes

Acquired By: M.siva
 Sample Set Name: 27082026 HPLC 40
 Acq. Method Set: HPLC 24_MIN
 Processing Method: LC PQ
 Channel Name: 260.0nm
 Proc. Chnl. Descr.: 2998 PDA 260.0 nm (2998)

Date Acquired: 08-27-2026 18:42:57 PM
 IST Date Processed: 08-27-2026 19:38:50 PM
 IST

METHOD INFORMATION:

BUFFER:

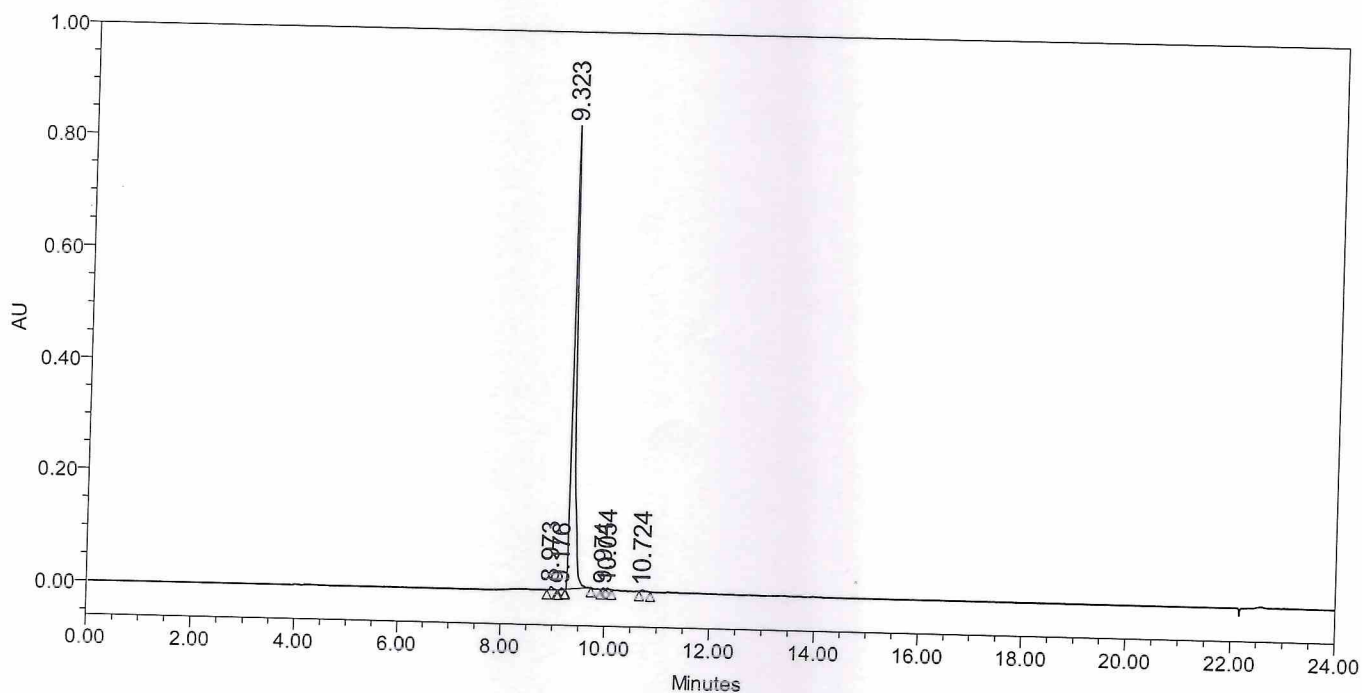
MP A 0.1% TFA IN 1000ML WATER

MP B: ACN:WATER(90:10)V/V

COLUMN: LUNA C18 (250MM*4.6*5um)

GRADIENT PRO: 0/10, 3/10, 10/100, 19/100, 19.5/10, 24/10

FLOW: 1.0ML/MIN



	RT	Area	% Area
1	8.973	22988	0.60
2	9.176	9783	0.25
3	9.323	3772564	98.30

	RT	Area	% Area
4	9.974	9105	0.24
5	10.054	9815	0.26
6	10.724	13638	0.36

Reported by User: M.siva

Report Method: HPLC 40 REPORT

Report Method ID: 4640

Page: 1 of 1

Project Name: AUGUST-2026

Date Printed:

08-27-2026

19:51:50 Asia/Kolkata

M.siva
22/08/2026

Page: 2 of 2



M.siva
22/08/2026