



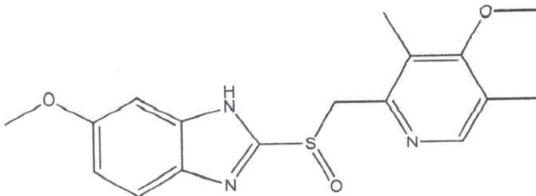
Certification & Accreditation
ISO 9001-2015 & 17034-2016



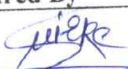
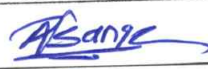
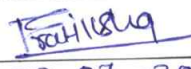
Ministry of MSME, Govt. of India

CERTIFICATE OF ANALYSIS

Date: 22-07-2025

Product Name	Omeprazole Inhouse Standard		
Chemical Name	6-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole		
Structure			
Batch No.	CL-002-OPS-IWS-15	CAS No.	73590-58-6
Analysis Date:	May-2025	Retest Date:	April-2027
Mol. Formula	C ₁₇ H ₁₉ N ₃ O ₃ S	Molecular Wt.	345.42
Long term Storage Condition	Store at 2-8 °C in a well closed container.		
Handling and Transit condition	25-30 °C in well closed container		

Test	Result
Appearance	Off white to cream solid
Solubility	DMSO, Methanol
¹ H NMR	Conforms to structure
MASS	Conforms to structure
LOD	0.17 %
ROI	0.03 %
Chromatographic purity	98.02 %
Potency	97.82 %
Potency = % Chromatographic purity - % LOD - % ROI = 99.02 % - 0.17 % - 0.03 % = 97.82 %	
Note: This material should be used as Analytical standard not for human or animal consumption. Any patent applicable for this product in any country is not applicable for this analytical standard/research chemical	

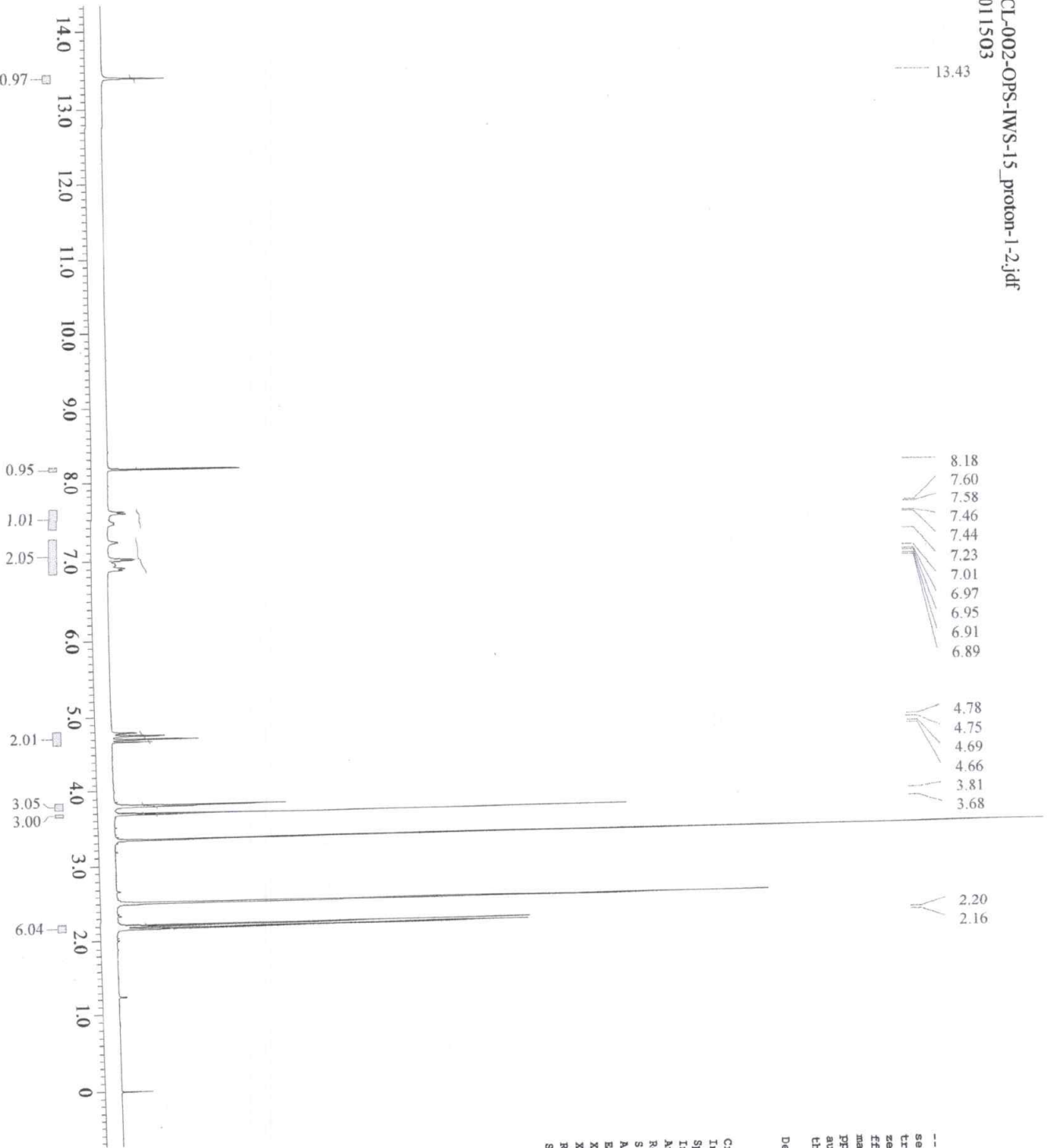
	Prepared By	Checked By	Approved by
Signature			
Date	22-07-2025	22-07-2025	22-07-2025



CLEANCHEM LABORATORIES LLP

Plot No. A-737/2, TTC Industrial Area, MIDC Khairane, Navi Mumbai, Maharashtra, INDIA- 400710

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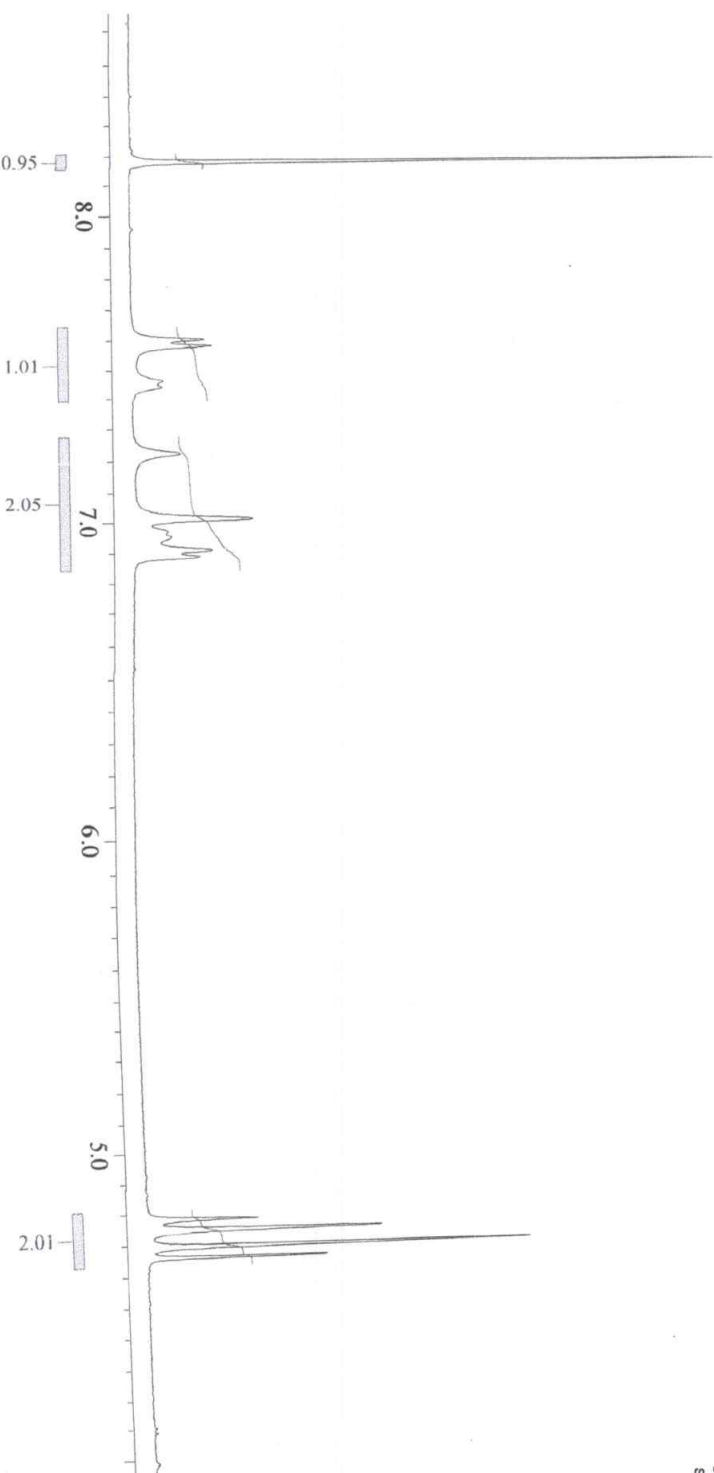
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 trapezoid (0 [%], 0 [%], 80 [%], 100 [%])
 zerofill (2, TRUE)
 fft (1, TRUE, TRUE)
 machphase
 ppm
 auto_reference (5 [%], TRUE)
 thresh (0.0697 [%], 1)
 Derived from: CL-002-OPS-IWS-15_proton-1-1.jd

Creation_Time = 16-APR-2024 15:28:57
 Instrument = NMR-400MHz (JEOL)
 Spectrometer = NMR-7001054L1
 Instrument_id = AENI/QC/NMR-01
 Author = 1039
 Reviewed by = NAK
 Solvent = DMSO-D6
 Acquisition Parameters
 Experiment = proton.jxp
 X_Offset = 7 [ppm]
 X_Sweep = 9.00576369 [kHz]
 Relaxation_Delay = 3 [s]
 Scans = 16



8.18
7.60
7.58
7.46
7.44
7.23
7.01
6.97
6.95
6.91
6.89

4.78
4.75
4.69
4.66



Abanl

```

----- PROCESSING PARAMETERS -----
sexp( 0.27483[Hz], 0.0[s] )
trapezoid( 0[%], 0[%], 80[%], 100[%] )
zerofill( 2, TRUE )
fft( 1, TRUE, TRUE )
machinphase
ppm
auto_reference( 5[%], TRUE )
thresh( 0.06097[%], 1 )
Derived from: CL-002-OPS-IWS-15_proton-1-1.jd

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Author             = 1030
Reviewed_by        = MAF
Solvent            = DMSO-D6
Acquisition_Parameters
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X_Sweep             = 9.00576369[kHz]
Relaxation_Delay    = 3[s]
Scans               = 16

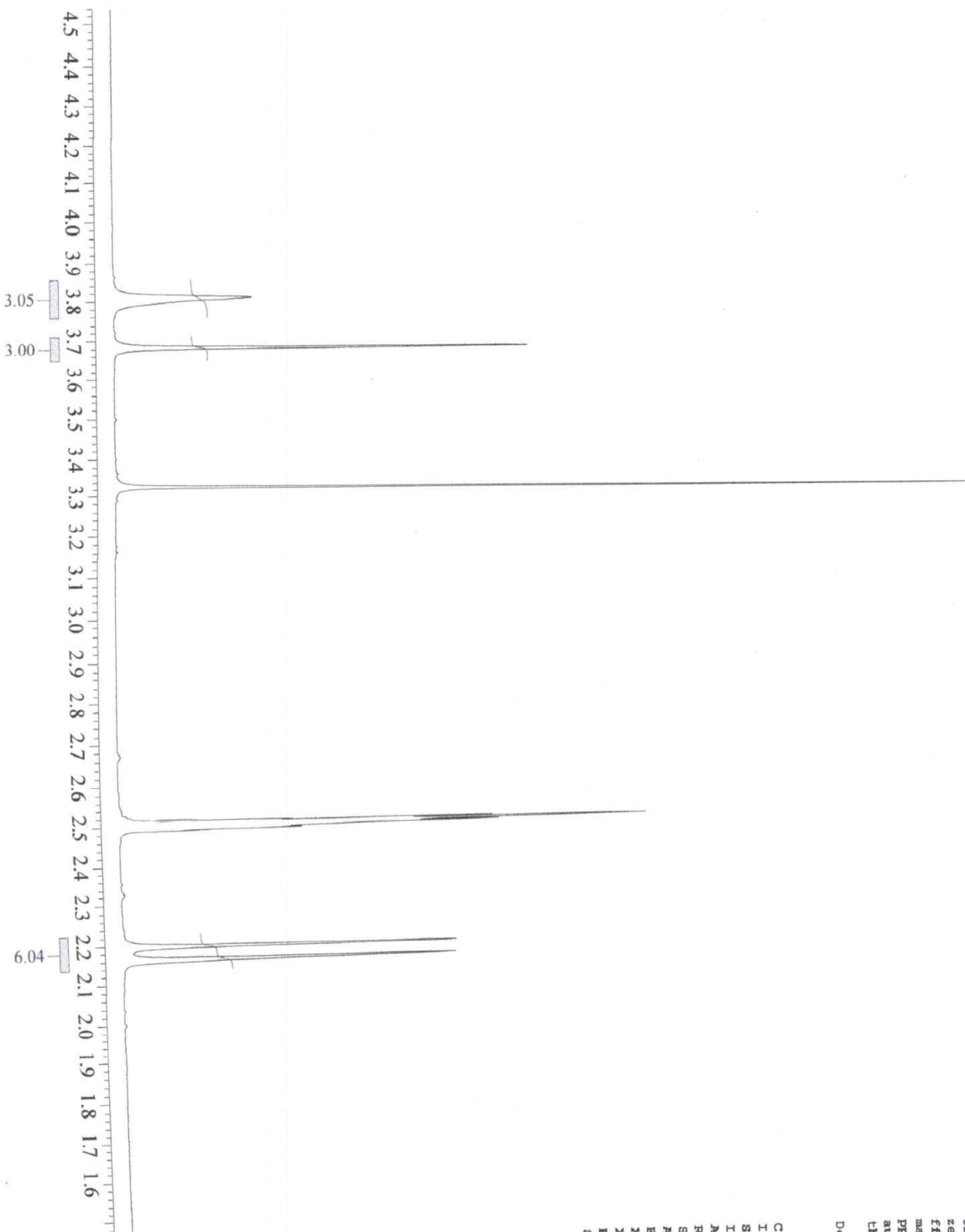
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3.81
3.68

2.20
2.16



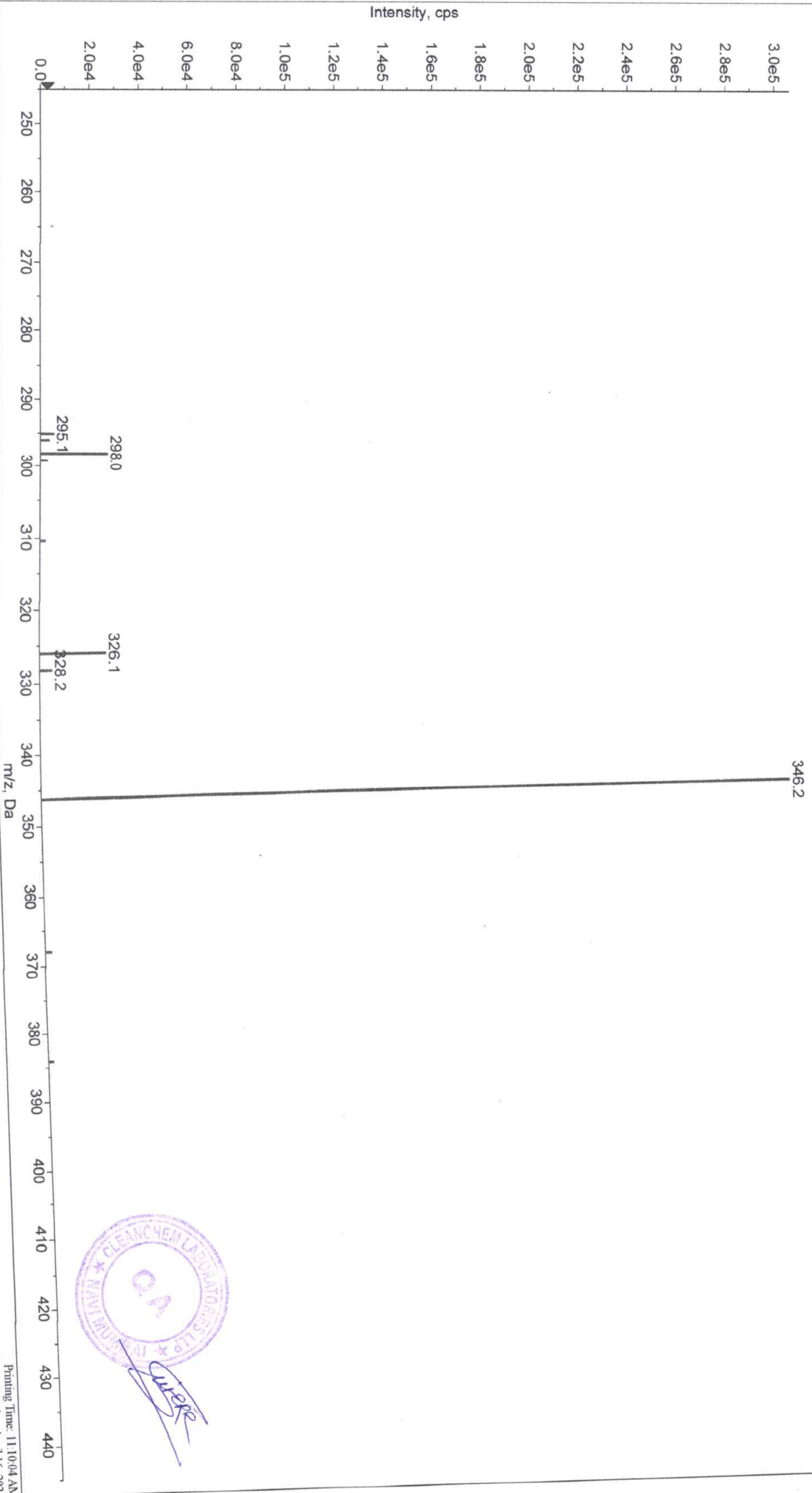
----- PROCESSING PARAMETERS -----
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 trapezoid (0 [%], 0 [%], 80 [%], 100 [%])
 zerofill (2, TRUE)
 fft (1, TRUE, TRUE)
 machinphase
 ppm
 auto_reference (5 [%], TRUE)
 thresh (0.06097 [%], 1)
 Derived from: CL-002-OPS-IWS-15_proton-1-1.jd

Creation_Time = 16-APR-2024 15:28:57
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 Spectrometer = RM-70010S4L1
 Instrument_id = ABN1/QC/NMR-01
 Author = 1030
 Reviewed by = MAR
 Solvent = DMSO-D6
 Acquisition_Parameters
 Experiment = proton.jxp
 X_Offset = 7 [ppm]
 X_Sweep = 9.00576369 [kHz]
 Relaxation_Delay = 3 [s]
 Scans = 16



+Q1: 0.735 min from Sample 5 (CL-002-OPS-IWS-15) of 16042024.wiff (Turbo Spray), Smoothed, Smoothed, Smoothed, Smoothed, Baseli...

Max. 3.1e5 cps.

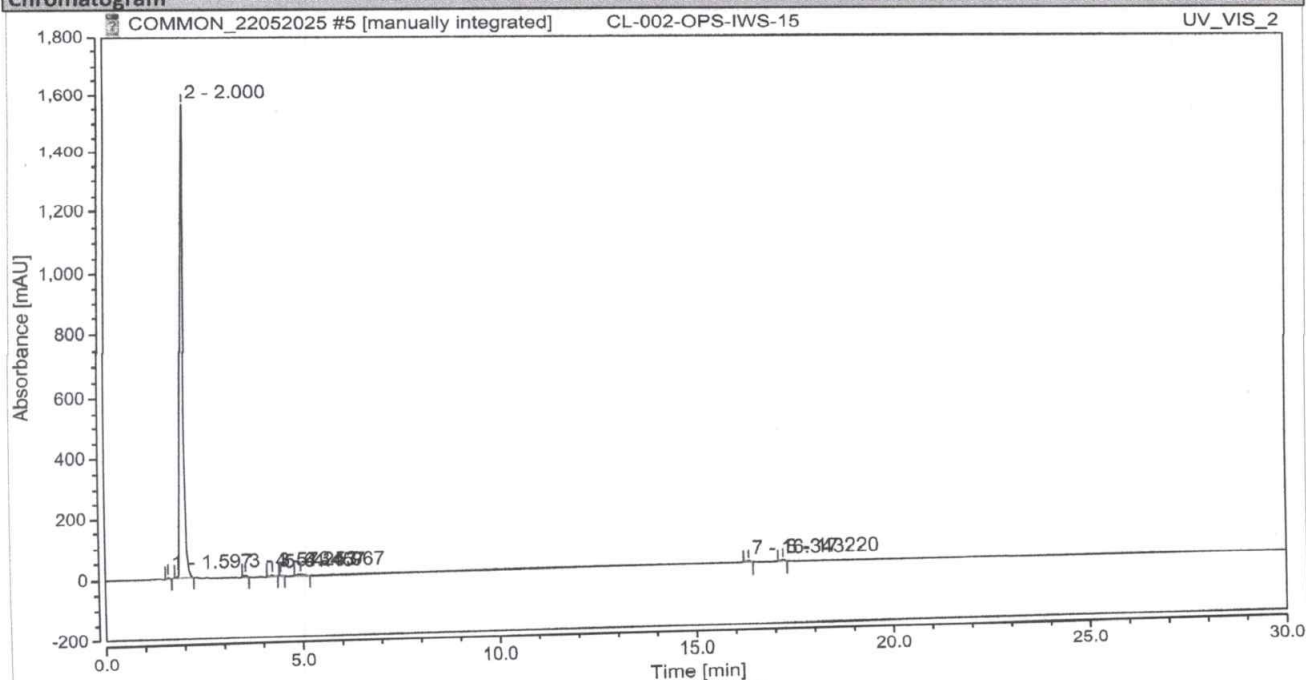


Chromatogram and Results

Injection Details

Injection Name:	CL-002-OPS-IWS-15	Run Time (min):	30.00
Vial Number:	RA1	Injection Volume:	10.00
Injection Type:	Unknown	Channel:	UV_VIS_2
Calibration Level:		Wavelength:	280
Instrument Method:	COMMON 1	Bandwidth:	4
Processing Method:	Quantitative	Column ID	n.a.
Injection Date/Time:	22-May-25 12:26	Sample Weight:	1.0000

Chromatogram



Integration Results

No.	Peakname	RetentionTime min	Area mAU*min	Height mAU	Relative Area %	Rel.Height %	Amount n.a.
1		1.597	0.2902	5.246	0.20	0.33	n.a.
2		2.000	144.8755	1562.255	98.02	98.31	n.a.
3		3.573	0.4769	5.440	0.32	0.34	n.a.
4		4.253	0.4552	3.983	0.31	0.25	n.a.
5		4.457	0.0689	0.784	0.05	0.05	n.a.
6		4.967	0.5046	2.779	0.34	0.17	n.a.
7		16.343	0.5071	3.823	0.34	0.24	n.a.
8		17.220	0.6184	4.830	0.42	0.30	n.a.
Total:			147.797	1589.139	100.000	100.000	



LOSS ON DRYING REPORT

Date: 19-04-2024

Sample Name	OMEPRAZOLE		
Batch No	CL-002-OPS-IWS-15		
Method	USP <731>		
Equipment ID	CL-VO-01	Balance ID	CL-BAL-03

Weight of empty Bottle (W1)	62.6138 g
Weight of sample + Bottle (W2)	63.7148 g
Weight of sample (W3)	1.1010 g
Weight of Bottle after Drying (W4)	63.7129 g
Formula of Loss on drying	$\frac{W2-W4}{W3} \times 100$
Result	0.17 %

	Analyzed By	Checked By
Signature	<u>Sandhya</u>	<u>[Signature]</u>
Date	19-04-2024	19-04-2024



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(As ISO 9001:2015 & 27001:2013 Certified Company)

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Phone: +91-40-27170174/75/76, Fax: +91-40-27150601, customercare@sapalaorganics.com, www.sapalaorganics.com

Residue on ignition Report

Batch number	CL-002-OPS-IWS-15	A.R No.	026651
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Weight of container (gr) (W ₁)	75.1089	After ignition Sample with container (gr)(W ₃)	75.1092
Weight of Sample with Container (gr) (W ₂)	76.1361	Weight of container (gr) (W ₁)	75.1089
Sample Weight (gr) (W ₂ -W ₁)	1.0272	Loss in Sample Weight (gr) (W ₃ -W ₁)	0.0003
Formula of ROI (Ash content) = $\frac{(W_3-W_1)}{(W_2-W_1)} \times 100$			
Result = 0.03%			



Analyzed by	A.Laxminarayana	Reviewed by	S.Chaitanya
Date	19-Apr-2024	Date	19-Apr-2024