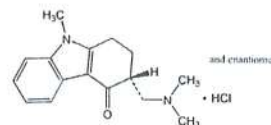


Product Name	Ondansetron Hydrochloride Dihydrate - Impurity A (Hydrochloride Salt)
Lot No.	PH-OND-02201S1V8F2
Product Code	PA 15 07010
CAS No.	119812-29-2
Release Date	04 Mar 2025
Retest Date	03 Mar 2028
Molecular Weight	292.80
Molecular Formula	C ₁₆ H ₂₁ ClN ₂ O
Storage	2 - 8°C in dark place
Shipping	Ambient temperature in dark condition
Synonyms	3-[(Dimethylamino)methyl]-1,2,3,9-tetrahydro-9-methyl-4H-carbazol-4-one Hydrochloride; 3-[(Dimethylamino)methyl]-1,2,3,4-tetrahydro-9-methyl-4H-carbazol-4-one Monohydrochloride



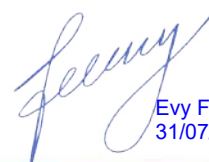
ANALYTICAL INFORMATION			
S. No.	Tests	Result	Specifications
1.	Description	Off white powder	White to off white powder
2.	Identification by: IR NMR MS	Conforms Conforms Conforms	To conform to structure To conform to structure To conform to structure
3.	LOD (% w/w)	0.04	-
4.	Residue on Ignition (% w/w)	0.02	-
5.	Chromatographic Purity (% by HPLC)	99.6	NLT 95.0
6.	Assay (% m/m) on as is basis	99.5	-
Summary		Product is characterized by using IR, NMR, MS, TGA, HPLC	
Caution: Do not dry the material. Use as such. For analytical and research purpose only, not for human and animal consumption.			
Quality concern, if any: Inform within three months of Invoice Date.			

Date of Issue	11 Jun 2026
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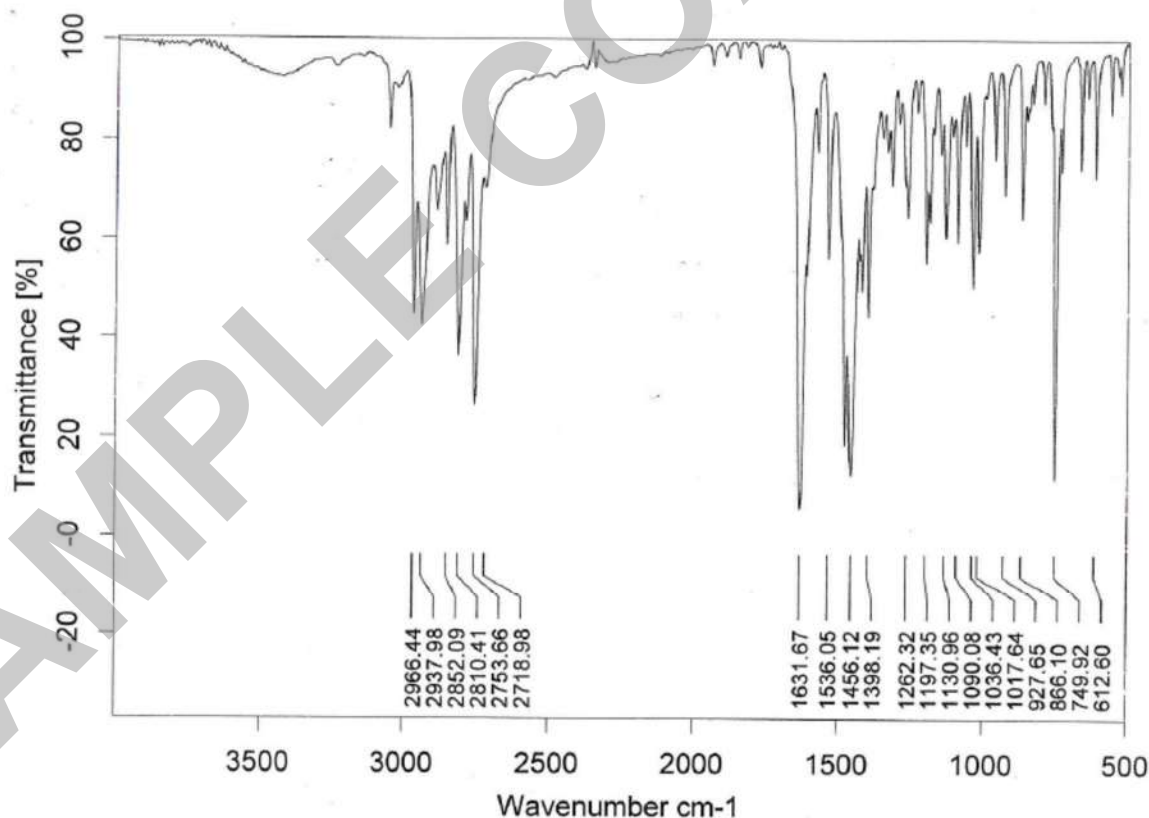
 Vial No. : 14657
 Version : 05


Authorized Signatory

 (A. Bhardwaj)
 Lot Certifier
 NS


 Evy Fenny V.
 31/07/2026

Infra-Red (IR) Spectra



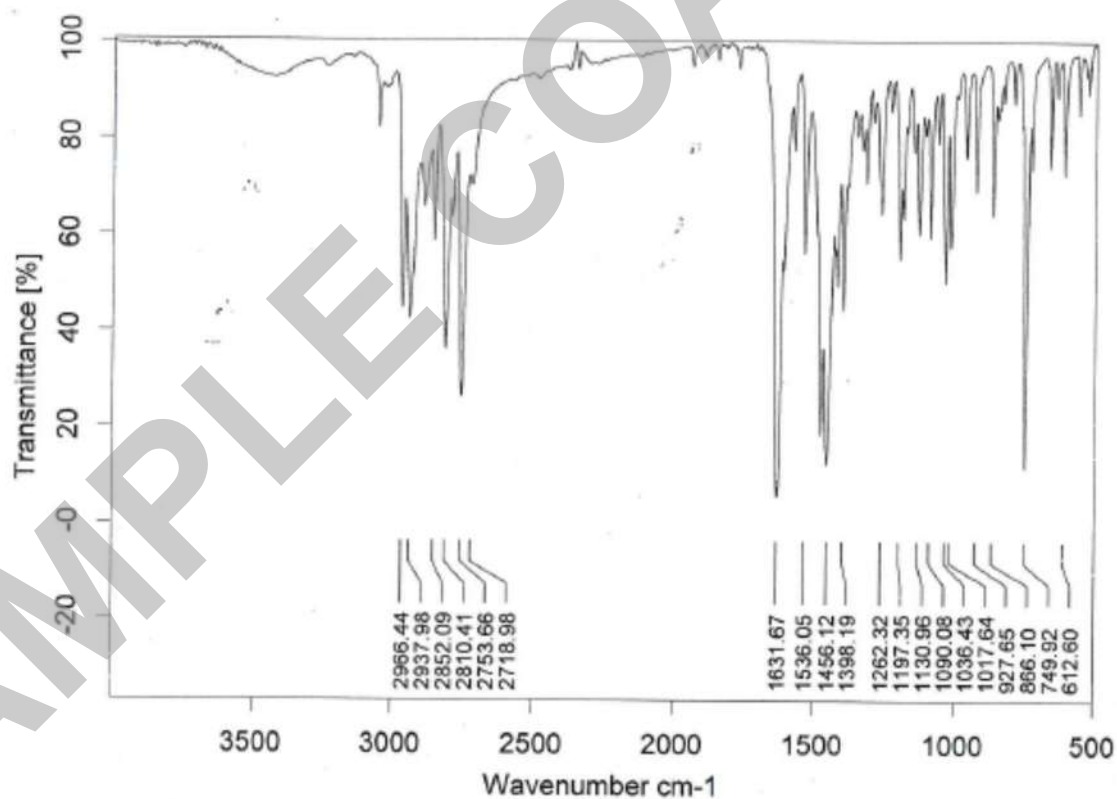
Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
2966.4429	0.443	0.235	9.5038	24.496817	0
2937.9773	0.425	0.417	31.4105	42.521271	0
2852.0939	0.583	0.215	9.2523	20.338226	0
2810.4071	0.364	0.415	17.7510	43.069515	0
2753.6612	0.264	0.736	26.2272	77.764763	0
1631.6651	0.055	0.945	28.5005	99.805069	0
1536.0527	0.561	0.337	11.5809	31.651594	0

FTIR PH-OND-02201S1V8F2

Remarks:

The signals of the IR spectrum are consistent with the structure.

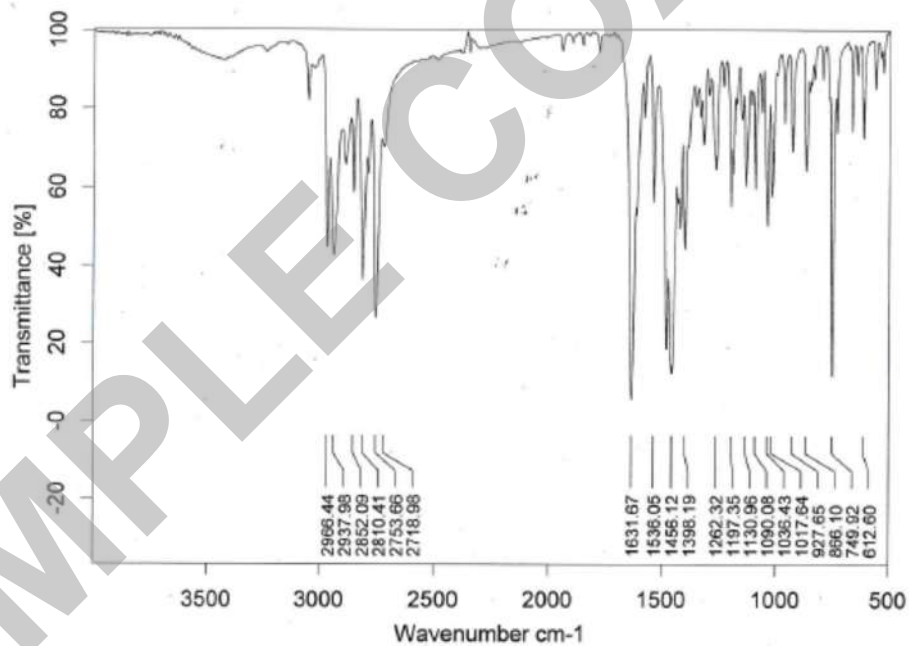
Infra-Red (IR) Spectra



Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
1456.1212	0.123	0.820	49.1976	86.250336	0
1398.1866	0.445	0.273	9.6739	28.382214	0
1262.3168	0.644	0.271	18.4251	27.625957	0
1197.3501	0.549	0.371	19.9799	38.246109	0
1130.9617	0.604	0.269	13.2311	26.334391	0
1090.0778	0.596	0.309	10.2185	32.331764	0
1036.4315	0.503	0.440	14.8430	44.596592	0

FTIR PH-OND-02201S1V8F2

Infra-Red (IR) Spectra



Wavenumber	Abs. intensity	Rel. intensity	Width	Found if threshold <	Shoulder
1017.6389	0.574	0.247	11.4920	25.388496	0
927.6493	0.687	0.264	10.3192	26.977104	0
866.0973	0.638	0.321	10.7771	33.695663	0
749.9156	0.103	0.869	12.4568	91.162704	0
662.9393	0.743	0.228	8.0486	23.797634	0
612.5968	0.726	0.259	8.5787	26.278994	0
3051.7870	0.821	0.121	10.4682	77.617569	0

FTIR PH-OND-02201S1V8F2

IR:

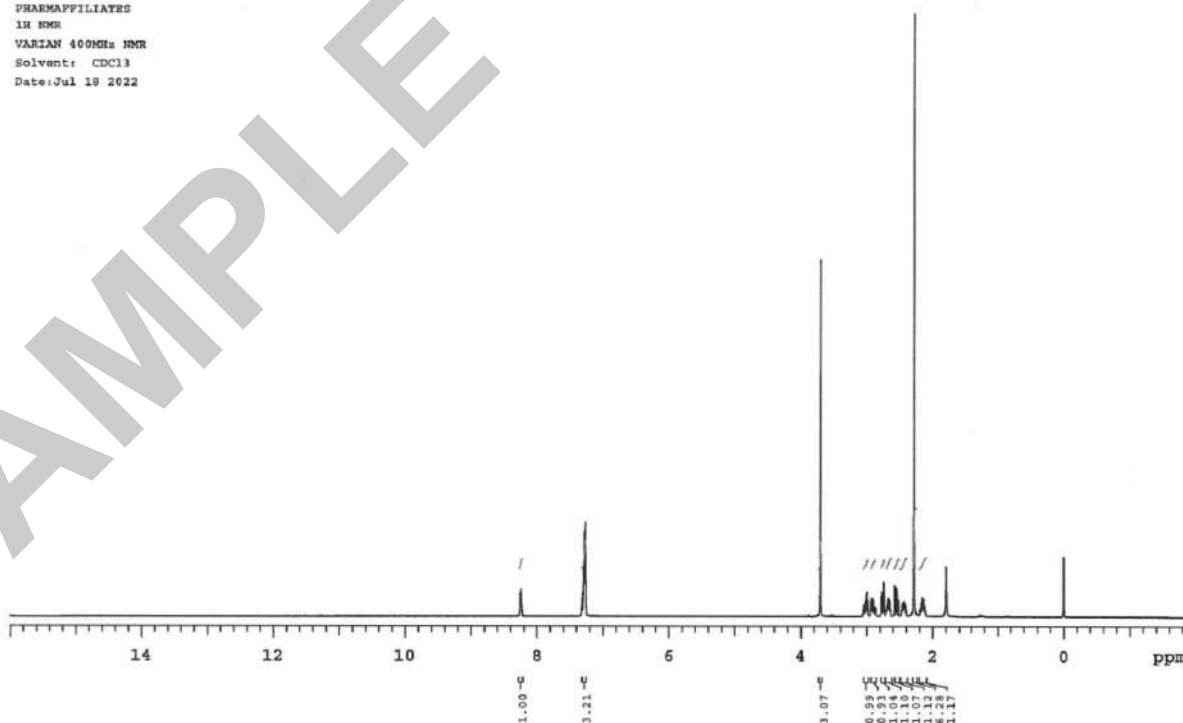
S. No.	Wave number	Assignment
1	3051.75 cm ⁻¹ , 2966.44 cm ⁻¹ .	Aromatic, -CH (Stretch)
2	2937.98 cm ⁻¹ .	Alkane, -C-H (Strong)
3	1631.67 cm ⁻¹ .	Carbonyl, -C=O (Stretch)
Comments		Complies

Comments: IR COMPLIES

¹H NMR Spectrum

Solvent: CDCl₃

Sample code: PH-OND-02201S1V8F2
 PHARMAFFILIATES
 1H NMR
 VARIAN 400MHz NMR
 Solvent: CDCl₃
 Date: Jul 18 2022

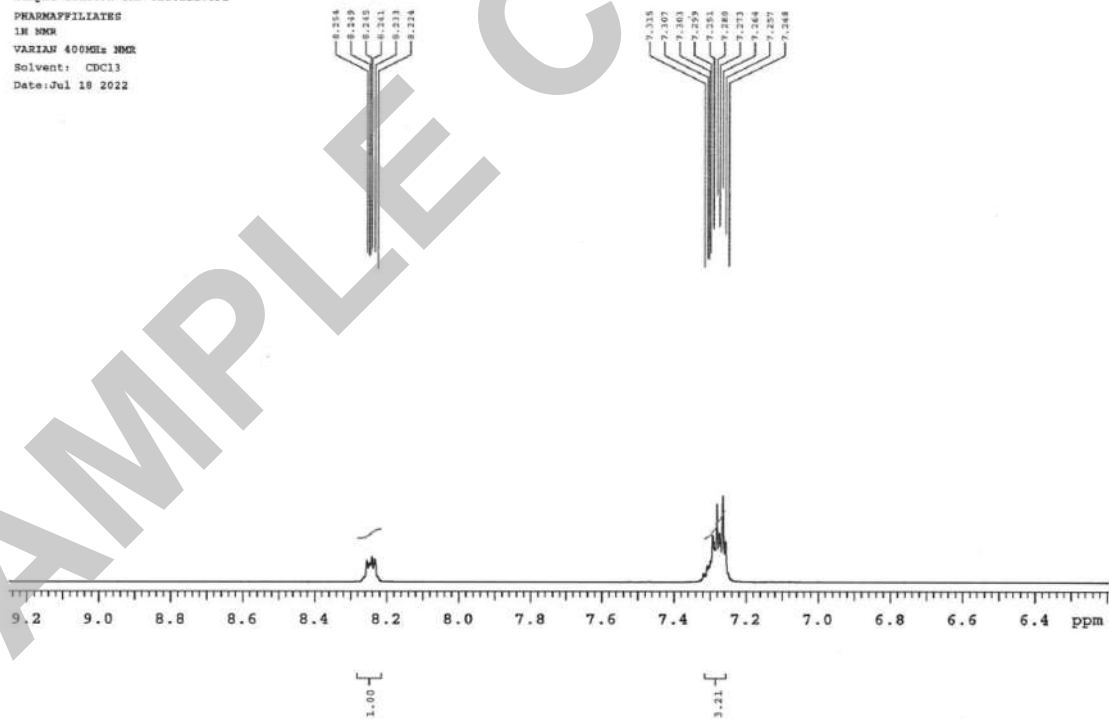


Plotname: PH-OND-02201S1V8F2_PROTON_01_plot01

¹H NMR Spectrum

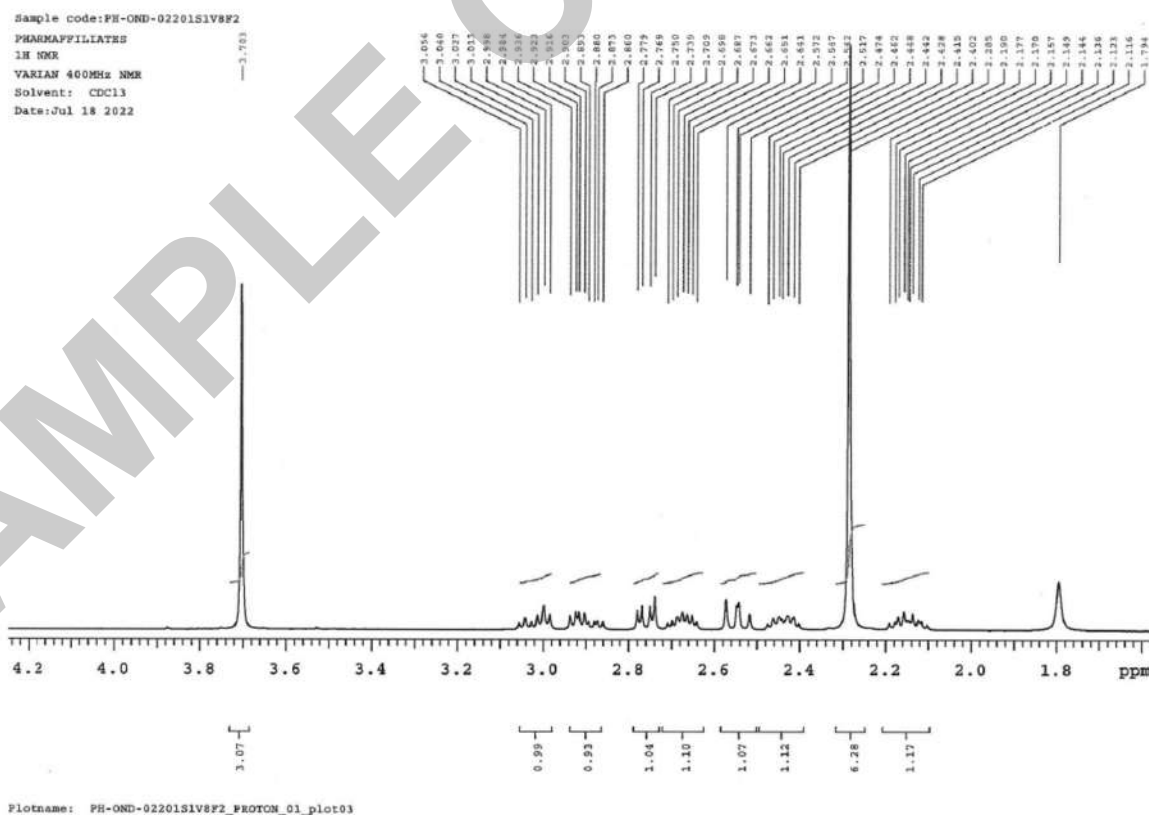
Zoomed Region Range

Sample code: PH-OND-02201S1V8F2
 PHARMAFFILIATES
 1H NMR
 VARIAN 400MHz NMR
 Solvent: CDCl₃
 Date: Jul 19 2022



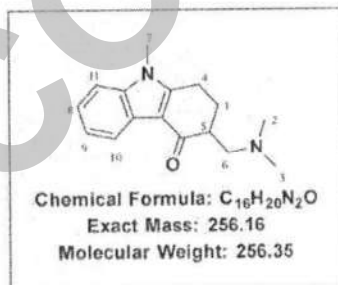
^1H NMR Spectrum

Zoomed Region Range



Remarks: The ^1H -NMR is consistent with the structure.

Structure:

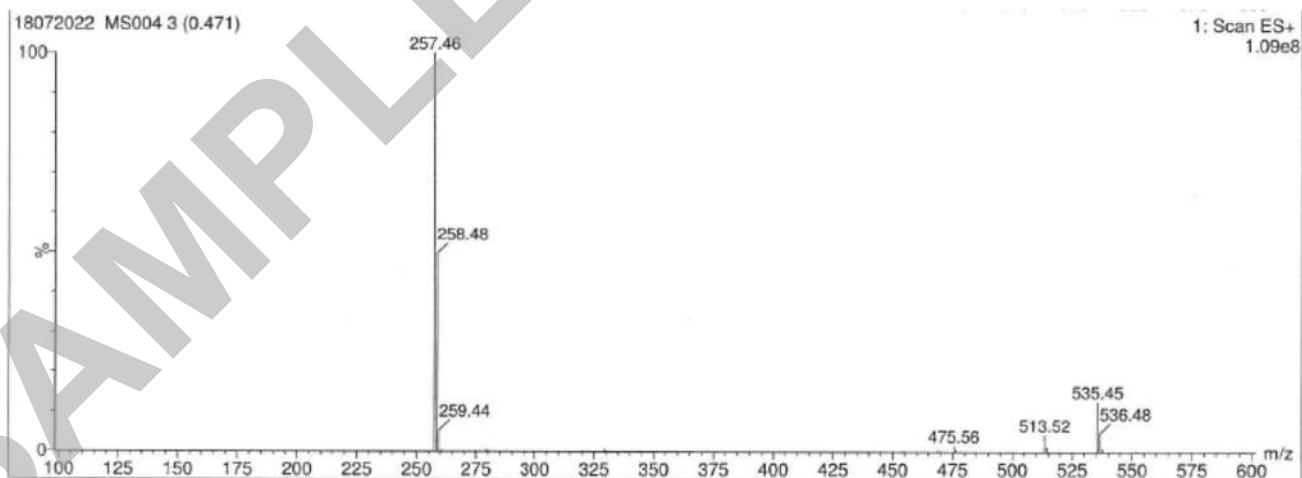


1H NMR:

S.No.	Chemical Protons	Chemical Shift values(ppm)
1	1	2.11-2.20 ppm (1H, m, -CH)
3	2, 3	2.36 ppm (6H, s, -CH ₃)
4	1	2.48-2.54 ppm (1H, m, -CH)
5	4	2.59-2.65 ppm (1H, m, -CH)
6	4	2.70-2.75 ppm (1H, m, -CH)
7	6	2.88-2.95 ppm (2H, m, -CH)
8	5	2.97-3.04 ppm (1H, m, -CH)
9	7	3.71 ppm (3H, s, -CH ₃)
10	8, 9, 10	7.27-7.32 ppm (3H, m, -ArCH)
11	11	8.22-8.24 ppm (1H, m, -ArCH)

Comments: 1H NMR COMPLIES

MS SPECTRUM



Mass Interpretation:

ESI⁺

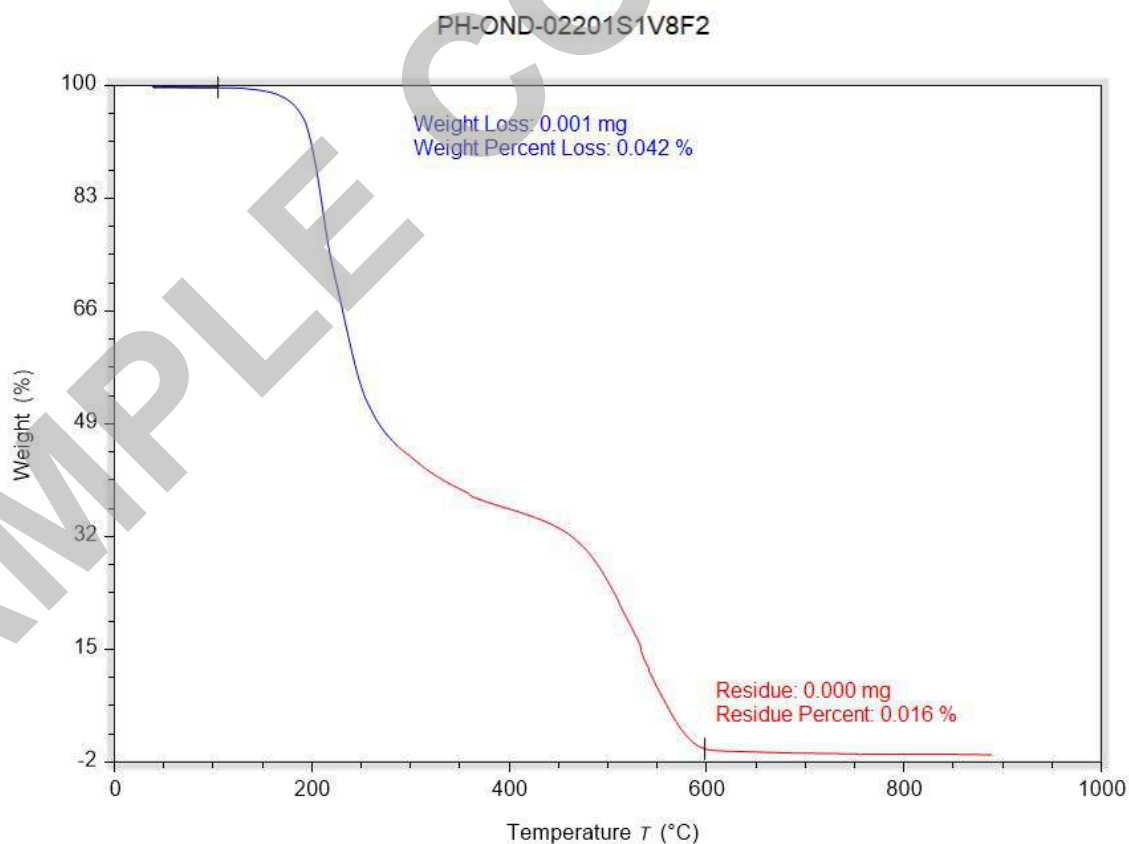
- 257.46m/z(M+H)⁺

Remarks : Observed mass is consistent with the structure.

TGA

Instrument Make: Discovery Series

Instrument Model: TGA-55



Instrument Conditions:

Segment 1 Equilibrate at 40°C

Segment 2 40°C to 300°C at Ramp 20°C/min

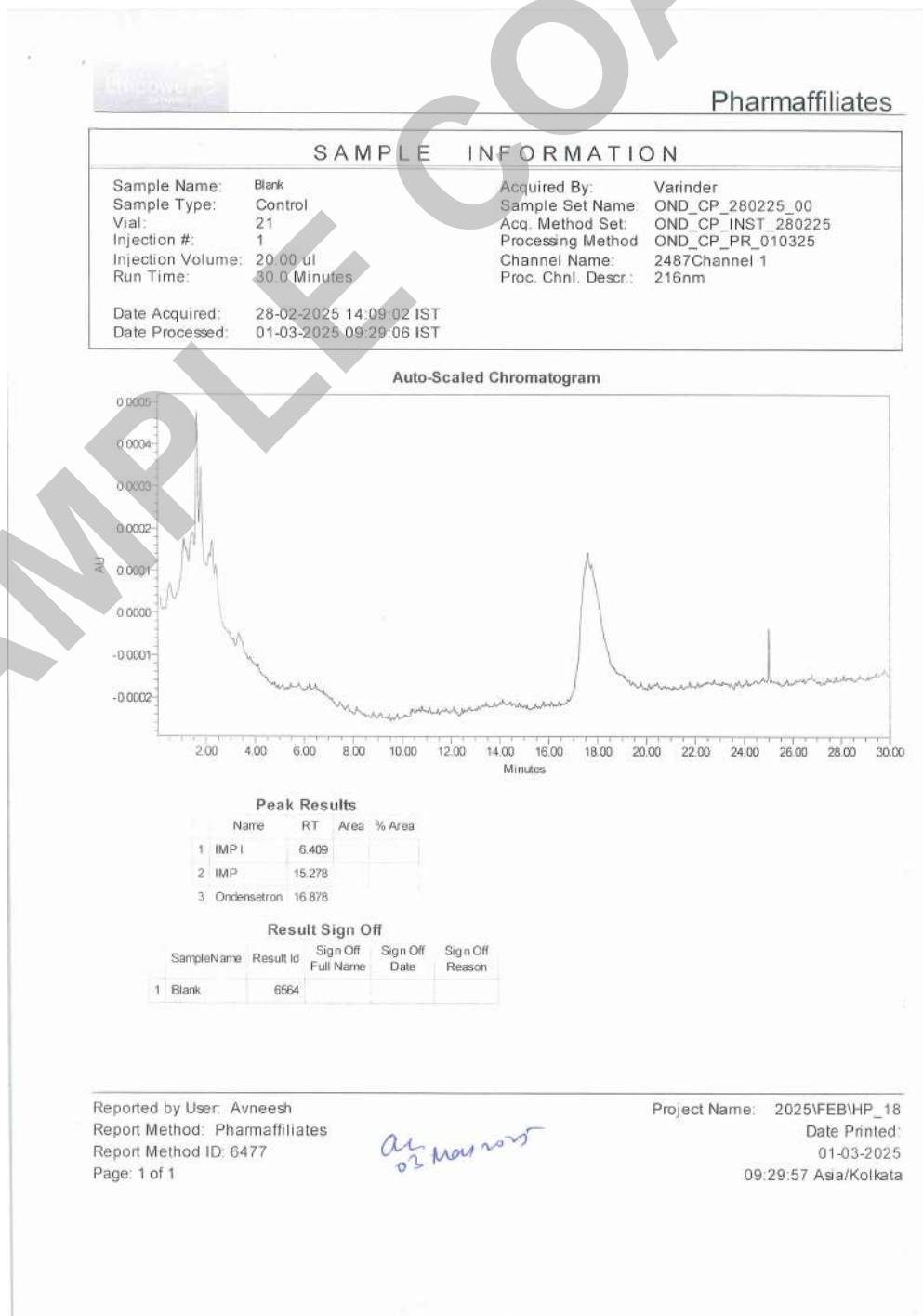
Segment 3 300°C to 900°C at Ramp 20°C/min

Loss on Drying (LOD): 0.042% (w/w)

Residue On Ignition (ROI): 0.016% (w/w)

Comments: LOD value constitutes Volatiles & ROI constitutes Ash content

Blank

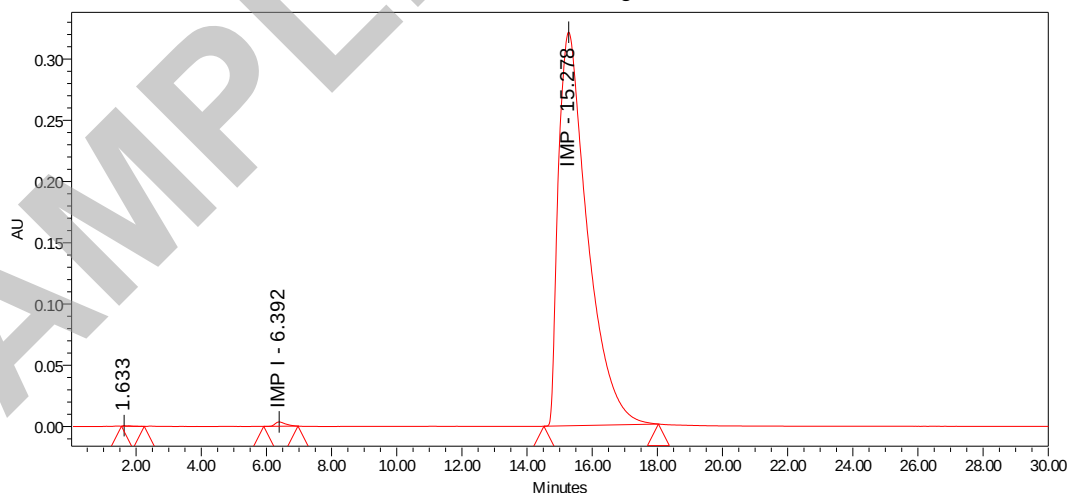


Chromatographic Purity

SAMPLE INFORMATION

Sample Name:	PH-OND-02201S1V8F2_14657	Acquired By:	Varinder
Sample Type:	Unknown	Sample Set Name:	OND_CP_280225_00
Vial:	22	Acq. Method Set:	OND_CP_INST_280225
Injection #:	1	Processing Method:	OND_CP_PR_010325
Injection Volume:	20.00 ul	Channel Name:	2487Channel 1
Run Time:	30.0 Minutes	Proc. Chnl. Descr.:	216nm
Date Acquired:	28-02-2025 15:09:13 IST		
Date Processed:	01-03-2025 09:29:06 IST		

Auto-Scaled Chromatogram



Peak Results

	Name	RT	Area	% Area
1		1.633	6758	0.03
2	IMP I	6.392	78789	0.40
3	IMP	15.278	19838520	99.57
4	Ondansetron	16.878		

Result Sign Off

	SampleName	Result Id	Sign Off Full Name	Sign Off Date	Sign Off Reason
1	PH-OND-02201S1V8F2_14657	6565			

Reported by User: Avneesh
 Report Method: Pharmaffiliates
 Report Method ID: 6477
 Page: 1 of 1

Project Name: 2025\FEB\HP_18
 Date Printed:
 01-03-2025
 09:30:29 Asia/Kolkata

Chromatography Method	
Buffer	Dissolved 2.80354 gm of Sodium dihydrogen phosphate in 1000mL water adjusted pH 5.409 with sodium hydroxide solution.
Mobile Phase A	Buffer: acetonitrile (800: 200)v/v
Diluent	Mobile phase
Test Solution	1.07 mg dissolved in 1.0mL of diluent.
Flow Rate	1.5 mL/min
Detector/Wavelength	216nm
Injection Volume	20µL
Column	Spherisorb CN (250mm x 4.6mm, 5.0µm)
Method	In House

Company having certification from ISO 9001, IS/ISO/IEC 17025, ISO 17034, GLP & Haryana state drug authority.