



VIRUPAKSHA ORGANICS LIMITED

Survey No.10, Gaddapotharam Village, Jinnaram Mandal,
Sangareddy Dist.-502 319, Telangana, INDIA.

CERTIFICATE OF ANALYSIS

Name of the Product	TRAMADOL HYDROCHLORIDE USP		
Batch No	ATDLC0621047	A.R. No	CB/TDL-2106143
Date of Mfg.	06.16.2021	Retest date	06.15.2026
Date of Analysis	28.06.2021		

S. No	TEST	SPECIFICATION	RESULT
1.	Description	White, crystalline powder.	White crystalline powder.
2.	Solubility	Freely soluble in water and in methanol, very slightly soluble in acetone.	Complies
3.	Identification by A. Infrared Absorption	To be concordant with working standard	Complies
	B. Chlorides test	It gives reaction of chlorides	Complies
	C. HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.	Complies
4.	Residue on ignition	Not more than 0.1%	0.05%
5.	Content of chloride	11.6% to 12.1%	11.8%
6.	Limit of Tramadol Related compound B by TLC	Not more than 0.2%	Less than 0.2%
7.	Related compounds by HPLC Tramadol related compound A	Not more than 0.2%	0.02%
	Any other unspecified impurity	Not more than 0.10%	0.03%
	Total impurities	Not more than 0.4 %	0.07%
8.	Water	Not more than 0.5 %	0.20%
9.	Acidity	Not more than 0.4 ml of 0.01 N sodium hydroxide is required to produce a yellow color	0.3 ml of 0.01 N NaOH is consumed.
10.	Assay by HPLC (on the anhydrous basis)	Not less than 98.0 % and Not more than 102.0 %	99.4%

Signature	Prepared by	Checked by	Approved by
	<i>Sy</i>	<i>L. Damodaram</i>	<i>M. Subba Reddy</i>
Date	04.08.2021	04.08.2021	04.08.2021
Name	S.Nagarjuna Reddy	L.Damodaram	M.Subba Reddy
Designation	QC Chemist	Deputy Manager- QC	Manager- QC

Corporate office: B-4, IDA, Gandhinagar, Hyderabad-500 037, Telangana, INDIA.
Tel: +91-40-23073417/65348442, Fax: +91-40-23720738. Email: info@virupaksha.com

Page 1 of 2

KalChem™
INTERNATIONAL
Compounding Chemicals You Can Trust

QA RELEASED
Dispatch Qty: 50.00 kgs
Sign: *Sy*
Date: 04.08.2021



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S. No	TEST	SPECIFICATION	RESULT
11.	Residual solvents by GC-HS (*)		
	Isopropyl alcohol	Not more than 5000 ppm	220 ppm
	Methanol	Not more than 3000 ppm	Not detected
	Toluene	Not more than 890 ppm	Not detected
	Tetrahydrofuran	Not more than 720 ppm	Not detected
	n-Hexane	Not more than 290 ppm	Below LOQ
12.	Specific optical rotation(*)	-0.10° to +0.10°	0.00°

Remarks: The product meets the requirements of USP and (*) additional specification.

Note: LOQ of n-Hexane is 7.88 ppm

Signature	Prepared by <i>[Signature]</i>	Checked by <i>L. Damodaram</i>	Approved by <i>[Signature]</i>
Date	04.08.2021	04.08.2021	04.08.2021
Name	S.Nagarjuna Reddy	L.Damodaram	M.Subba Reddy
Designation	QC Chemist	Deputy Manager- QC	Manager- QC

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Page 2 of 2

QA RELEASED

Dispatch Qty : 50.00 kg
Sign : *[Signature]*
Date : 04.08.2021