Kalchem International, Inc.
Compounding Chemicals You Can Trust
224 S. Main • Lindsay, OK 73052

SUPRIYA LIFESCIENCE LTD.
Creating true values that binds global health

Certificate of analysis

Product	:	Tramadol hydrochloride USP	License No.	:	KD-129
Batch No.	:	SLL/TDM/0818013	Date of Manufacturing	:	Aug-2018
Batch Qty.	:	1000.0 kg	Date of ~~re-test~~/Expiry	:	July-2023
A. R. No.	:	SLL/QC/FP/18/0736	Date of Release	:	12/08/2018

S.No.	Test	Specifications	Results
1.	Description	White crystalline powder.	A white crystalline powder.
2.	Solubility	Freely soluble in water and in methanol, very slightly soluble in acetone.	Conforms
3.	Identification:		
	A. IR Absorption	The infra red absorption spectrum should be concordant with the reference spectrum of Tramadol hydrochloride.	Complies
	B. Reaction of chloride	White precipitate formed.	Complies
	C.Retention time by HPLC	The retention time of the major peak Of the sample solution corresponds to that of the standard ,as obtained in the assay test.	Complies
4.	Assay by HPLC (on anhydrous basis) (%, w/w)	98.0 – 102.0	100.17
5.	Inorganic Impurities		
	i. Residue on ignition (%, w/w)	Not more than 0.1	0.05
	iii. Content of chloride (%, w/w)	11.6 - 12.1	11.8
6.	Organic Impurities		
	Procedure 1 by TLC: Limit of Tramadol related compound B (%)	Any secondary spot from the sample solution corresponding to tramadol related compound B should be not more intense than a corresponding spot from std solution.(NMT 0.2)	Complies

Corporate Office : 207/208, Udyog Bhavan, Sonawala Road, Goregaon (East), Mumbai 400 063. Maharashtra, India.
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S.No.	Test	Specifications	Results
6.	Procedure 2 by HPLC (%)		
	i. Tramadol related compound A	Not more than 0.2	0.01
	ii. Individual impurity	Not more than 0.10	0.06
	iii. Total impurities	Not more than 0.4	0.09
7.	Water determination (%, w/w)	Not more than 0.5	0.19
8.	Acidity (ml)	Not more than 0.4ml of 0.01N Sodium Hydroxide required.	0.3
9.	**Additional Test:**		
	Residual Solvents by GC-HS (ppm)		
	i. Cyclohexane	Not more than 3880	BDL
	ii. Isopropanol	Not more than 5000	613
	iii. Toluene	Not more than 890	14
	iv. Tetra hydro furan	Not more than 720	2

Remarks: The product is complies with respect to above mentioned test as per **USP40** specifications.

Storage: Preserve in tight containers, and store at controlled room temperature.

Ambre 18/08/18	18/08/18	18/08/18
Compiled by QC	Checked by QC	Approved by Head - QC
QC Chemist (A.A.Ambre)	QC Executive (D.D.Jadhav)	QC Dy.Sr.Manager(S.U.Takale)

SUPRIYA LIFESCIENCE MUMBAI

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