

# Kalchem International

## Chemicals & Compounding Supplies

### Certificate Of Analysis

Name of Product : Tramadol HCL, USP  
 Lot Number : 4216-TDM0914021  
 Manufacture Date : September 2014  
 Re-Test Date : August 2019

Test	Specification	Result
Description	White Crystalline Powder	White Crystalline Powder
Solubility	Freely soluble in water and in methanol, very slightly soluble in acetone	Conforms
Identification		
A : IR Absorption	The infra red absorption spectrum should be concordant with the reference spectrum of Tramadol Hydrochloride.	Positive
B : Reaction of Chloride	White precipitate formed	Positive
Assay by HPLC (% w/w)	NLT 98.0% & NMT 102.0% (on anhydrous basis)	100.06%
Inorganic Impurities		
- Residue on Ignition(% w/w)	Not more than 0.1%	0.06%
- Heavy Metals (ppm)	Not more than 20ppm	Less than 20ppm
- Content of Chloride(% w/w)	11.6% - 12.1%	11.9%
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%)	Positive
Procedure 2 by HPLC %		
- Tramadol related Compound A	Not more than 0.2%	Not detected
- Individual Impurities	Not more than 0.10%	Not detected
- Total Impurities	Not more than 0.4%	Not detected
Water Determination(% w/w)	Not more than 0.6%	0.34%
Acidity (ml)	Not more than 0.4ml of 0.01N N <sub>2</sub> OH required	0.3
Residual Solvents by GC-MS (ppm)		
- Cyclohexane	Not more than 3880ppm	Not Detected
- Isopropanol Alcohol	Not more than 5000ppm	Less Than 1000
- Toluene	Not more than 890ppm	Not Detected
- Tetra Hydro Furan	Not more than 720ppm	Not Detected

**Conclusion :** The Specification conforms with USP35 Standards

Kalchem International, Inc  
 224 South Main Street - Lindsay, OK 73052  
 Toll Free 888-298-9905 | FAX: 405-756-2373