WRS
T 28-2

(17)

VIRUPAKSHA
Organics Limited

CERTIFICATE OF ANALYSIS
WORKING STANDARD

Name of the product	TRAMADOL HYDROCHLORIDE BP		
Batch No	ATDCLC0415156	Date of Analysis	28.10.2015
A.R.No	CB/TDL-1504158	Use Before	27.10.2016
Date of Mfg.	April 2015	Date of Exp.	March 2019
Quantity	1.0 gm		

NATIONAL QUALITY CONTROL LABORATORY
RECEIVED
12 MAY 2016
Tel: 2726963/4/5/6/7/8 Fax: 2718073
P. O. Box 29726 - 00202, NAIROBI

Sr.No	TEST	SPECIFICATION	RESULT
01.	Description	A white or almost white, crystalline powder.	A white crystalline powder.
02.	Solubility	Freely soluble in water and in methanol, very slightly soluble in acetone.	Complies
03.	Identification by A. Infrared absorption spectrophotometry B.Impurity E by thin-layer chromatography C. Chlorides test	Compare the spectrum with that obtained with tramadol hydrochloride RS or with the reference spectrum of tramadol hydrochloride. The principle spot in the chromatogram obtained with test solution (b) corresponds to the principle spot in the chromatogram obtained with reference solution (a). It gives reaction (a) of chlorides.	Complies Complies Complies
04.	Appearance of solution	A 5 percent w/v solution is clear and colorless.	Complies
05.	Acidity	Not more than 0.4 ml of 0.01 M sodium hydroxide is required.	0.36 ml of 0.01 M NaOH consumed.
06.	Specific optical rotation	-0.010^0 to $+0.10^0$	0.00^0
07.	Impurity E by thin-layer chromatography	Not more than 0.20%	Complies
08.	Related substances by HPLC Impurity A Any other impurity Total impurities	 Not more than 0.20% Not more than 0.10% Not more than 0.40%	 0.02% 0.04% 0.12%
09.	Heavy metals	Not more than 20 ppm	Less than 20 ppm
10.	Sulphated ash	Not more than 0.10%	0.05%
11.	Water	Not more than 0.50%	0.14%
12.	Assay	99.00% to 101.00%	99.84%

Remarks : The product meets the requirements of BP specification. AS IS BASIS 99.70% (Assay)

Signature			
Date	28.10.2015	28.10.2015	28.10.2015

TRIVENI FORMULATIONS LTD. * SURAMPALLI *