

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

Name of the Product	: CYCLOBENZAPRINE HYDROCHLORIDE USP-31	Page	: 1 of 2
Batch Number	: CBP/13 10051	A.R.No.	: CBP/13064
Manufacturing Date	: SEP'2013	Expiry Date	: AUG'2018
Dispatch Quantity	: 1Kg	Analyzed on	: 04/10/2013

S.No	TEST	RESULT	SPECIFICATION
1.0	Description	White odorless crystalline powder	White to off-white, odorless, crystalline powder.
2.0	Solubility	Complies	Freely soluble in water, in alcohol, and in methanol, sparingly soluble in isopropanol, slightly soluble in chloroform and methylene chloride, insoluble in n-Hexane.
3.0	IDENTIFICATION		
A	Infrared Spectrum (In mineral oil)	Complies	The IR absorption spectrum obtained with the test sample should be concordant with that of reference spectrum of Cyclobenzaprine HCl or with the spectrum obtained with Cyclobenzaprine HCl Reference/working standard.
B	Ultraviolet absorption (15 µg per ml in methanol) (Calculated on dried basis)	2.25%	Absorptivity of sample and Cyclobenzaprine hydrochloride working standard/Reference standard at 290 nm, on dried basis should not differ by more than 3.0%.
C	Test for chlorides	Complies	Should responds to the test for chloride
4.0	Melting Range	217.0°C-218.2°C	Between 215°C and 219°C (The range between beginning and ending should not exceed 2°C)
5.0	Loss on drying	0.22%	Not more than 1.0 % w/w
6.0	Residue on Ignition	0.05%	Not more than 0.1% w/w
7.0	Heavy metals	Complies	Not more than 0.001%
8.0	Chromatographic purity by TLC		
	Any other spot	Complies	Not more than 0.5%
9.0	Assay by potentiometry (on dried basis)	100.0%	Not less than 99.0% w/w and not more than 101.0% w/w

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CERTIFICATE OF ANALYSIS

Name of the Product	CYCLO BENZAPRINE HYDROCHLORIDE USP-35	Page	: 2 of 2
Batch Number	: CBP/1310051	A.R.No.	: CBP/13064
Manufacturing Date	: SEP'2013	Expiry Date	: AUG'2018
Dispatch Quantity	: 3Kg	Analyzed on	: 04/10/2013

S.No	TEST	RESULT	SPECIFICATION
10.0	ADDITIONAL TEST		
10.1	Related Substances by HPLC		
	Impurity-A(DDBS)	Not detected	Not more than 0.15%
	Impurity-B(AMPT)	0.01%	Not more than 0.15%
	Impurity-C(5-HICBP)	Not detected	Not more than 0.15%
	Impurity-D(N-Oxide)	Not detected	Not more than 0.15%
	Impurity-E (ATQ)	Not detected	Not more than 0.15%
	Unidentified impurity	0.01%	Not more than 0.10%
	Total impurities	0.03%	Not more than 0.50%
10.2	Residual Solvents by GC HS		
	Methanol	Not detected	Not more than 1500 ppm
	Acetone	13 ppm	Not more than 2500 ppm
	Isopropyl alcohol	173 ppm	Not more than 2500 ppm
	Tetrahydrofuran	Not detected	Not more than 500 ppm
	Toluene	38 ppm	Not more than 500 ppm

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