

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS Cyclobenzaprine Hydrochloride

COA No.: 16621	Manufacture Date:	Jun, 2016
Lot No.: CBP/1606004	Expiry date:	May, 2021

Items	Standard	Results
Description	White to off-white, odorless, crystalline powder	complies
Solubility	Freely soluble in water, alcohol, methanol, sparing soluble in isopropanol, slightly soluble in chloroform and methylene chloride, insoluble in n-Hexane	complies
Identification		
A. IR absorption	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.	Complies
B. Assay by HPLC	The retention time of major peak of the sample solution corresponds to that of the standard solution as obtained in the assay	Complies
C. Test for chloride	Should respond to the test for chloride	Complies
Loss on drying	NMT 1.0% w/w	0.15%
Residue on ignition	NMT 0.1% w/w	0.05%
Heavy metals	NMT 0.001%	Complies
Organic impurities by HPLC		
Cyclobenzaprine related compound A	NMT 0.15%	BDL
Cyclobenzaprine related compound B	NMT 0.15%	0.02%
Cyclobenzaprine N-oxide	NMT 0.15%	BDL
Amitriptyline	NMT 0.15%	BDL
Dibenzocycloheptenone	NMT 0.15%	BDL
Any individual unspecified impurity	NMT 0.10%	BDL
Total impurities	NMT 1.0%	0.02%
Assay by HPLC (dry basis)	98.0% ~ 102.0% w/w	99.7%
Residual solvents by GC HS		
Methanol	NMT 1500ppm	111 ppm
Acetone	NMT 2500 PPM	BDL
Isopropyl alcohol	NMT 2500 PPM	BDL
Tetrahydrofuran	NMT 500 ppm	BDL
Toluene	NMT 500ppm	55 ppm
Conclusion	The above product complies with USP standard.	

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