

CYPROHEPTADINE HYDROCHLORIDE

Batch N°:	3400/01/13	ANALYSIS CERTIFICATE N°	150064	Date:	21/01/2015
Kg:	353.00	Formula:	C ₂₁ H ₂₁ N.HCl. 1½ H ₂ O	M.W.:	350.9
Man. date:	20/03/2013	Retest date:	Mar/2018	Complies with:	Ph.Eur. BP USP JP
Solubility: Freely soluble in methanol; soluble in chloroform; sparingly soluble in ethanol (96 per cent); slightly soluble in water; practically insoluble in diethyl ether.					

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white or slightly yellow crystalline powder, odourless or almost odourless	complies
IDENTIFICATION	(1): IR spectrum (2): UV spectrum (3): chlorides test (4): fluorescence test (5): HPLC retention time	complies complies complies complies complies
ACIDITY	not more than 0.05% as HCl	complies
WATER	7.0% to 9.0%	7.8%
LOSS ON DRYING	7.0% to 9.0%	7.3%
SULPHATED ASH	not more than 0.1%	0.02%
RELATED SUBSTANCES (HPLC)	(1): impurity 1 not more than 0.10% (2): impurity 2 not more than 0.10% (3): impurity 3 not more than 0.10% (4): any other impurity not more than 0.10%	< 0.02% < 0.02% < 0.02% < 0.02%
	(5): sum of all impurities not more than 0.50%	complies

This material has been prepared following the current Good Manufacturing Practice (cGMP).

Q.C. Manager

Q.A. Manager

Qualified Person

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Revision 3400-01

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TESTS	SPECIFICATIONS	RESULTS
HEAVY METALS	not more than 20 ppm	complies
ASSAY	(A): 98.5% to 100.5% calculated on the anhydrous basis (USP) (B): 98.5% to 101.0% with reference to the anhydrous substance (Ph.Eur.) (C): not less than 98.5% with reference to the dried substance (JP)	99.5% 100.5% 99.9%
RESIDUAL SOLVENTS	(1): acetone not more than 200 ppm (2): isopropanol not more than 1000 ppm	72 ppm 198 ppm

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