olon s.p.a.

Revision 3400-02

CYPROHEPTADINE HYDROCHLORIDE

Batch N°:	**3400/04/16**	**ANALYSIS CERTIFICATE N°**	**171642**	**Date:**	**02/08/2017**
Kg:	375.00	Formula:	$C_{21}H_{21}N.HCl.1½\ H_2O$	M.W.:	350.9
Man. date:	25/02/2016	Retest date:	Feb/2021	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	complies
	(2): UV spectrum	complies
	(3): chlorides test	complies
	(4): fluorescence test	complies
	(5): HPLC retention time	complies
ACIDITY	not more than 0.05% as HCl	complies
WATER	7.0% to 9.0%	7.7%
LOSS ON DRYING	7.0% to 9.0%	7.1%
SULPHATED ASH	not more than 0.1%	0.01%
RELATED SUBSTANCES (HPLC)	(1): impurity 1 not more than 0.10%	< 0.02%
	(2): impurity 2 not more than 0.10%	< 0.02%
	(3): impurity 3 not more than 0.10%	< 0.02%
	(4): any other impurity not more than 0.10%	< 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 .....

02/08/17 02/08/17

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TESTS	SPECIFICATIONS	RESULTS
ORGANIC IMPURITIES (HPLC)	(1): cyproheptadine impurity A not more than 0.10%	< 0.05%
	(2): amitriptyline impurity A not more than 0.10%	< 0.05%
	(3): cyproheptadine impurity C not more than 0.10%	< 0.05%
	(4): any other impurity not more than 0.10%	RRT 0.46: 0.05%
	(5): sum of all impurities not more than 0.50%	0.05%
HEAVY METALS	not more than 20 ppm	complies
ASSAY	(A): 98.0% to 102.0% calculated on the anhydrous basis (USP) (HPLC)	100.5%
	(B): 98.5% to 101.0% with reference to the anhydrous substance (Ph.Eur.) (pot)	100.8%
	(C): not less than 98.5% with reference to the dried substance (JP)	99.5%
RESIDUAL SOLVENTS	(1): acetone not more than 200 ppm	< LOQ
	(2): isopropanol not more than 1000 ppm	248 ppm

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

Q.C. Manager ..... 02/08/17 **Q.A. Manager** ..... 2/8/17 **Qualified Person** 02/08/17

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