

Sifavor s.r.l.Via Livelli 1 - 20152 Casaleggio Lodigiano Fraz. Mairano (LO) - ITALY
Tel. 0371-73591 - Fax: 0371-73105 - e-mail: sifavor@infagroup.com**CERTIFICATE OF ANALYSIS**

This batch has been produced following current good manufacturing practices

CYPROHEPTADINE HYDROCHLORIDE

Revision: 29/06/2007

Page 1 of 1

Analysis Number 121673

Analysis Date 27/09/2012

Batch 3400/06/2012 (Katalona) 337.00

Formula:

 $C_{21}H_{21}N HCl \cdot 3/2 H_2O$

M.W:

350.90

Manufacturing Date 18/09/2012

Test Date 09/09/2012

Complies with:
Ph.Eur.-BP-USP

TEST	RESULTS	SPECIFICATIONS
DESCRIPTION Aspetto	complies	white or slightly yellow crystalline powder; odourless or almost odourless
IDENTIFICATION Identificazione	complies complies complies complies	(1) IR spectrum (2) UV spectrum (3) chlorides test (4) fluorescence test
ACIDITY Acidità	complies	not more than 0.05% as HCl
WATER Acqua	7.54%	btw 7.0% and 9.0%
SULPHATED ASH Ceneri solforiche	0.01%	not more than 0.1%
HEAVY METALS Metalli pesanti	complies	not more than 20 ppm
RELATED SUBSTANCES (HPLC) Impurezze organiche (HPLC)	(1): < LOD (2): < LOD (3): < 0.02% (4): < 0.02% (5): complies	(1) imp.1 or dibenzosuberone nmt 0.10% (2) imp.2 or hydroxyderivative nmt 0.10% (3) imp.3 or dibenzocycloheptene nmt 0.10% (4) each unknown impurity nmt 0.10% (5) sum of all impurities nmt 0.50%
ASSAY Titolo	(1): 100.44% (2): 100.30%	(1) btw 98.5% and 101.0% with reference to the anhydrous substance (NaOH 0.1N) (2) btw 98.5% and 100.5% calculated on the anhydrous basis (HClO4 0.1N)
RESIDUAL SOLVENTS Solventi residui	(1): 95 ppm (2): 410 ppm FAGRON IBÉRICA, S.A. Corresponde al lote de Fagron, 43010202	(1) acetone nmt 200 ppm (2) isopropanol nmt 1000 ppm

Director Técnico S.

 27/09/12	 27/09/12	 24/09/2012
Issue: QUALITY CONTROL Dr. Andrea Rebona	Control: QUALITY ASSURANCE Dr. Attilio Virgili	Approval: QUALIFIED PERSON Dott.ssa Chiara Magnone