

Sifavitor S.r.l.
Via Livelli 1 - 20052 Cassaleto Lodigiano Fraz. Mairano (LO) - ITALY
Tel. 0371-73991 - Fax 0371-73108 - e-mail: sifavitor@infagroup.com

CERTIFICATE OF ANALYSIS

This batch has been produced following current good manufacturing practices

AMITRIPTYLINE HYDROCHLORIDE

Revision: 23/11/2011

Page 1 of 2

Analysis Number 131143

Analysis Date 07/03/2014

Batch: 3200/03/14

Kg: 212.00

Formula:

$C_{20}H_{23}N \cdot HCl$

M.W:

313.86

Manufacturing Date 12/04/2013

Retest Date 04/2018

Complies with:

Ph.Eur.-BP-USP-JP-IP

TEST	RESULTS	SPECIFICATIONS
DESCRIPTION Aspetto	complies	white or almost white crystalline powder
IDENTIFICATION Identificazione	complies complies complies	(1) IR spectrum (2) HPLC retention time (3) chlorides reaction
APPEARANCE OF SOLUTION Aspetto della soluzione	complies	a 5.0% solution in water is clear and not more intensely coloured than reference solution B9
ACIDITY OR ALKALINITY Acidità o basicità	complies	complies EP test
MELTING RANGE Intervallo di fusione	195°-196°C	btw 195°C and 199°C
pH (1% solution) pH (soluzione all'1%)	5.5	btw 5.0 and 6.0
pH (5% solution) pH (soluzione al 5%)	4.4	btw 4.0 and 5.0
RELATED SUBSTANCES (HPLC USP) Sostanze correlate (HPLC USP)	(1): < LOD (2): < LOD (3): 0.01% (4): < LOD (5): < LOD (6): 0.01%	(1) dibenzosuberone nmt 0.05% (2) amitriptinol nmt 0.10% (3) cyclobenzaprine nmt 0.10% (4) nortriptyline nmt 0.10% (5) each unknown impurity nmt 0.10% (6) sum of all impurities nmt 0.30%
RELATED SUBSTANCES (HPLC EP) Sostanze correlate (HPLC EP)	(1): < 0.05% (2): < 0.05% (3): < 0.05% (4): complies	(1) dibenzosuberone nmt 0.05% (2) cyclobenzaprine nmt 0.10% (3) each unknown impurity nmt 0.10% (4) sum of all impurities nmt 0.30%
LOSS ON DRYING Perdita all'essiccamento	0.06%	not more than 0.5%
SULPHATED ASH Ceneri solforiche	0.02%	not more than 0.1%
HEAVY METALS Metalli pesanti	complies	not more than 10 ppm

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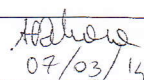
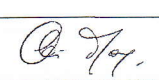
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TEST	RESULTS	SPECIFICATIONS
ASSAY Titolo	(1): 100.67% (2): 100.37%	(1) btw 98.0% and 102.0% with reference to the dried substance (HPLC) (2) btw 99.0% and 101.0% with reference to the dried substance (NaOH 0.1N) (pot.)
RESIDUAL SOLVENTS Solventi residui	(1): < LOQ (2): 114 ppm	(1) methanol nmt 200 ppm (2) ethyl acetate nmt 500 ppm

 07/03/14	 07/03/14	 07/03/2014
Issue: QUALITY CONTROL Dr. Andrea Rebora	Control: QUALITY ASSURANCE Dr. Attilio Virgili	Approval: QUALIFIED PERSON Dott.ssa Chiara Magnone