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Mod.05/01-8 REV.3 del 17/09/2009

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CERTIFICATE OF ANALYSIS

DOXEPIN HYDROCHLORIDE

Revision: 09/04/2008

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Analysis Number 101556

Batch: 3700/04/10

Kg: 350.00

Formula:

$C_{19}H_{21}NO \cdot HCl$

M.W:

315.84

Analysis Date 23/09/2010

Manufacturing Date 07/09/2010

Retest Date 09/2015

Complies with:

Ph Eur.-BP- USP

TEST	RESULTS	SPECIFICATIONS
DESCRIPTION Aspetto	complies	a white or almost white crystalline powder ✓
IDENTIFICATION Identificazione	complies complies complies	(1) IR spectrum ✓ (2) HPLC retention time ✓ (3) chlorides test ✓
APPEARANCE OF SOLUTION Aspetto della soluzione	complies	a 2% solution in water is clear and colourless ✓
ACIDITY Acidità	complies	not more than 0.1 ml of 0.1M sodium hydroxide is required ✓
LOSS ON DRYING Perdita all'essiccamento	0.11%	not more than 0.5% ✓
SULPHATED ASH Generi 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): < LOD (4): < LOD (5): < LOD (6): < LOQ (7): complies	(1) impurity A (doxepinon) nmt 0.10% ✓ (2) impurity B (doxepinol) nmt 0.10% (3) impurity C nmt 0.10% (4) impurity D nmt 0.10% (5) impurity E nmt 0.10% (6) each other impurity nmt 0.10% (7) sum of all impurities nmt 0.30%
ASSAY Titolo	(A): 100.49% (B): 100.06%	(A) btw 98.0% and 101.0% (pot) ✓ with reference to the dried substance (B) btw 98.0% and 102.0% (HPLC) with reference to the dried substance
Z-ISOMER Isomero Z	(A): 17.25% (B): 17.24%	btw 13.0% and 18.5% (HPLC) ✓ btw 13.6% and 18.1% (HPLC)
E-ISOMER Isomero E	82.71%	btw 81.4% and 88.2% (HPLC)

DOXEPIN HYDROCHLORIDE			Revision: 09/04/2008	Page 2 of 2
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Analysis Date 23/09/2010				
Manufacturing Date 07/09/2010	Retest Date 09/2015	Complies with: Ph.Eur.-BP-USP		
TEST	RESULTS	SPECIFICATIONS		
RESIDUAL SOLVENTS Solventi residui	(1): 296 ppm (2): < LOQ (3): < LOQ (4): < LOQ	(1) ethyl acetate nmt 2000 ppm (2) ethanol nmt 500 ppm (3) tetrahydrofuran nmt 100 ppm (4) toluene nmt 100 ppm		

<i>Ribora</i> 23/09/10	<i>Attilio</i> 23/09/10	<i>Sergio</i> 23.09.2010
Issue: QUALITY CONTROL Dr Andrea Rebora	Control: QUALITY ASSURANCE Dr Attilio Virgili	Approval: QUALIFIED PERSON Dr Sergio Freddi