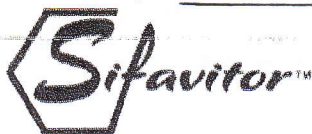


Lote: 9020316

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Revision 3700-00

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## DOXEPIN HYDROCHLORIDE

Batch N°: 3700/03/14 ANALYSIS CERTIFICATE N° 141947 Date: 30/10/2014  
Kg: 203.00 Formula:  $C_{19}H_{21}NO \cdot HCl$  M.W.: 315.8  
Man. date: 20/10/2014 Retest date: Oct/2019 Complies with: Ph.Eur.-BP-USP

Solubility: freely soluble in water, in ethanol (96 per cent) and in methylene chloride.

TESTS	SPECIFICATIONS	RESULTS
Z-ISOMER (HPLC)	(A): 13.0% to 18.5% (Ph.Eur.) (B): 13.6% to 18.1% (USP)	15.3% 15.4%
E-ISOMER (HPLC)	81.4% to 88.2% (HPLC)	85.3%
ASSAY	(A): 98.0% to 101.0% with reference to the dried substance (pot.) (B): 98.0% to 102.0% with reference to the dried substance (HPLC)	100.1% 100.7%
RESIDUAL SOLVENTS	(1): ethyl acetate not more than 2000 ppm (2): ethanol not more than 500 ppm (3): tetrahydrofuran not more than 100 ppm (4): toluene not more than 100 ppm	276 ppm < LOQ < LOQ < LOQ

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

Q.C. Manager

Q.A. Manager

Qualified Person

Stabilimento / Plant

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## DOXEPIN HYDROCHLORIDE

Batch N°:	3700/03/14	ANALYSIS CERTIFICATE N°	141947	Date:	30/10/2014
Kg:	203.00	Formula:	C <sub>19</sub> H <sub>21</sub> NO. HCl	M.W.:	315.8
Man. date:	20/10/2014	Retest date:	Oct/2019	Complies with:	Ph.Eur.-BP-USP
Solubility:	freely soluble in water, in ethanol (96 per cent) and in methylene chloride.				
TESTS		SPECIFICATIONS		RESULTS	
DESCRIPTION		white or almost white crystalline powder		complies	
IDENTIFICATION		(1): IR spectrum (2): HPLC retention time (3): chlorides reaction		complies complies complies	
APPEARANCE OF SOLUTION		a 2.0% solution in water is clear and colourless		complies	
ACIDITY		not more than 0.1 ml of NaOH 0.1M for 0.5 g		complies	
LOSS ON DRYING		not more than 0.5%		0.08%	
SULPHATED ASH		not more than 0.1%		0.02%	
HEAVY METALS		not more than 20 ppm		complies	
RELATED SUBSTANCES (HPLC)		(1): impurity A not more than 0.10% (2): impurity B not more than 0.10% (3): impurity C not more than 0.10% (4): any other impurity not more than 0.10%		< LOD < LOD < LOD < LOQ	
		(5): sum of all impurities not more than 0.30%		complies	
This material has been prepared following the current Good Manufacturing Practice (cGMP).					

Q.C. Manager ..... Q.A. Manager ..... Qualified Person ..... 30/10/2014

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