Lote: 9020516

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Sifavitor™

Revision 3700-00

DOXEPIN HYDROCHLORIDE

Batch N°:	**3700/03/14**	**ANALYSIS CERTIFICATE N°**	**141947**	**Date:**	**30/10/2014**
Kg:	203.00	Formula:	$C_{19}H_{21}NO.HCl$	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
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% wiht 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 ..... 30/10/14 Q.A. Manager ..... 30/10/14 Qualified Person 30/10/2014

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TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	white or almost white crystalline powder	complies
IDENTIFICATION	(1): IR spectrum	complies
	(2): HPLC retention time	complies
	(3): chlorides reaction	complies
APPEARANCE OF SOLUTION	a 2.0% solution in water is clear and colouless	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%	< LOD
	(2): impurity B not more than 0.10%	< LOD
	(3): impurity C not more than 0.10%	< LOD
	(4): any other impurity not more than 0.10%	< 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 .... 30/10/14 **Q.A. Manager** .... 30/10/14 **Qualified Person** 30/10/2014

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