

lot 0100185

A member of Info Group



Revision 3700-02

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DOXEPIN HYDROCHLORIDE

Batch N°: 3700/01/16 ANALYSIS CERTIFICATE N° 161213 Date: 17/05/2016
Kg: 413.00 Formula: $C_{19}H_{21}NO \cdot HCl$ M.W.: 315.8
Man. date: 25/03/2016 Retest date: Mar/2021 Complies with: Ph.Eur.-BP-USP
Solubility: freely soluble in water, in ethanol (98 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%	0.07%
SULPHATED ASH	not more than 0.1%	0.01%
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% (5): sum of all impurities not more than 0.30%	< 0.04% < 0.04% < 0.04% < 0.04% complies

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

Q.C. Manager Q.A. Manager Qualified Person
17/05/16 17/05/16 17/05/16
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