



Cambrex Profarmaco Milano S.r.l.

Via Curiel 34, 20067 Paolo (MI) - ITALY

Certificate of Analysis

Product	AMIODARONE HYDROCHLORIDE	C.A.S. n.	19774-82-4
Batch	131518	Formula	C25H29I2NO3.HCl
Production date	June 2014	M.W.	681.8
Expiration Date	May 2019	T.S.	016.008
Analysis	June 19 2014		

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White crystalline powder, odourless	COMPLIES
SOLUBILITY	Methylene chloride	Clear solution COMPLIES
APPEARANCE OF SOLUTION	Methanol	Clear and MACT GYS COMPLIES
COLOR	Abs. at 420 nm in Methanol	NMT 0.100 0.044
IDENTIFICATIONS	IR spectrum	Conforms to standard COMPLIES
	Chlorides	Positive COMPLIES
RESIDUE ON IGNITION		NMT 0.1 % 0.0
HEAVY METALS		NMT 20 ppm COMPLIES
LOSS ON DRYING		NMT 0.5 % 0.1
WATER		NMT 0.5 % 0.1
pH		3.2 / 3.8 3.4
IODIDES		NMT 150 ppm COMPLIES
IMPURITY B BY TLC	Diethylaminoethylchloride HCl (EP/USP-H)	NMT 0.01 % ND
RELATED SUBSTANCES BY HPLC	Diiodo butyl (EP/USP-D)	NMT 0.200 % 0.006
	Mono iodo Amiodarone (EP/USP-C)	NMT 0.100 % ND
	Bis desiodo Amiodarone (EP/USP-A)	NMT 0.100 % 0.011
	Any unspecified impurity	NMT 0.100 % 0.038
	Total unspecified impurities	NMT 0.300 % 0.073
	Total impurities	NMT 0.500 % 0.090
ASSAY	By titration (on dried basis)	98.5 / 101.0 % 100.3
	Assay by HPLC (on dried basis)	98.5 / 101.0 % 99.9
RESIDUAL SOLVENTS BY GLC	Ethanol	NMT 2000 ppm 281
	Acetone	NMT 50 ppm 3
	Chloroform	NMT 50 ppm ND
	Methylene Chloride	NMT 100 ppm ND

FAGRON IBÉRICA, S.A.U

Corresponde al lote de Fagron:

614090125

Director Técnico

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7)

The product conforms to requirements of:
EuPh8.0 - USP17QUALIFIED PERSON / QUALITY DIRECTOR
Dr. Roberto Baima
15/06/2014

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