



Cambrex Profarmaco Milano S.r.l.

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Certificate of Analysis

Product	AMIODARONE HYDROCHLORIDE	C.A.S. n.	19774-82-4
Batch	612932	Formula	C25H29I2NO3.HCl
Production date	November 2017	M.W.	681.8
Expiration Date	November 2022	T.S.	016.012
Analysis	December 7 2017		
Coa Number	CA5.853		

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White crystalline powder, odourless	COMPLIES
SOLUBILITY	Methylene chloride	Clear solution
APPEARANCE OF SOLUTION	Methanol	Clear and NMCT 0.5
COLOR	Abs. at 420 nm in Methanol	NMT 0.100
IDENTIFICATIONS	IR spectrum	Conforms to standard
	Chlorides	Positive
RESIDUE ON IGNITION		NMT 0.1 %
HEAVY METALS		NMT 20 ppm
LOSS ON DRYING		NMT 0.5 %
WATER		NMT 0.5 %
pH		3.2 / 3.6
IODIDES		NMT 150 ppm
IMPURITY R BY TLC	Diethylaminoethylchloride HCl (EP/USP-II)	NMT 0.01 %
RELATED SUBSTANCES BY HPLC	Diiodo butyl (EP/USP-D)	NMT 0.200 %
	Mono iodo Amiodarone (EP/USP-C)	NMT 0.100 %
	Bis desiodo Amiodarone (EP/USP-A)	NMT 0.100 %
	Any unspecified impurity	NMT 0.100 %
	Total unspecified impurities	NMT 0.300 %
	Total impurities	NMT 0.500 %
ASSAY	By titration (on dried basis)	98.5 / 101.0 %
	Assay by HPLC (on dried basis)	98.5 / 101.0 %
RESIDUAL SOLVENTS BY GLC	Ethanol	NMT 2000 ppm
	Acetone	NMT 50 ppm
	Chloroform	NMT 50 ppm
	Methylene Chloride	NMT 100 ppm

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: USP 40/EUPH 9

Approved by Qualified Person / Quality Director
Roberto Baima
12-11-2017

This Certificate of Analysis has been approved by the Qualified Person / Quality Director and produced automatically with validated electronic signature