CAMBREX

Cambrex Profarmaco Milano S.r.L.

Via Curiel 34, 20067 Paullo (MI) - ITALY Tel.: +39 02 90 62 60.1

Certificate of Analysis

Product	AMIODARONE HYDROCHLORIDE	C.A.S. n.	19774-82-4
Batch	217174	Formula	C25H29I2NO3.HCl
Production date	March 2015	M.W.	681.8
Expiration Date	March 2020	T.S.	016.009
Analysis	December 21 2015		
Coa Number	CA1.554		

DETERMINATION	SPECIFICATION		RESULT
DESCRIPTION	White crystalline powder, odourless		COMPLIES
SOLUBILITY	Methylene chloride	Clear solution	COMPLIES
APPEARANCE OF SOLUTION	Methanol	Clear and NMCT GY5	COMPLIES
COLOR	Abs.at 420 nm in Methanol	NMT 0.100	0.053
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 %	0,0
WATER		NMT 0.5 %	0.1
pH		3.2 / 3.8	3,5
IODIDES		NMT 150 ppm	COMPLIES
IMPURITY H 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 %	ND
	Any unpecified impurity	NMT 0.100 %	0.042
	Total unspecified impurities	NMT 0.300 %	0.086
	Total impurities	NMT 0.500 %	0.092
ASSAY	By titration (on dried basis)	98.5 / 101.0 %	100.2
	Assay by HPLC (on dried basis)	98.5 / 101.0 %	100.0
RESIDUAL SOLVENTS BY GLC	Ethanol	NMT 2000 ppm	347
	Acetone	NMT 50 ppm	1
	Chloroform	NMT 50 ppm	ND
	Methylene Chloride	NMT 100 ppm	ND

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 - USP38

Approved by Qualified Person / Quality Director
Roberto Baima
12-21-2015

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