



Cambrex Profarmaco Milano S.r.l

Via Curiel 34, 20067 Paullo (MI)

Certificate of Analysis

Product	AMIODARONE HYDROCHLORIDE	C.A.S. n	19774-82-4
Batch	960105	Formula	C25H29I2NO3.HCl
Production date	September 2012	M.W	681.8
Expiration date	September 2017	T.S.	016.005
Analysis	September 21 2012		

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White crystalline powder, odourless	COMPLIES
SOLUBILITY	Methylene chloride	Clear solution COMPLIES
APPEARANCE OF SOLUTION	Methanol	Clear and NMCT GVS COMPLIES
COLOR	Abs. at 420 nm in Methanol	NMT 0.100 0.045
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 3.7
IODIDES		NMT 150 ppm COMPLIES
IMPURITY R BY TLC	Diethylaminoethylchloride HCl (EP/USP-R)	NMT 0.01 % ND
RELATED SUBSTANCES BY HPLC	Diiodo butyl (EP/USP-D)	NMT 0.240 % 0.004
	Mono iodo Amiodarone (EP/USP-C)	NMT 0.100 % ND
	Bis desiodo Amiodarone (EP/USP-A)	NMT 0.100 % 0.017
	Any unspecified impurity	NMT 0.100 % 0.041
	Total unspecified impurities	NMT 0.300 % 0.075
	Total impurities	NMT 0.500 % 0.056
ASSAY	By titration (on dried basis)	98.5 / 101.0 % 100.4
	Assay by HPLC (on dried basis)	98.5 / 101.0 % 100.3
RESIDUAL SOLVENTS BY GLC	Ethanol	NMT 2000 ppm 360
	Acetone	NMT 50 ppm 3
	Chloroform	NMT 50 ppm 3
	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:
EuPh7.5 - USP35

QUALITY ASSURANCE DIRECTOR

Dr. Domenico Casucci