



Cambrex Profarmaco Milano S.r.l
Via Curiel 34, 20067 Paullo (MI)

Certificate of Analysis

Product **AMIODARONE HYDROCHLORIDE**
Batch **960105**
Production date **September 2012**
Expiration date **September 2017**
Analysis **September 21 2012**

C.A.S. n **19774-82-4**
Formula **C₂₅H₂₉I₂NO₃ · HCl**
M.W **681.8**
T.S. **016.005**

DETERMINATION	SPECIFICATION	RESULT
DESCRIPTION	White crystalline powder, odourless	COMPLIES
SOLUBILITY	Methylene chloride	COMPLIES
APPEARANCE OF SOLUTION	Methanol	COMPLIES
COLOR	Abs. at 420 nm in Methanol	NMT 0.100 0.045
IDENTIFICATIONS	IR spectrum Chlorides	Conforms to standard Positive NMT 0.1 % 0.0
RESIDUE ON IGNITION		NMT 20 ppm COMPLIES
HEAVY METALS		NMT 0.5 % 0.1
LOSS ON DRYING		NMT 0.5 % 0.1
WATER		3.2 / 3.8 3.7
pH		NMT 150 ppm COMPLIES
IODIDES		NMT 0.01 % ND
IMPURITY B BY TLC	Diethylaminoethylchloride HCl (EP/USP-R)	NMT 0.200 % 0.004
RELATED SUBSTANCES BY HPLC	Dilodo butyl (EP/USP-D)	NMT 0.100 % ND
	Mono iodo Amiodarone (EP/USP-C)	NMT 0.100 % 0.017
	Bis desiodo Amiodarone (EP/USP-A)	NMT 0.100 % 0.041
	Any unspecified impurity	NMT 0.100 % 0.075
	Total unspecified impurities	NMT 0.500 % 0.036
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

[Signature] 24/9/12