



Cambrex Profarmaco Milano S.r.l.

Via Curiel 34, 20067 Paillo (MI)

Certificate of Analysis

Product AMIODARONE HYDROCHLORIDE
 Batch 041720
 Production date March 2013
 Expiration date March 2018
 Analysis April 9 2013

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	
SOLUBILITY	Methylene chloride	COMPLIES
APPEARANCE OF SOLUTION	Methanol	COMPLIES
COLOR	Abs.at 420 nm in Methanol	Clear solution
IDENTIFICATIONS	IR spectrum	Clear and NMCT GYS
RESIDUE ON IGNITION	Chlorides	NMT 0.100
HEAVY METALS		Conforms to standard
LOSS ON DRYING		Positive
WATER		NMT 0.1 %
pH		NMT 20 ppm
IODIDES		NMT 0.5 %
IMPURITY R BY TLC	Diethylaminoethylchloride HCl (EP/USP-H)	3.2 / 3.6
RELATED SUBSTANCES BY HPLC	Diiodo butyl (EP/USP-D)	NMT 150 ppm
	Mono iodo Amiodarone (EP/USP-C)	NMT 0.01 %
	Bis desiodo Amiodarone (EP/USP-A)	NMT 0.200 %
	Any unspecified impurity	NMT 0.100 %
	Total unspecified impurities	NMT 0.100 %
	Total impurities	NMT 0.300 %
ASSAY	By titration (on dried basis)	NMT 0.500 %
	Assay by MPLC (on dried basis)	98.5 / 101.0 %
RESIDUAL SOLVENTS BY GLC	Ethanol	100.4
	Acetone	98.5 / 101.0 %
	Chloroform	NMT 2000 ppm
	Methylene Chloride	NMT 50 ppm
		NMT 50 ppm
		NMT 100 ppm

FAGRON IBÉRICA, S.A.U
 Corresponde al lote de Fagron:

L13070191

26.9.13 Director Técnico S.

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:
 RuPh7.5 - USP35

QUALITY CONTROL MANAGER
 Dr.ssa Stefania Targa

QUALIFIED PERSON
 Dr. Edoardo Gianolli

x
 09.04.13

09/04/13