



Cambrex Profarmaco Milano S.r.L.

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Certificate of Analysis

Product AMIODARONE HYDROCHLORIDE
Batch 217174
Production date March 2015
Expiration Date March 2020
Analysis December 21 2015
Coa Number CA1.554

C.A.S. n. 19774-82-4
Formula C₂₅H₂₉I₂NO₃.HCl
M.W. 681.8
T.S. 016.009

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 Chlorides	Conforms to standard 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) Mono iodo Amiodarone (EP/USP-C) Bis desiodo Amiodarone (EP/USP-A) Any unspecified impurity Total unspecified impurities Total impurities	NMT 0.200 % 0.006 ND NMT 0.100 % ND NMT 0.100 % 0.042 NMT 0.300 % 0.086 NMT 0.500 % 0.092
ASSAY	By titration (on dried basis) Assay by HPLC (on dried basis)	98.5 / 101.0 % 98.5 / 101.0 % 100.2 100.0
RESIDUAL SOLVENTS BY GLC	Ethanol Acetone Chloroform Methylene Chloride	NMT 2000 ppm 347 NMT 50 ppm 1 NMT 50 ppm ND 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