



Cambrex Profarmaco Milano S.r.L.

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Certificate of Analysis

Product	AMIODARONE HYDROCHLORIDE	C.A.S. n.	19774-82-4
Batch	760106	Formula	C25H29I2NO3.HCl
Production date	October 2018	M.W.	681.8
Expiration Date	September 2023	T.S.	016.013
Analysis	October 17 2018		
Coa Number	CA7.607		

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 0.050
IDENTIFICATIONS	IR spectrum	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 3.6
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 unspecified impurity	NMT 0.100 % 0.057
	Total unspecified impurities	NMT 0.300 % 0.115
	Total impurities	NMT 0.500 % 0.121
ASSAY	By titration (on dried basis)	98.5 / 101.0 % 100.4
	Assay by HPLC (on dried basis)	98.5 / 101.0 % 99.7
RESIDUAL SOLVENTS BY GLC	Ethanol	NMT 2000 ppm 371
	Acetone	NMT 50 ppm 2
	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: USP
41/EUPH 9Approved by Qualified Person / Quality Director
Laura Bigini
10-17-2018

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