



TECHNICAL DATA SHEET

0160-TDS-ENG-2025

AMIODARONA HCL (EUR. PH.)		
DESCRIPTION DCI: AMIODARONE HYDROCHLORIDE		DESCRIPTION DOE: AMIODARONA HIDROCLORURO
CAS Nº: 19774-82-4	EC Nº: 243-293-2	AEMPS CODE: 392CH
MOL. WEIGHT: 681,8	MOL. FORMULA: C ₂₅ H ₂₉ I ₂ NO ₃ ·HCl	ARTICLE CODE: 0160

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, fine, crystalline powder
Solubility	Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution GY5 o BY5
pH	3.2 - 3.8
Impurity H	=< 0.02 %
Related substances	
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity G	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Iodide	=< 150 ppm
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.5 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.7

STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from light.

REMARKS

Amiodarone Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.