

AMIODARONA HCL (EUR. PH.)

PRODUCT CODE: 0160	CAS Nº: 19774-82-4	ANALYSIS Nº: 169/25
MANUFACTURER BATCH: 25AM000053	CERTIFICATE ID: 46.837	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/02/2025	
METAPH BATCH: 0040625	EXPIRY DATE: 30/01/2030	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, fine, crystalline powder	White, fine, crystalline powder
Solubility	Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution GY5 o BY5	Complies
pH	3.2 - 3.8	3.3
Impurity H	=< 0.02 %	< 0.02 %
Related substances		
Impurity C	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	< 0.05 %
Impurity G	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Iodide	=< 150 ppm	< 150 ppm
Loss on drying	=< 0.5 %	0.02 %
Sulfated ash	=< 0.1 %	0.08 %
Assay	98.5 - 101.0 %	98.9 %

COMPLIES WITH

European Pharmacopoeia 11.7

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 28/07/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001238
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