



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 220259

Product:	AMIODARONE HYDROCHLORIDE
Lot:	220259
Expiry date:	01/10/2025
Reference:	Cumple PhEur10.6
Synonyms:	
Formula:	C ₂₅ H ₃₀ ClI ₂ NO ₃
Molecular weight:	681,8 g/mol

Assay	Result	Specification	
Sulphated ashes	<= 0,1 %	<= 0,1 %	=
Loss on drying	0,08 %	<= 0,5 %	
Assay (acidimetry)	99,1 %	98,5% - 101,0 %	
Related substances (HPLC)	Conform		=
Total impurities	<= 0,5 %	<= 0,5 %	=
Impurity H (TLC)	< 0,02 %	<= 0,02 %	=
Unspecified Impurities	<= 0,10 %	<= 0,10 %	=
Elemental impurities	Conform	Test PhEur	#
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Iodides	<= 150 ppm	<= 150 ppm	=
Residual solvent: Ethanol	<= 5000 ppm	<= 5000 ppm	#
Organoleptic properties	Conform	PhEur	
Impurity E	<= 0,2 %	<= 0,2 %	=
Identification	Conform (A,B)	Test PhEur (A,B)	
Impurity D	<= 0,2 %	<= 0,2 %	=
pH of 5% aqueous solution	3,4	3,2 - 3,8	=
Impurity G	<= 0,2 %	<= 0,2 %	=
Appearance of MeOH 5% solution	Conform		=
Impurity F	<= 0,2 %	<= 0,2 %	=
Impurity A	<= 0,2 %	<= 0,2 %	=
Impurity C	<= 0,2 %	<= 0,2 %	=
Impurity B	<= 0,2 %	<= 0,2 %	=

Organoleptic characteristics: White or almost white, fine, crystalline powder. Very slightly soluble in water, freely soluble in methylene chloride, soluble in methanol, sparingly soluble in ethanol 96%.

Conservation: In tightly closed containers. Protect from light and moisture.

Date of analysis: 17/03/2022

Responsible: C. Codina

Judgement:
APPROVED

Technical director: Montserrat Enrique

Manufacturer: F00027 ISOCHEM

Manufacturer batch: 2001090059

Product	Name	Capacity	Batch
1103547	AMIODARONA CLORHIDRATO	5 g	220259-E-1
1103547	AMIODARONA CLORHIDRATO	5 g	220259-E-2
1103547	AMIODARONA CLORHIDRATO	5 g	220259-E-3
1103547	AMIODARONA CLORHIDRATO	5 g	220259-E-4
1103548	AMIODARONA CLORHIDRATO	25 g	220259-G-1
1103548	AMIODARONA CLORHIDRATO	25 g	220259-G-2
1103548	AMIODARONA CLORHIDRATO	25 g	220259-G-3
1103548	AMIODARONA CLORHIDRATO	25 g	220259-G-4
1103549	AMIODARONA CLORHIDRATO	1 kg	220259-P-1
1103549	AMIODARONA CLORHIDRATO	1 kg	220259-P-2
1370169	AMIODARONA CLORHIDRATO (FLB) (INACTIVO)	10 g	220259-F-1

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

www.acofarma.com

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