



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 252096

Product:	AMIODARONE HYDROCHLORIDE
Lot:	252096
Expiry date:	30/05/2030
Reference:	Cumple PhEur12.1
Synonyms:	
Formula:	C ₂₅ H ₂₉ I ₂ NO ₃ .HCl
Molecular weight:	682 g/mol

Assay	Result	Specification	
Identification	Conform (A,B)	Test PhEur (A,B)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		
pH	3,7	3,2 - 3,8	
Impurity H	<= 0,02 %	<= 0,02 %	
Related substances (HPLC)	Conform		
Iodides	<= 150 ppm	<= 150 ppm	
Elemental impurities	Conform	Test PhEur	#
Loss on drying	0,05 %	<= 0,5 %	
Sulphated ashes	0,00 %	<= 0,1 %	
Assay	99,8 %	98,5 - 101,0 %	
Impurity C	< 0,05 %	<= 0,2 %	
Impurity D	< 0,05 %	<= 0,2 %	
Impurity G	< 0,05 %	<= 0,2 %	
Unspecified Impurities	< 0,05 %	<= 0,10 %	
Total impurities	< 0,05 %	<= 0,5 %	
Residual solvent: Ethanol	< 5000 ppm	<= 5000 ppm	#
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Residual solvent: Benzene	< 2 ppm	<= 2 ppm	#
Residual solvent: Methanol	< 3000 ppm	<= 3000 ppm	#
Residual solvent: Isopropanol	< 5000 ppm	<= 5000 ppm	#
Nitrosamine impurities	Conform		#

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: 19/01/2026

Responsible: B.Chia

Judgement:
APPROVED

Technical director: Montserrat Enrique
Manufacturer: F00399 CTX Lifesciences Pvt Ltd.
Manufacturer batch: 25AM000126

Product	Name	Capacity	Batch
1103547	AMIODARONA CLORHIDRATO	5 g	252096-E-1
1103547	AMIODARONA CLORHIDRATO	5 g	252096-E-2
1103548	AMIODARONA CLORHIDRATO	25 g	252096-G-1
1103548	AMIODARONA CLORHIDRATO	25 g	252096-G-2
1103549	AMIODARONA CLORHIDRATO	1 kg	252096-P-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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