



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 215959

Product:	FLECAINIDE ACETATE
Lot:	215959
Expiry date:	01/09/2025
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₁₉ H ₂₄ F ₆ N ₂ O ₅
Molecular weight:	474,4 g/mol

Assay	Result	Specification	
Impurity D	NDT	<= 0,2 %	
Identification	Conform (A,C)	Test PhEur (A,C)	
Impurity E	NDT	<= 0,2 %	
Impurity A	<= 0,05 %	<= 0,2 %	
Impurity C	<= 0,05 %	<= 0,2 %	
pH of the 2,5% aqueous solution	7,0	6,7-7,1	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#
Impurity B	<= 0,2 %	<= 0,2%	
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	<= 0,05 %	<= 0,10 %	
Appearance of solution	Conform	Test PhEur	
Total impurities	<= 0,05 %	<= 0,5 %	
Loss on drying	0,15 %	<= 0,5%	
Sulphated ashes	0,03 %	<= 0,1%	
Related substances (HPLC)	Conform	Test Ph. Eur.	
Heavy metals	<= 20 ppm	<= 20 ppm	
Assay	99,8 %	98,0-101,0%	

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 10/11/2021

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: FC0A1319

Product	Name	Capacity	Batch
1144249	FLECAINIDA ACETATO	5 g	215959-E-1

1144249	FLECAINIDA ACETATO	5 g	215959-E-2
1144250	FLECAINIDA ACETATO	10 g	215959-F-1
1144250	FLECAINIDA ACETATO	10 g	215959-F-2
1144251	FLECAINIDA ACETATO	25 g	215959-G-1
1144251	FLECAINIDA ACETATO	25 g	215959-G-2
1144252	FLECAINIDA ACETATO	50 g	215959-I-1
1144252	FLECAINIDA ACETATO	50 g	215959-I-2

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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