



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 225164

Product:	FLECAINIDE ACETATE
Lot:	225164
Expiry date:	28/02/2026
Reference:	Cumple PhEur10.8
Synonyms:	
Formula:	C ₁₉ H ₂₄ F ₆ N ₂ O ₅
Molecular weight:	474,4 g/mol

Assay	Result	Specification	
pH of the 2,5% aqueous solution	6,9	6,7-7,1	=
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Appearance of solution	Conform	Test PhEur	=
Total impurities	< 0,5 %	<= 0,5 %	=
Organoleptic properties	Conform	PhEur	
Unspecified Impurities	< 0,10 %	<= 0,10 %	=
Identification	Conform (A,B)	Test PhEur (A,C)	
Impurity E	< 0,2 %	<= 0,2 %	=
Loss on drying	0,03 %	<= 0,5%	
Heavy metals	< 20 ppm	<= 20 ppm	=
Related substances (HPLC)	Conform	Test Ph. Eur.	=
Impurity B	< 0,2 %	<= 0,2%	=
Impurity D	< 0,2 %	<= 0,2 %	=
Impurity C	< 0,2 %	<= 0,2 %	=
Impurity A	< 0,2 %	<= 0,2 %	=
Assay	100,0 %	98,0-101,0%	
Sulphated ashes	0,04 %	<= 0,1%	=

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/10/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: FC0A2304

Product	Name	Capacity	Batch
1144249	FLECAINIDA ACETATO	5 g	225164-E-1

1144250	FLECAINIDA ACETATO	10 g	225164-F-1
1144250	FLECAINIDA ACETATO	10 g	225164-F-2
1144250	FLECAINIDA ACETATO	10 g	225164-F-3
1144251	FLECAINIDA ACETATO	25 g	225164-G-1
1144252	FLECAINIDA ACETATO	50 g	225164-I-1
1144252	FLECAINIDA ACETATO	50 g	225164-I-2
1144252	FLECAINIDA ACETATO	50 g	225164-I-3
1144253	FLECAINIDA ACETATO	250 g	225164-N-1
1144253	FLECAINIDA ACETATO	250 g	225164-N-2
1144253	FLECAINIDA ACETATO	250 g	225164-N-3
1144255	FLECAINIDA ACETATO	1 Kg	225164-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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