



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 241893

Product:	FLECAINIDE ACETATE
Lot:	241893
Expiry date:	30/07/2028
Reference:	Cumple PhEur11.5
Synonyms:	
Formula:	C ₁₉ H ₂₄ F ₆ N ₂ O ₅
Molecular weight:	474,4 g/mol

Assay	Result	Specification	
Identification	Conform (A,C)	Test PhEur (A,C)	
Organoleptic properties	Conform	PhEur	
Appearance of solution	Conform		=
pH of the 2,5% aqueous solution	6,8	6,7-7,1	=
Impurity B	<= 0,2 %	<= 0,2%	=
Related substances (HPLC)	Conform	Test Ph. Eur.	=
Loss on drying	0,05 %	<= 0,5%	
Sulphated ashes	0,03 %	<= 0,1%	=
Assay	100,0 %	98,0-101,0%	
Impurity A	< 0,05 %	<= 0,2 %	=
Impurity C	< 0,01 %	<= 0,2 %	=
Impurity D	< 0,01 %	<= 0,2 %	=
Impurity E	< 0,01 %	<= 0,2 %	=
Unspecified Impurities	< 0,03 %	<= 0,10 %	=
Total impurities	< 0,05 %	<= 0,5 %	=
Residual solvent: Toluene	< 890 ppm	<= 890 ppm	#
Elemental impurities	Conform	Test PhEur	#
Nitrosamine impurities	Conform	Test PhEur	#

Organoleptic characteristics:

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 02/10/2024

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00393 QUÍMICA SINTÉTICA, S.A.

Manufacturer batch: FC0A4313

Product	Name	Capacity	Batch
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1144249	FLECAINIDA ACETATO	5 g	241893-E-1
1144249	FLECAINIDA ACETATO	5 g	241893-E-2
1144249	FLECAINIDA ACETATO	5 g	241893-E-3
1144250	FLECAINIDA ACETATO	10 g	241893-F-1
1144250	FLECAINIDA ACETATO	10 g	241893-F-2
1144250	FLECAINIDA ACETATO	10 g	241893-F-3
1144251	FLECAINIDA ACETATO	25 g	241893-G-1
1144251	FLECAINIDA ACETATO	25 g	241893-G-2
1144251	FLECAINIDA ACETATO	25 g	241893-G-3
1144252	FLECAINIDA ACETATO	50 g	241893-I-1
1144252	FLECAINIDA ACETATO	50 g	241893-I-2
1144252	FLECAINIDA ACETATO	50 g	241893-I-3

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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