

CERTIFICATE OF ANALYSIS

PRODUCT **FLECAINIDE ACETATE**

COMPLIES WITH PH.EUR-R1CEP2013-145 REV01

BATCH

FC0A2304

Manufacturing Date: **02.2022**

Retest Date: **02.2026**

Release Date: **05.2022**

TEST	REQUIREMENT	RESULT
DESCRIPTION	White or almost white crystalline powder	Conforms
IDENTIFICATION: A) Melting point:	146°C -152°C	151 °C
IDENTIFICATION A): Melting range:	Not greater than 3°C	2,9
IDENTIFICATION: B) IR:	Positive	Positive
IDENTIFICATION C): UV, Specific absorbance at 298 nm maximum:	61-65	62
IDENTIFICATION:(D) Acetate:	Positive	Positive
APPEARANCE OF SOLUTION:	Clear and colourless	Conforms
pH:	6,7-7,1	6,9
SULPHATED ASH:	Not more than 0.1%	0,04 %
LOSS ON DRYING:	Not more than 0.5%	0,06 %
CHROMATOGRAPHIC PURITY (TLC)		
Impurity B:	Not more than 0.2%	Conforms
ASSAY (0,1N HClO ₄):	98,0%-101,0% (on the dried substance)	99,9 %
BULK DENSITY:	Not more than 0.5 g/ml	0,37 g/ml
PARTICLE SIZE		
D (v, 0,1):	Not more than 15 µm	4 µm
D (v, 0,5):	Not more than 35 µm	16 µm
D (v, 0,9):	Not more than 75 µm	39 µm
RELATED SUBSTANCES (HPLC)		
Impurity A:	Not more than 0.2%	0,00 %
Impurity C:	Not more than 0.2%	0,00 %

Nº lote ACOFARMA:

225164

Firma y fecha:

27/09/22

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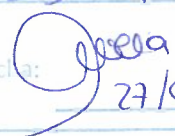
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TEST	REQUIREMENT	RESULT
✓ Impurity D:	Not more than 0.2%	0,00 %
✓ Impurity E:	Not more than 0.2%	0,00 %
✓ Unspecified impurities:	Not more than 0.10%	<0,05 %
✓ Total impurities:	Not more than 0.5%	<0,05 %
RESIDUAL SOLVENT (GC)		
✓ Toluene:	Not more than 890 ppm	315 ppm

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