



Certificate of Analysis

FLECAINIDE ACETATE

Batch ID: FC0A3335

Product Description: FLECAINIDE ACETATE

Manufacturing Date: Dec-2023

Re-Test Date: Dec-2027

Product SAP Code: 102628

TEST	SPECIFICATION	RESULT
DESCRIPTION	White or almost white crystalline powder	Complies
IDENTIFICATION		
IDENTIFICATION A) Melting point	146 - 152 °C	151 °C
IDENTIFICATION B) Melting Range	Not greater than 3°C	1 °C
IDENTIFICATION C) IR	Positive	Complies
IDENTIFICATION D) UV, Specific absorbance at 298 nm maximum	61-65	62
IDENTIFICATION E): Acetate	Positive	Complies
SULPHATED ASH	Not more than 0.1%	0.03 %
APPEARANCE OF SOLUTION	Clear and colourless	Complies
pH	6.7 - 7.1	6.8
LOSS ON DRYING	Not more than 0.5%	0.1 %
ASSAY (HClO4 0.1N)	98.0 - 101.0 % (on the dry substance)	99.3 %
CHROMATOGRAPHIC PURITY (TLC)	Not more than 0.2%	Complies
Impureza B		
PARTICLE SIZE		
D(v,0.1)	Not more than 15 µm	9 µm
D(v,0.5)	Not more than 35 µm	30 µm
D(v,0.9)	Not more than 75 µm	54 µm
BULK DENSITY	Not more than 0.5 g/ml	0.53 g/mL
RELATED SUBSTANCES (HPLC)		
Impurity A	Not more than 0.2%	<0.05 %
Impurity C	Not more than 0.2%	<0.01 %
Impurity D	Not more than 0.2%	<0.01 %
Impurity E	Not more than 0.2%	<0.01 %
Unspecified Impurities	Not more than 0.10%	<0.05 %
Total Impurities	Not more than 0.5%	<0.05 %
RESIDUAL SOLVENTS (GC)	Not more than 890 ppm	285 ppm
Toluene		

Nº lote ACOFARMA:

240384

Firma y fecha

Quera

19/02/24

Complies with Ph.Eur.R1CEP 2013-145 Rev 01 and customer specifications. Manufactured in compliance with cGMP requirements.

Dispositioned By: Francisco Fernandez (QA Release Manager)

Disposition Date: 21-Dec-2023

This is an electronic signature

Result: Approved