

METAPHARMACEUTICAL

N DE LOTE:

0360925

Alondra
26/09/2025



Redefining Healthcare
Unimark Remedies Ltd, Vapi

CERTIFICATE OF ANALYSIS

Product	FLECAINIDE ACETATE Ph. Eur.		
Batch No.	FLA-0061224	Date of Mfg.	December - 2024
Batch Qty	25.0 Kg	Date of Exp.	November - 2029
Date of Release	18-08-2025	Page No.	01 of 02

Sr. No.	Test	Results	Specification
1	Description	A white, very hygroscopic, crystalline powder	A white or almost white, crystalline powder, very hygroscopic
2	Solubility	Complies	Soluble in water and in anhydrous ethanol. It is freely soluble in dilute acetic acid and practically insoluble in dilute hydrochloric acid
3	Identification: First Identification: A, C		
	A. Melting point	149.2°C to 150.3°C	146°C to 152°C with a melting range not greater than 3°C.
	C. Infrared Absorption	Complies	The IR spectrum of the sample to be concordant with the IR spectrum of Flecaïnide acetate working standard
4	Appearance of Solution	Complies	Solution is clear and colourless.
5	Loss on drying	0.12	Not more than 0.5% w/w.
6	Sulphated ash	0.04	Not more than 0.1% w/w.
7	pH	6.92	Between 6.7 and 7.1
8	Impurity B (TLC)	Complies	Any spot due to impurity B is not more intense than the corresponding spot in the chromatogram obtained with the reference solution(a) (Not more than 0.2%)
9	Related substance (By HPLC)		
	Impurity A	Below Disregard Limit	Not more than 0.20% w/w
	Impurity C	Below Disregard Limit	Not more than 0.20% w/w
	Impurity D	Not Detected	Not more than 0.20% w/w
	Impurity E	Not Detected	Not more than 0.20% w/w
	Any unspecified impurities	Below Disregard Limit	Not more than 0.10% w/w
	Total impurities	Below Disregard Limit	Not more than 0.50% w/w
10	Heavy metals	Complies	Not more than 20 ppm
11	Acetate content	12.7	Between 12.4% and 12.8%
12	Assay (On dried basis)	100.3	Not less than 98.0% and Not more than 101.0%



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13	Residual solvents by GCHS		
	Isopropyl alcohol	Not Detected	Not more than 5000 ppm
	Methylene Chloride	Not Detected	Not more than 600 ppm
	Cyclohexane	Not Detected	Not more than 3880 ppm
	N, N-Dimethyl acetamide	Not Detected	Not more than 1090 ppm
	Toluene	211 ppm	Not more than 890 ppm
	Additional customer tests		
14	PSD (By Malvern Mastersizer) (μm)		
	D (50)	34.0	For information
	D (90)	154.0	For information
15	Bulk Density (g/mL)		
	Untapped density	0.23	For information
	Tapped density	0.45	For information

Storage : Store in an airtight container, protected from light.

Remark : The material complies as per EP specification

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