

FLECAINIDA ACETATO (EUR. PH.)

PRODUCT CODE: 010316	CAS Nº: 54143-56-5	ANALYSIS Nº: 305/25
MANUFACTURER BATCH: FLA-0061224	CERTIFICATE ID: 48.457	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/12/2024	
METAPH BATCH: 0360925	EXPIRY DATE: 30/11/2029	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, very hygroscopic, crystalline powder	White, very hygroscopic, crystalline powder
Solubility	Soluble in water and in anhydrous ethanol. It is freely soluble in dilute acetic acid and practically insoluble in dilute hydrochloric acid	Complies (*)
Identification A	Complies	Complies
Identification C	Complies	Complies
Melting point	146 - 152 °C	149 °C
Appearance of solution	Clear and colourless	Clear and colourless
pH	6.7 - 7.1	6.9
Impurity B	=< 0.2 %	< 0.2 %
Related substances		
Impurity A	=< 0.2 %	< 0.05 %
Impurity C	=< 0.2 %	< 0.05 %
Impurity D	=< 0.2 %	Not Detected
Impurity E	=< 0.2 %	Not Detected
Unspecified impurities	=< 0.10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Loss on drying	=< 0.5 %	0.06 %
Sulfated ash	=< 0.1 %	0.04 %
Assay	98.0 - 101.0 %	100.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Flecainide Acetate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

All data controlled by Metapharmaceutical Industrial SL.

(*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Keep the container tightly closed and protected from moisture and direct sun light.

Analysis date: 06/11/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40001572
 UNIMARK REMEDIES LTD
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 396195 VAPI
 GUJARAT(India)

