



TECHNICAL DATA SHEET

010316-TDS-ENG-2023

FLECAINIDA ACETATO (EUR. PH.)		
DESCRIPTION DCI: FLECAINIDE ACETATE		DESCRIPTION DOE: FLECAINIDA ACETATO
CAS Nº: 54143-56-5	EC Nº: 258-997-5	AEMPS CODE: 2363AC
MOL. WEIGHT: 474.40	MOL. FORMULA: C ₁₉ H ₂₄ F ₆ N ₂ O ₅	ARTICLE CODE: 010316

ATTRIBUTES	SHOULD BE
Appearance	White or almost 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
Identification A	Complies
Identification C	Complies
Melting point	146 - 152 °C
Appearance of solution	Clear and colourless
pH	6.7 - 7.1
Impurity B	=< 0.2 %
Related substances	
Impurity A	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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".

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.