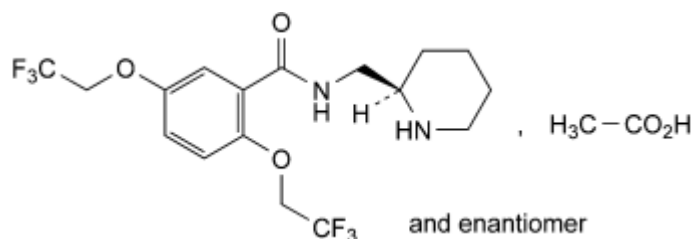


Product Specification

PRODUCT Flecainide Acetate EP/BP

CAS [54143-56-5]

C₁₉H₂₄F₆N₂O₅



CHARACTERISTICS

A white or almost white, very hygroscopic, crystalline powder.
Soluble in water and in anhydrous ethanol. It is freely soluble in dilute acetic acid and practically insoluble in dilute hydrochloric acid.
Melting point 146°C to 152°C.

TEST	SPECIFICATION
Content	98.0-101.0% (dried substance)
Identification	Complies with EP/BP tests
Appearance of solution	The solution is clear and colourless
pH	6.7 to 7.1
Impurity B (by TLC)	Maximum 0.2%
Related substances	Individual impurities A,C,D,E Maximum 0.2% (each) Unspecified impurities Maximum 0.1% Total impurities Maximum 0.5%
Heavy metals	Maximum 20 ppm
Loss on drying	Maximum 0.5%
Sulphated ash	Maximum 0.1%

STORAGE

Should be stored in a well-closed, light resistant container in a cool, dry place.

THIS PRODUCT COMPLIES WITH THE SPECIFICATION OF EP/BP

