

Lote 0070616

COMO, 09/05/2016

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ANALYSIS No. F124/2016

BATCH No. 128316009

Manufacturing date: May 2016

Retest date: May 2021

Batch size: 561,00 Kg

PRODUCT

FLECAINIDE ACETATE NS
CAS N. 54143-56-5

Physical State: Hygroscopic crystalline powder

Molecular weight: 474.4

Colour: White to almost white

Formula : C₁₇H₂₀F₆N₂O₃·C₂H₄O₂

Odour:

Method No. 4181 Ed. V

Solubility: Soluble in water and ethanol. Freely soluble in dilute acetic acid, practically insoluble in dilute HCl.

DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
IDENTIFICATION				
I.R. Spectrum	Positive	Positive	Positive	Positive
UV in alcohol	Positive	Positive	Positive	Positive
Clarity and Colour of solution	Clear Colorless	Clear Colorless	Clear Colorless	Clear Colorless
Melting range	150.0 °C - 151.0 °C	min. 146°C max. 152°C range: n.m.t. 3°C	min. 146°C max. 152°C range: n.m.t. 3°C	min. 146°C max. 152°C range: n.m.t. 3°C
Loss on drying	0.09 %	n.m.t. 0.5%	n.m.t. 0.5%	n.m.t. 0.5%
Residue on ignition	0.03 %	n.m.t. 0.2%	n.m.t. 0.1%	n.m.t. 0.1%
Heavy Metals	I.t. 20 ppm	n.m.t. 20 ppm	n.m.t. 20 ppm	n.m.t. 20 ppm
Chromatographic purity HPLC				
Cyclized derivative*	I.t. 0,004%	n.m.t. 0.5%	n.m.t. 0.2%	n.m.t. 0.1%
Acid derivative	I.t. 0,01%	n.m.t. 0.5%	n.m.t. 0.2%	n.m.t. 0.1%
Acetyl derivative	I.t. 0,01%	n.m.t. 0.5%	n.m.t. 0.15%	n.m.t. 0.10%
Pyridyl derivative	I.t. 0,004%	n.m.t. 0.5%	n.m.t. 0.2%	n.m.t. 0.1%
Ester derivative	I.t. 0,011%	n.m.t. 0.5%	n.m.t. 0.15%	n.m.t. 0.10%
Single unknown impurity	I.t. 0,005%	n.m.t. 0.10%	n.m.t. 0.10%	n.m.t. 0.10%
Total impurities	I.t. 0,011%	n.m.t. 2.0%	n.m.t. 0.5%	n.m.t. 0.50%
Content of Acetate (on dried substance)	12.69 %	min. 12.4% max. 12.8%		min. 12.4% max. 12.8%

Qualified Person

Quality Control Manager

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PRODUCT

FLECAINIDE ACETATE NS
CAS N. 54143-56-5

Physical State: Hygroscopic crystalline powder

Molecular weight: 474.4

Colour: White to almost white

Formula : C17H20F6N2O3·C2H4O2

Odour:

Method No. 4181 Ed. V

Solubility: Soluble in water and ethanol. Freely soluble in dilute acetic acid, practically insoluble in dilute HCl.

DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Assay HClO4 0.1N on dried substance	100.31 %	min. 98.0% max. 101.0%	min. 98.0% max. 101.0%	min. 98.0% max. 101.0%
pH	6.93		min. 6.7 max. 7.1	min. 6.7 max. 7.1
(Piperidin-2-yl) methanamine (TLC)	I.t. 0,04%		n.m.t. 0.2%	n.m.t. 0.2%
Residual Solvents GC Ethyl acetate	93 ppm			n.m.t. 1000 ppm
Particle size VMD d (0.5) d (0.9)	18.80 mcm 9.14 mcm 44.14 mcm			n.m.t. 40 mcm n.l.t. 5 mcm n.m.t. 100 mcm

* USP and Ph. Eur. related compound A Class 1 solvents are absent according to ICH Q3C. We hereby certify that the material identified above has been analyzed and found in accordance with U.S.P., Ph. Eur. and A.M.S.A. specifications. This batch was manufactured in compliance with the cGMPs, according to ICH Q7A and to the filed DMF.


 Qualified Person


 Quality Control Manager

Release date: 09/05/2016