

COMO, 02/11/2020

ANALYSIS No. F2132020

BATCH No. 128320001

Manufacturing date: March 2020

Re-test date: March 2025

Batch size: 584,50 Kg

PRODUCT

FLEGAINIDE ACETATE NS
CAS N. 54143-58-3

Physical State: Hygroscopic crystalline powder

Colour: White to almost white

Odour: n/a

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

Molecular weight: 474,4

Formula : C₁₇H₂₀F₆N₂O₃·C₂H₄O₂

Method No. 4181 Ed. VII

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	148.1 °C - 150.2 °C	min. 146°C max. 152°C range: n.m.l. 3°C	min. 146°C max. 152°C range: n.m.l. 3°C	min. 146°C max. 152°C range: n.m.l. 3°C
Loss on drying	0.06 %	n.m.l. 0.5 %	n.m.l. 0.5 %	n.m.l. 0.5 %
Residue on Ignition	0.05 %	n.m.l. 0.2 %	n.m.l. 0.1 %	n.m.l. 0.1 %
Chromatographic purity HPLC				
Cyclized derivative*	lt. 0.0025%	n.m.l. 0.5 %	n.m.l. 0.2 %	n.m.l. 0.1 %
Acid derivative	lt. 0.01%	n.m.l. 0.5 %	n.m.l. 0.2 %	n.m.l. 0.1 %
Acetyl derivative	lt. 0.0025%	n.m.l. 0.5 %	n.m.l. 0.15 %	n.m.l. 0.10 %
Pyridyl derivative	lt. 0.0025%	n.m.l. 0.5 %	n.m.l. 0.2 %	n.m.l. 0.1 %
Ester derivative	lt. 0.01%	n.m.l. 0.5 %	n.m.l. 0.15 %	n.m.l. 0.10 %
Single unknown impurity	lt. 0.025%	n.m.l. 0.10%	n.m.l. 0.10%	n.m.l. 0.10%
Total impurities	lt. 0.025%	n.m.l. 2.0%	n.m.l. 0.5 %	n.m.l. 0.50%
Content of Acetate (on dried substance)	12.66 %	min. 12.4 % max. 12.8 %		min. 12.4 % max. 12.8 %

N° DI LOTTO ASSEGNATO

202100181 -

B. B.
Qualified Person

CFM Co. FARMACEUTICI MILANESE SpA

10/13/21

Boatelli
Quality Control Manager





S.P.A.

AMSA - ANONIMA MATERIE SINTETICHE & AFFINI S.P.A.
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ANALYSIS No. F213/2020		BATCH No. 128320001		
Manufacturing date: March 2020		Releas date: March 2025		Batch size: 584,50 Kg
PRODUCT		FLECAINIDE ACETATE N9 CAS N. 84143-58-5		
Physical State: Hygroscopic crystalline powder				
Colour:	White to almost white	Molecular weight:	474,4	
Odour:	n/a	Formula:	C ₁₇ H ₂₀ F ₈ N ₂ O ₃ ·C ₂ H ₄ O ₂	
Solubility:	Soluble in water and ethanol. Freely soluble in dilute acetic acid, practically insoluble in dilute HCl.	Method No.	4161 Ed. VII	
DETERMINATIONS	RESULTS	LIMITS USP	LIMITS EP	IN-HOUSE LIMITS
Assay HClO ₄ 0.1N on dried substance	100.02 %		min. 98.0% max. 101.0%	min. 98.0% max. 101.0%
pH	6.95		min. 6.7 max. 7.1	min. 6.7 max. 7.1
(Piperidin-2-yl) methanamine (TLC)	l.t. 0.04%		n.m.t. 0.2%	n.m.t. 0.2%
Residual Solvents GC Ethyl acetate	220 ppm			n.m.t. 1000 ppm
Particle size VMD (D ₄ :3)	22.3 mm			n.m.t. 40 mm
Dv (50)	14.6 mm			n.l. 5 mm
Dv (90)	47.2 mm			n.m.t. 100 mm

* 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.

N° DI LOTTO ASSEGNATO

202100181 -

CFM Co. FARMACEUTICA MILANESE SpA

Release date: 08/05/2020

Quality Control Manager

C.I.C. COMO N. 70858 C.E. MILANO N. 601857 REGISTRO DELLE IMPRESE 139136 CODICE FISCALE E PARTITA IVA 00795320189

