

Lot: 0161019

Sample Nr. 210113738 Manufacturing Date 18/02/2019 Retest Date 03/04/2022

Code Lot/Batch Description Product Class
G1MR 0000290106 DALFAMPRIDINE MICRONIZED FERT CLASSE A

Tests	Results	Units	Specification
CHARACTERS			
APPEARANCE	Complies to specification	-	White to off-white powder
C-USP<197> - C-EP 2.2.24.			
IR IDENTIFICATION	Complies to specification	-	Complies with Ref.STD
IDENTIFICATION HPLC G1T			
RETENTION TIME	Complies to specification	-	Complies with Ref.STD
RELATED SUBSTANCES HPLC G1			
2-Aminopyridine	Not Detected	%	NMT 0.1%
Isonicotinic Acid	Not Detected	%	NMT 0.1%
Each unknown impurity	Not Detected	%	NMT 0.10%
Total impurities	Not Detected	%	NMT 0.5%
RELATED SUBSTANCES UPLC-MS G1			
3-Aminopyridine	Not Detected	-	NMT 75 ppm
Dalfampridine Dimer	Not Detected	-	NMT 75 ppm
Isonicotinamide	Complies to specification	-	NMT 75 ppm
Dalfampridine n-oxide	Complies to specification	-	NMT 75 ppm
ASSAY HPLC G1T			
ASSAY (Anhydrous and solvent free basis)	99.7	%	Between 98.0% and 102.0%
C-USP <921> METHOD I - C-EP 2.5.12.			
WATER			
RESIDUAL SOLVENTS GC G1SR	0.05	%	NMT 0.5%
Acetone	<160	ppm	NMT 5000 ppm
Isobutyl alcohol	Not Detected	ppm	NMT 5000 ppm
MIBK	Not Detected	ppm	NMT 4500 ppm
Total residual solvents	0	ppm	NMT 5000 ppm
C-USP<281> - C-EP 2.4.14.			
RESIDUE ON IGNITION/SULPHATED ASH			
C-USP<231>METHOD II - C-EP 2.4.8.	0.01	%	NMT 0.1%
HEAVY METALS	Complies to specification	-	NMT 10 ppm

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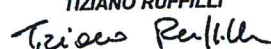
Tests	Results	Units	Specification
C-USP<941> - C-EP 2.9.33. (X-RAY DIFFR)			
Crystallinity	Complies to specification		Complies with Ref.STD

Notes
FERT
PROCOS CLASS

Pharmaceutical Active Ingredient
PRODUCT COMPLIES WITH PROCOS SPECIFICATIONS

Lot Released : Complies with all specifications of the testing instruction and with GMP standard.

Cameri, September 18, 2019
Prococo Spa
Quality Control

Authorized Person
TIZIANO RUFFILLI


A.C.E.F. S.p.A