

0060918

Sample Nr. 210082083 Manufacturing Date 04/04/2017 Retest Date 04/04/2022

Code	Lot/Batch	Description	Product Class	
G1MR	0000254876	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	<0.02 (LOQ)	%	NMT 0.10%	
Total Impurities	0.00	%	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)	100.8	%	Between 98.0% and 102.0%	
C-USP <921> METHOD I - C-EP 2.5.12.				
WATER	0.03	%	NMT 0.5%	
RESIDUAL SOLVENTS GC G1SR				
Acetone	<160 (LOQ)	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	Not Detected	%	NMT 0.1%	
C-USP<231>METHOD II - C-EP 2.4.8.				
HEAVY METALS	Complies to specification	-	NMT 10 ppm	

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G1MR	0000254876	DALFAMPRIDINE MICRONIZED	FERT CLASSE A

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	Pharmaceutical Active Ingredient		
PROCOS CLASS	PRODUCT COMPLIES WITH PROCOS SPECIFICATIONS		

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

Cameri, June 21, 2018

Procos Spa
Quality Control

Authorized Person
TIZIANO RUFFILLI

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

21/06/18
T. Ruffilli