

Certificate of Analysis

Sample Nr. 210203564

Manufacturing Date 04-MAR-22

Retest date 04-MAR-27

Code	Lot/Batch	Description	Product Class
G1MR	0000353338	DALFAMPRIDINE MICRONIZED	FERT G1MR-CLASSE A

Tests	Results	Units	Specifications
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	0.03	%	NMT 0.1%
Each unknown impurity	<0.02 (LOQ)	%	NMT 0.10%
Total impurities	0.03	%	NMT 0.5%
RELATED SUBSTANCES UPLC-MS G1			
3-Aminopyridine	Not Detected	-	NMT 75 ppm
Dalfampridine Dimer	Not Detected	-	NMT 75 ppm
Isonicotinamide	Not Detected	-	NMT 75 ppm
Dalfampridine n-oxide	Complies to specification	-	NMT 75 ppm
ASSAY HPLC G1T			
ASSAY (Anhydrous and solvent free basis)	100.2	%	Between 98.0% and 102.0%
C-USP <921> METHOD I - C-EP 2.5.12.			
WATER	0.07	%	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	0.01	%	NMT 0.1%
C-USP<231>METHOD II - C-EP 2.4.8.			
HEAVY METALS	Complies to	-	NMT 10 ppm

Certificate of Analysis

Sample Nr. 210203564 Manufacturing Date 04-MAR-22 Retest date 04-MAR-27

Code	Lot/Batch	Description	Product Class
G1MR	0000353338	DALFAMPRIDINE MICRONIZED	FERT G1MR-CLASSE A

Tests	Results	Units	Specifications
	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,

Procos SpA
Quality Control

Analytical Release Date: 09/07/2024
CoA Issuing Date: 30/09/2025

A.C.E.F. S.R.L.

Authorized Person

Tiziano Ruffilli



METAPHARMACEUTICAL

N DE LOTE:

0321025


30/10/2025