

## 4-AMINOPIRIDINA (FAMPRIDINA) MICRONIZADA

PRODUCT CODE: 009065	CAS Nº: 504-24-5	ANALYSIS Nº: 319/24
MANUFACTURER BATCH: 0000353230	CERTIFICATE ID: 44.500	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 03/03/2022	
METAPH BATCH: 0061224	RETEST DATE: 03/03/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white powder	White powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification HPLC	Complies	Complies
Melting point	158 - 162 °C	159 °C
Related substances		
2-aminopyridine	=< 0.1 %	Not detected
Isonicotinic acid	=< 0.1 %	Not detected
Any other impurity	=< 0,10 %	< 0.05 %
Total impurities	=< 0.5 %	< 0.05 %
Related substances UPLC-MS		(*)
3-aminopyridine	=< 75 ppm	Not detected
Dalfampridine dimer	=< 75 ppm	Not detected
Isonicotinamide	=< 75 ppm	Not detected
Dalfampridine n-oxide	=< 75 ppm	< 75 ppm
Assay	98.0 - 102.0 %	99.7 %
Water	=< 0.5 %	0.1 %
Residual solvents		(*)
Acetone	=< 5000 ppm	< 160 ppm
Isobutyl alcohol	=< 5000 ppm	Not detected
Methyl Isobutyl Ketone	=< 5000 ppm	Not detected
Total residual solvents	=< 5000 ppm	< 160 ppm
Residue on ignition	=< 0.1 %	0.01 %
Heavy metals	=< 10 ppm	< 10 ppm (*)
Cristallinity	Complies	Complies (*)

### COMPLIES WITH

Manufacturer specifications

### REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

4-Aminopyridine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(\*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Analysis date: 29/01/2025  
 Signature: Albert Sanchez Lopez (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40000159  
 PROCOS SpA, CBC group  
 Via G. Matteotti,, 249  
 28062 CAMERI (NO)  
 (Italia)





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### STORAGE

Keep the container closed. Store it in a well-ventilated place and away from direct sunlight.

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