

TECHNICAL DATA SHEET

009065-TDS-ENG-2025

4-AMINOPIRIDINA (FAMPRIDINA) MICRONIZADA		
DESCRIPTION DCI: 4 AMINOPYRIDINE		DESCRIPTION DOE: 4 AMINOPIRIDINA
CAS Nº: 504-24-5	EC Nº: 207-987-9	AEMPS CODE: 8154B
MOL. WEIGHT: 94.11	MOL. FORMULA: C ₅ H ₆ N ₂	ARTICLE CODE: 009065

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Identification A	Complies
Identification B	Complies
Identification HPLC	Complies
Melting point	158 - 162 °C
Related substances	
2-aminopyridine	=< 0.1 %
Isonicotinic acid	=< 0.1 %
Any other impurity	=< 0,10 %
Total impurities	=< 0.5 %
Related substances UPLC-MS	
3-aminopyridine	=< 75 ppm
Dalfampridine n-oxide	=< 75 ppm
Dalfampridine dimer	=< 75 ppm
Isonicotinamide	=< 75 ppm
Assay	98.0 - 102.0 %
Water	=< 0.5 %
Residual solvents	
Acetone	=< 5000 ppm
Isobutyl alcohol	=< 5000 ppm
Methyl Isobuthyl Ketone	=< 5000 ppm
Total residual solvents	=< 5000 ppm
Residue on ignition	=< 0.1 %
Heavy metals	=< 10 ppm
Cristallinity	Complies

COMPLIES WITH

Manufacturer specifications

STORAGE

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

REMARKS

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

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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.