



## TECHNICAL DATA SHEET

009065-TDS-ENG-2023

AMINOPIRIDINA-4 MICRONIZADO PHARMA		
DESCRIPTION DCI: 4 AMINOPYRIDINE		DESCRIPTION DOE: 4 AMINOPIRIDINA
CAS N°: 504-24-5	EC N°: 207-987-9	AEMPS CODE: 8154B
MOL. WEIGHT: 94.11	MOL. FORMULA: C5H6N2	ARTICLE CODE: 009065

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Identification A	Complies
Identification B	Complies
Identification HPLC	Complies
Cristallinity	Complies
Melting point	158 - 162 °C
Related substances	
2-aminopyridine	= < 0.1 %
Isonicotinic acid	= < 0.1 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 0.5 %
Related substances UPLC-MS	
3-aminopyridine	= < 75 ppm
Dalfampridine dimer	= < 75 ppm
Isonicotinamide	= < 75 ppm
Dalfampridine n-oxide	= < 75 ppm
Water	= < 0.5 %
Residue on ignition	= < 0.1 %
Heavy metals	= < 10 ppm
Assay	98.0 - 102.0 %
Residual solvents	
Acetone	= < 5000 ppm
Isobutyl alcohol	= < 5000 ppm
Methyl Isobuthyl Ketone	= < 5000 ppm
Total residual solvents	= < 5000 ppm
Microbiological control	
TAMC	= < 1000 CFU/g
TYMC	= < 100 CFU/g
Escherichia coli	Absence/1g
Candida Albicans	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Salmonella	Absence/1g

### COMPLIES WITH

Manufacturer specifications



## TECHNICAL DATA SHEET

009065-TDS-ENG-2023

### AMINOPIRIDINA-4 MICRONIZADO PHARMA

DESCRIPTION DCI: 4 AMINOPYRIDINE		DESCRIPTION DOE: 4 AMINOPIRIDINA
CAS N°: 504-24-5	EC N°: 207-987-9	AEMPS CODE: 8154B
MOL. WEIGHT: 94.11	MOL. FORMULA: C <sub>5</sub> H <sub>6</sub> N <sub>2</sub>	ARTICLE CODE: 009065

#### 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.

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.