



TECHNICAL DATA SHEET

151420-TDS-ENG-2024

PIMOBENDAN USO VETERINARIO (EUR. PH.)		
DESCRIPTION DCI: PIMOBENDANE		DESCRIPTION DOE: PIMOBENDAN
CAS Nº: 74150-27-9	EC Nº: 640-420-7	AEMPS CODE: 7190A
MOL. WEIGHT: 334,37	MOL. FORMULA: C19H18N4O2	ARTICLE CODE: 151420

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, hygroscopic powder.
Solubility	Practically insoluble in water, freely soluble in dimethylformamide, slightly soluble in acetone and in methanol
Melting point	About 242 °C
Identification	Complies
Related substances	
Unspecified impurities	<= 0.20 %
Total impurities	<= 0.20 %
Water	<= 1.0 %
Sulfated ash	<= 0.10 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store in a cool place. Keep the container tightly closed, in a dry and well-ventilated place.

REMARKS

Pimobendan is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.