



TECHNICAL DATA SHEET

001956-TDS-ENG-2024

FENBENDAZOL FOR VETERINARY USE (EUR. PH.)		
DESCRIPTION DCI: FENBENDAZOLE		DESCRIPTION DOE: FENBENDAZOL
CAS Nº: 43210-67-9	EC Nº: 256-145-7	AEMPS CODE: 90390A
MOL. WEIGHT: 299,35	MOL. FORMULA: C15H13N3O2S	ARTICLE CODE: 001956

ATTRIBUTES	SHOULD BE
Appearance	White or almost white powder
Solubility	Practically insoluble in water, sparingly soluble in dimethylformamide, very slightly soluble in methanol
Identification	Complies
Related substances	
Impurity A	=< 0.5 %
Impurity B	=< 0.5 %
Unspecified impurities	=< 0.5 %
Total impurities	=< 1.0 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.3 %
Assay	98.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Preserve in well-closed, light-resistant containers.

REMARKS

Fenbendazole 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.