

**TECHNICAL DATA SHEET**

M010229-TDS-ENG-2026

<b>MEBENDAZOLE (EUR. PH.)</b>		
DESCRIPTION DCI: mebendazole		DESCRIPTION DOE: MEBENDAZOL
CAS N°: 31431-39-7	EC N°: 250-635-4	AEMPS CODE: 1877A
MOL. WEIGHT: 295.3	MOL. FORMULA: C <sub>16</sub> H <sub>13</sub> N <sub>3</sub> O <sub>3</sub>	ARTICLE CODE: M010229

<b>ATTRIBUTES</b>	<b>SHOULD BE</b>
Appearance	White or almost white powder
Solubility	Practically insoluble in water, in ethanol (96%) and in methylene chloride
Identification	Complies
Related substances	
Impurity G	=< 0.5 %
Impurity A	=< 0.25 %
Impurity B	=< 0.25 %
Impurity C	=< 0.25 %
Impurity D	=< 0.25 %
Impurity E	=< 0.25 %
Impurity F	=< 0.25 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 1.0 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

**COMPLIES WITH**

European Pharmacopoeia 12.2

**STORAGE**

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

**REMARKS**

It shows polymorphism.

Mebendazole 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.