



## TECHNICAL DATA SHEET

46433106-TDS-ENG-2024

MILTEFOSINA VETERINARIA (ESP. FAB.)		
DESCRIPTION DCI: miltefosine		DESCRIPTION DOE: MILTEFOSINA
CAS Nº: 58066-85-6	EC Nº: 622-572-6	AEMPS CODE: 7274A
MOL. WEIGHT: 236,74	MOL. FORMULA: C <sub>21</sub> H <sub>46</sub> NO <sub>4</sub> P	ARTICLE CODE: 46433106

ATTRIBUTES	SHOULD BE
Appearance	White powder
Solubility	Soluble in water (<2,5mg/mL at 25°C)
Identification (1)	Complies
Identification (2)	Complies
Melting point	231°C - 234°C
Water	4,0% - 6,0%
Chromatographic purity	
Individual impurities	=< 0,5%
Total impurities	=< 1%
Assay	98,0% - 102,0%
Residual solvents	
Acetone	=< 0,5%
Dimethylformamide	=< 880 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Staphylococcus aureus	Absence/g
Escherichia coli	Absence/g
Pseudomonas aeruginosa	Absence/g

### COMPLIES WITH

Manufacturer's Specifications

### STORAGE

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

### REMARKS

Veterinary Miltefosine 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.