

**MILTEFOSINA VETERINARIA (ESP. FAB.)**

PRODUCT CODE: 46433106	CAS Nº: 58066-85-6	ANALYSIS Nº: 266/24
MANUFACTURER BATCH: 0000002911	CERTIFICATE ID: 43.920	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 23/05/2022	
METAPH BATCH: 0201024	EXPIRY DATE: 30/04/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	White powder	White powder
Solubility	Soluble in water (<2.5mg/mL at 25°C)	Complies (*)
Identification (1)	Complies	Complies
Identification (2)	Complies	Complies
Melting point	231°C - 234°C	233 °C
Water	4.0% - 6.0%	4.9 %
Chromatographic purity		
Individual impurities	=< 0.5%	Not Detected
Total impurities	=< 1%	Not Detected
Assay	98.0% - 102.0%	100.9 %
Residual solvents		
Acetone	=< 0.5%	< 0.005 %
Dimethylformamide	=< 880 ppm	< 50 ppm
Microbiological control		
TAMC	=< 1000 CFU/g	< 10 CFU/g
TYMC	=< 100 CFU/g	< 10 CFU/g
Staphylococcus aureus	Absence/g	Absence/g
Escherichia coli	Absence/g	Absence/g
Pseudomonas aeruginosa	Absence/g	Absence/g

COMPLIES WITH

Manufacturer's Specifications

REMARKS

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 29/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001512