



西安菲斯弗生物科技有限公司

Xi'an Faithful Biological Technology Co., Ltd.

Certificate of Analysis-Milbemycin oxime

CAS: 129496-10-2

Batch Number: **FTF0250309** Batch Quantity: 16kg

Manufacture Date: Mar.07th,2025 Analysis Date:Mar.08th,2025 Certificate Date: Mar.09th,2025

Storage Store in cool & dry place. Store in well-closed containers.
Shelf life 3 years when properly stored.

Items	Standard	Result
Appearance	White or light yellow, amorphous powder	White powder
Identification A(IR)	The IR spectrum of the substance to be examined corresponds to the spectrum of Milbemycin Oxime RS.	Conforms
Identification B(HPLC)	The 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time and size to the 2 principal peaks in the chromatogram obtained with reference solution (a).	Conforms
Residue on Ignition	≤0.2%	0.11%
Heavy metals	≤10ppm	<10ppm
Water	≤2.0%	1.3%
Related Substance	11'-Desmethylnilbemycin A ₄ oxime: Not more than 0.5%	0.05%
	(20'R)-Hydroxynilbemycin A ₄ keto form: Not more than 0.5%	0.01%
	Milbemycin A ₄ keto form: Not more than 0.7%	0.13%
	Milbemycin D oxime: Not more than 2.0%	0.14%
	Any other impurity: Not more than 0.20%	0.15%
	Total impurities: Not more than 3.5%	0.88%
Residual solvents	Methanol: Not more than 3000ppm	10ppm
	Ethanol: Not more than 5000ppm	1468ppm
	Dichloromethane: Not more than 600ppm	8ppm
	n-Hexane: Not more than 290ppm	5ppm
	Chloroform: Not more than 60ppm	3ppm
	n-Heptane: Not more than 5000ppm	8ppm
	Acetone: Not more than 5000ppm	10ppm
Bioburden	Total Aerobic Bacteria: ≤500 cfu/g	<2cfu/g
	Total combined yeast and Mold: ≤100 cfu/g	<2cfu/g
	Escherichia coli: Should be absent	Absent
Assay	Milbemycin Oxime (A ₃ +A ₄): 95.0% ~ 101.0% (Calculated on the anhydrous basis)	100.2%
	Ratio A ₃ /(A ₃ +A ₄): Not more than 0.20	0.195
	Ratio A ₄ /(A ₃ +A ₄): Not less than 0.80	0.804

Conclusion: Conform with enterprise specification .

QC MANAGER: 刘娟 INSPECTOR: 黄子烨

