江苏威凌生化科技有限公司

JIANGSU WILLING BIO-TECH CO., LTD.

Certificate of Analysis for Milbemycin oxime（USP）

Report No： F-20170619-001

WL-QS-FP007-R02（01）

Batch No： F170501	**Mfg Date：** 2017.05.14	**Retest Date：** 2019.05.13
Report Date： 2017.06.19	**Batch Size：** 21.93kg	**Standard：** WL-QS-FP007

Test Items	Specification	Result
Appearance	White or almost white or light yellow, amorphous powder.	White amorphous powder
Identification	IR spectrum of sample corresponds to that of reference substance.	Comply
	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Comply
Water	≤3.0%	1.4%
Residue on ignition	≤0.5%	0.2%
Assay	(Sum of Milbemycin A_4 oxime and Milbemycin A_3 oxime)：95.0%-102.0% on the anhydrous basis.	100.1%
	Ratio of Milbemycin A_4 oxime：≥0.75	0.92
	Ratio of Milbemycin A_3 oxime：≤0.25	0.08
Organic impurities	Impurity a：11'- DesmethylMilbemycin A_4 oxime ≤0.7%	0.05%
	Impurity b：(20' R)-Hydroxymilbemycin A_4 keto form ≤0.5%	0.04%
	Impurity c：Milbemycin A_4 keto form ≤0.7%	0.3%
	Impurity d：Milbemycin D oxime ≤3.0%	0.2%
	Any other individual impurity ≤0.5%	0.3%
	Total impurities（excluding impurity d）≤3.5%	1.1%
	Reporting threshold：0.10%	
Solvent residue	Trichloromethane ≤60ppm	Not detected
	N-Heptane ≤5000ppm	8ppm
	Ethanol ≤5000ppm	39ppm
Conclusion	The product complies with the specification(USP)	
Storage	Preserve in tight containers,store at room temperature,protected from light.	

Reported by/Date: Fan Qingrong 2017.06.19

QC manager/Date: Zheng Jianhuang 2017.06.19

Reviewed by QA/Date: Lin Yanchang 2017.06.19

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