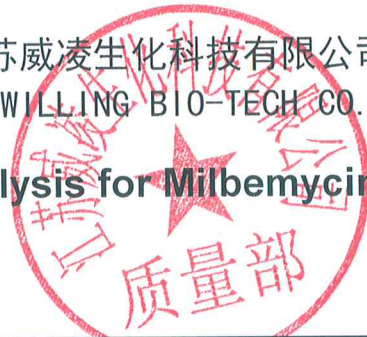


Certificate of Analysis for Milbemycin oxime (USP)

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 Yanhang
2017.06.19

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