JIANGSU WILLING BIO-TECH CO, LTD.

Certificate of Analysis for Doramectin (BHT)

Report No: K-20180625-001

File encoding: WL-QS-FP012-R02 (02)

Batch No: K180201		Mfg Date: 2018.02.01		Retest Date: 2020.01.31	
Report Date: 2018.06.25		Batch Size: 45.49kg Standar		d: WL-QS-FP012	
Test Items	Test Items Specification				Result
Appearance	White or almost white crystalline powder				White crystalline powder
Claroty and color of	The solution is clear and not more intensely				Comply
solution	coloured than reference solution BY ₆				
Identification	HPLC: The retention time of the major peak				Comply Comply +15°
	corresponds to that of the reference substance				
	solution, as obtained in the Assay.				
	IR spectrum of sample corresponds to that of				
	reference.				
Specific rotation	+11°~+15°				
(anhydrous substance)	≤3.0%				1.8%
Water					
Sulfated ash	≤0.1%				0.06%
Heavy metals	≤20ppm			<20ppm	
Related substances	Avermectin RRT=0.72 ≤1.0%			0.25%	
	Avermectin RRT=0.84		≤1.0%		0.66%
	Any single impurity		≤1.0%		0.50%
	Total impurities ≤5.0%			3.5%	
Assay (anhydrous substance)	≥95.0%			96.1%	
Residual solvents	Methanol		≤3000ppm		1225ppm
	Acetone		≤5000ppm		327ppm
	Ethar	Ethanol ≤5000ppm		1	Not detected
ВНТ	≤0.2%			0.15%	
Conclusion	The product complies with the in-house standards.				
Storage	Preserve in well-closed container at 2-8 ℃.				

Reported by/Date: Cai Ye QC manager/Date: Zheng) ianhu ang Reviewed by QA/Date: Lin Jome Lang
2018.06.25 2018.06.25