

检验报告书

CERTIFICATE OF ANALYSIS

Product Name: Milbemycin Oxime		CAS No.: 129496-10-2
Batch No.: QYB20171030		Quantity:16.2kg
Manufacture Date : Oct., 30, 2017		Report Date: Nov.,17, 2017
Retest Date : To be confirmed		Test according to: EP9.2
ITEMS	STANDARDS	RESULTS
Appearance	White to off white powder	White powder
Identification	IR, HPLC	Complies
Solubility	Practically insoluble in water, very soluble in acetonitrile, in anhydrous ethanol and in ethyl acetate	Complies
Related Substances	Impurity G \leq 2.0% Impurity E \leq 0.7% Impurity H \leq 0.5% Impurity I \leq 0.5% Any other impurity \leq 0.3% Total impurities \leq 3.5%	0.21% 0.2% 0.1% Not detected 0.1% 1.0%
Water	\leq 2.0%	1.3%
Residual Solvents	Ethanol \leq 5000ppm Acetone \leq 5000ppm Dichloromethane \leq 600ppm N-Heptane \leq 5000ppm Chloroform \leq 60ppm	94ppm 5ppm 4ppm 23ppm Not detected
Assay	Milbemycin Oxime(A3+A4) 95.0%~102.0% (Anhydrous substance)	100.2%
	Ratio A4/(A3+A4) not less than 80%	82.4%
Microbial limit	Total Aerobic Bacteria NMT 500CFU/g Total combined yeasts and molds NMT 100CFU/g Escherichia Coli Absent/g	6CFU/g 16CFU/g Not detected
Conclusion	Complies to EP9.2	