

Milbemycin Oxime COA EP-20160201



Hubei Honch Pharmaceutical Co.,Ltd.

Certificate of Analysis

Milbemycin Oxime



File encoding: ATT-003-STP-QS-05-010-1.0

Batch Number	V01-20160201	Batch Size	1000g
Quantity	929.9g	Manufacture Date	2016-02-23
Report Date	2016-08-06	Retest Date	2018-02-22

Items	Method	Specification	Result
Characters	In-house		
Appearance		White or light yellow amorphous powder	White powder
Solubility		Practically insoluble in water, very soluble in acetonitrile, in anhydrous ethanol and in ethyl acetate.	Conforms
Identification	EP 2.2.24		
Identification A (by IR)		The IR spectrum of the substance to be examined corresponds to the spectrum of Milbemycin Oxime RS	Conforms
Identification B (by HPLC)		Examine the chromatograms obtained in the assay, the 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time to the 2 principal peaks chromatogram obtained with reference solution (a)	Conforms
Related substances	EP 2.2.29		
Impurity G		Not more than 2.0%	0.010%
Impurity E		Not more than 0.7%	0.05%
Impurity H		Not more than 0.5%	0.1%
Impurity I		Not more than 0.5%	0.1%
Any other impurity		Not more than 0.20%	0.16%
Total Impurities		Not more than 3.5%	0.42%
Water	EP 2.5.12	Not more than 2.0%	1.5%
Residual solvents	In-house		
Methanol		Not more than 3000ppm	9 ppm
Ethanol		Not more than 5000ppm	1725 ppm
Acetone		Not more than 5000ppm	2 ppm
Dichloromethane		Not more than 600ppm	4 ppm
n-Hexane		Not more than 290ppm	1 ppm
n-Heptane		Not more than 5000ppm	6 ppm
Chloroform		Not more than 60ppm	56 ppm
Assay	EP 2.2.29		
Milbemycin Oxime (A ₃ +A ₄) (Anhydrous substance)		95.0% ~ 102.0%	100.7%
Ratio A ₄ /(A ₃ +A ₄)		Not less than 80%	84%
Microbial limit	EP2.6.12		
Total Aerobic Bacteria		Not more than 500CFU/g	<2CFU/g
Total Combined Yeasts and Molds		Not more than 100CFU/g	<2CFU/g
Escherichia Coli		Absent/g	Not detected

Conclusion: The product complies with the enterprise standard.

Analyst/Date: Jin cheng Jiang 2016.08.06
 Checker/Date: Li Liu 2016.08.06

QC Supervisor/Date: Cheng Liu 2016.08.06

Final Batch Disposition: Rejected Approved

By: peidong Li

Manufactured By: Hubei Honch Pharmaceutical Co., Ltd.

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