

Items 项目	Specification 标准	Result 结果
Characters 性状		
Appearance 外观	White or off-white powder. 白色或类白色粉末	White powder 白色粉末
Solubility 溶解度	Practically insoluble in water, very soluble in acetonitrile, in anhydrous ethanol and in ethyl acetate. 本品易溶于乙腈、无水乙醇和乙酸乙酯，难溶于水	Conforms 符合规定
Identification 鉴别		
Identification A (by IR) 鉴别 A	The IR spectrum of the substance to be examined corresponds to the spectrum of Milbemycin Oxime RS. 本品的红外吸收图谱应与对照品的图谱一致	Conforms 符合规定
Identification B (by HPLC) 鉴别 B	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). 在含量测定项下记录的色谱图中，供试品溶液中的两个主峰保留时间应分别与对照品溶液两个主峰的保留时间一致	Conforms 符合规定
Related substances 有关物质		
Impurity G 杂质 G	NMT 2.0% 不得过 2.0%	0.21%
Impurity E 杂质 E	NMT 0.7% 不得过 0.7%	0.2%
Impurity H 杂质 H	NMT 0.5% 不得过 0.5%	0.1%
Impurity I 杂质 I	NMT 0.5% 不得过 0.5%	Not Detected
Any other impurity 其他任何杂质	NMT 0.3% 不得过 0.3%	0.1%
Total Impurities 总杂	NMT 3.5% 不得过 3.5%	1.0%
Water 水分	NMT 2.0% 不得过 2.0%	1.3%

Residual solvents 残留溶剂

Ethanol 乙醇	NMT 5000ppm 不得过 5000ppm	94ppm
Acetone 丙酮	NMT 5000ppm 不得过 5000ppm	5ppm
Dichloromethane 二氯甲烷	NMT 600ppm 不得过 600ppm	4ppm
n-Heptane 正庚烷	NMT 5000ppm 不得过 5000ppm	23ppm
Chloroform 三氯甲烷	NMT 60ppm 不得过 60ppm	Not detected

Assay 含量

Milbemycin Oxime (A3+A4) 米尔贝肟 (A3+A4)	95.0% ~102.0%(Anhydrous substance)	100.2%
Ratio A4 /(A3 +A4) A4 肟/(A3 肟 + A4 肟)	Not less than 80% 不得小于 80%	82.4%

Microbial limit 微生物限度

Total Aerobic Bacteria 需氧菌数	NMT 500CFU/g 不得过 500CFU/g	6cfu/g
Total Combined Yeasts and Molds 霉菌和酵母菌数	NMT 100CFU/g 不得过 100CFU/g	16cfu/g
Escherichia Coli 大肠埃希菌	Absent/g 不得检出/g	Not detected

Conclusion: The product complies with the enterprise standard.The standard reference EP.

结论：本品符合企业内控标准，该标准参考 EP.