

LOTE NO: 190199

HUO(07103119)

检验报告单

Certificate of Analysis

HISUN
海正药业

IVERMECTIN 伊维菌素

BATCH NUMBER 批号 4025-B181001 MANUFACTURE DATE 生产日期 2018.10.14
 QUANTITY 数量 3kg TEST DATE 检验日期 2018.10.18
 RETEST DATE 复测期 2021.10.13 REPORT DATE 报告日期 2019.02.02

13-10-21

ITEM 项目	STANDARD 标准	RESULT 结果
Appearance 性状	White or yellowish-white, crystalline powder 白色或类白色结晶性粉末	White crystalline powder 白色结晶性粉末
Identification 鉴别	A、IR	Conforms 符合规定
	B、HPLC	Conforms 符合规定
Appearance of solution 溶液外观	The solution is clear and not more intensely coloured than reference solution BY ₇ 溶液应澄清, 溶液颜色不深于 BY ₇	Clear 澄清 < BY ₇
Water 水分	≤1.0%	0.1%
Specific optical rotation 比旋度	-17° ~ -20°	-19°
Sulphated Ash 炽灼残渣	≤0.1%	0.0%
Residual Solvents 残留溶剂		
Ethanol 乙醇	≤5.0%	4.2%
Formamide 甲酰胺	≤3.0%	2.3%
Related Substances 相关物质		
Individual Impurity 单个杂质	≤1%	0.3%
Impurities with RRT 1.3 to 1.5 RRT 1.3~1.5 杂质	≤2.5%	1.26%
Total Impurities 总杂质	≤5%	2.4%
Assay (On the anhydrous, solvent-free basis) 含量 (无水, 无溶剂计)		
H ₂ B ₁ a + H ₂ B ₁ b	95.0% ~ 102.0%	98.3%
H ₂ B ₁ a / (H ₂ B ₁ a + H ₂ B ₁ b) 峰面积之比	≥90.0% (area normalization)	98.3%

Conclusion: The results conform to EP standard.

结论: 本品符合 EP 标准。

Analyst 化验员 Checker 复核人 QC Manager 质检经理

FINAL BATCH DISPOSITION

Approved

Rejected

By:

Manufacturer
Zhejiang Hisun Pharmaceutical Co., Ltd.
46 Waisha Road, Jiaojiang District
Taizhou City, Zhejiang Province
People's Republic of China

Tel: 0086-576-88827900
Fax: 0086-576-88827887

Manufacturing Site
Zhejiang Hisun Pharmaceutical Co., Ltd.
56 Binhai Road, Jiaojiang District
Taizhou City, Zhejiang Province
People's Republic of China

Version 1.4 EP
10/22/18
Hisun Pharm



扫描全能王 创建