

检验报告单

Certificate of Analysis



IVERMECTIN 伊维菌素

BATCH NUMBER 批号	4025021N231204	MANUFACTURE DATE 生产日期	2023.12.15
BATCH SIZE 批量	143.25kg	TEST DATE 检验日期	2023.12.27
RETEST DATE 复测期	2026.12.14	REPORT DATE 报告日期	2024.03.14

TEST 项目	ACCEPTANCE CRITERIA 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 B、HPLC	Conforms 符合规定 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	Conforms 符合规定
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%	4.5%
Formamide 甲酰胺	≤3.0%	2.4%
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%	0.90%
Total Impurities 总杂质	≤5%	1.8%
Assay (On the anhydrous, solvent-free basis) 含量 (无水, 无溶剂计)		
H ₂ B _{1a} + H ₂ B _{1b}	95.0%~102.0%	98.1%
H ₂ B _{1a} /(H ₂ B _{1a} +H ₂ B _{1b}) 峰面积之比	≥90.0% (area normalization)	99.8%

Conclusion: The results conform to EP standard.

结论: 本品符合 EP 标准。

Prepared by 制单人: 杨晓

Reviewed by 审核人: 郑学强

FINAL BATCH DISPOSITION

Approved

Rejected

By: 郑学强 2024.03.18

METAPHARMACEUTICAL

N DE LOTE:

0090424

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

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

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

09/04/2024
EP3 Version 1.0
03/30/23
Zhejiang Hisun Pharmaceutical Co., Ltd.