METAPHARMACEUTICAL

N DE LOTE: 0131221

检验报告单

20/12/2021.

Certificate of Analysis

HISUN 海正药业

IVERMECTIN 伊维菌素

BATCH NUMBER 批 号	4025021N210909	MANUFACTURE DATE 生产日期	2021.09.17
QUANTITY 数 量	2kg	TEST DATE 检验日期	2021.10.11
RETEST DATE 复测期	2024.09.16	REPORT DATE 报告日期	2021.11.22

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	Conforms 符合规定
Water 水分	≤1.0%	0.2%
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%	4.3%
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%	1.19%
Total Impurities 总杂质	≤5%	2.1%
Assay (On the anhydrous,solvent-free basis)含量 (无水，无溶剂计)		
H_2B_1a+ H_2B_1b	95.0%~102.0%	98.4%
$H_2B_1a/(H_2B_1a+H_2B_1b)$ 峰面积之比	≥90.0%（area normalization）	98.7%

浙江海正药业股份有限公司 质量检测中心

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: _____ 2021.11.25

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