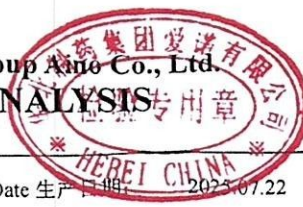


North China Pharmaceutical Group Aino Co., Ltd.

CERTIFICATE OF ANALYSIS



NO.: HAN-I001-out-8

Product name: 产品名称: Ivermectin 伊维菌素原药	Manuf. Date 生产日期: 2025.07.22
Batch No.批号: I20250719	Expiration date 失效日期: 2027.07
Quantity 数量: 121.066Kg	

Analytical results 检验结果

Item 项目	Specification 控制指标	Result 结果
1. Appearance 外观	white or yellowish- white crystalline powder 白色至黄白色结晶粉末	white crystalline powder 白色结晶粉末
2. Identification 鉴别	Infrared Absorption 红外 HPLC 高效液相色谱	Conform Conform
3. Specific rotation (°) 比旋度*	-17—20	-19
4. Related compounds 相关物质		
H ₄ B _{1a} isomers and Δ ^{2,3} H ₂ B _{1a} (%)	≤2.5	1.3
8a-oxo- H ₂ B _{1a} (%)	≤1	ND
Avermectin B _{1a} (%)	≤0.7	0.11
Any other Individual impurity (%)	≤0.5	0.46
The sum of all unidentified Impurity (%)	≤1	0.95
The sum of all related compounds (%)	≤4	2.3
5. Limit of alcohol (%) 乙醇	≤5.0	4.2
Limit of formamide (%) 甲酰胺	≤3.0	2.4
6. Water (%) 水分	≤1.0	0.18
7. Residue on ignition (%) 炽灼残渣	≤0.1	0.07
8. Assay 含量 (%)		
The content of (H ₂ B _{1a} +H ₂ B _{1b}) *	95.0-102.0	98.3
H ₂ B _{1a} / (H ₂ B _{1a} +H ₂ B _{1b}) (The ratio by area)	≥90.0	98.2
9. Residual solvent 残留溶剂		
Methanol (ppm) 甲醇	≤2000	<199
Benzene (ppm) 苯	≤2	<1.8
Toluene (ppm) 甲苯	≤890	<0.45

Note: The item with * calculated on the water, alcohol, formamide and residual solvent free basis.

注: 带*项以无水、乙醇、甲酰胺、残留溶剂计。

Conclusion: Complies with USP2025

结论: 符合美国药典 2025

Reported by: 孟卫勇 2025.08.05

Reviewed by: 王艳敏 2025.08.05

Date of Release: 2025.08.06

Approved by QA: 李柳娟 / 2025.08.06