North China Pharmaceutical Group Aino Co., Ltd.

CERTIFICATE OF ANALYSIS

NO.: HAN-I001-out-7

Product name: Ivermectin 产品名称：伊维菌素原药	Manuf. Date 生产日期： 2021.11.14
Batch No.批号： I20211116	Expiration date 失效日期： 2023.11
Quantity 数量： 121.621Kg	

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	-18
4. Related compounds 相关物质		
H_4B_{1a} isomers and $\triangle^{2,3}H_2B_{1a}$ (%)	≤2.5	1.4
8a-oxo- H_2B_{1a} (%)	≤1	ND
Avermectin B_{1a} (%)	≤0.7	0.07
Any other Individual impurity (%)	≤0.5	0.33
The sum of all unidentified Impurity (%)	≤1	0.76
The sum of all related compounds (%)	≤4	2.3
5. Limit of alcohol (%) 乙醇	≤5.0	3.5
Limit of formamide (%) 甲酰胺	≤3.0	2.2
6. Water (%) 水分	≤1.0	0.10
7. Residue on ignition (%) 炽灼残渣	≤0.1	0.01
8. Assay 含量		
The content of (H_2B_{1a}+H_2B_{1b}) (%)	95.0-102.0	97.4
H_2B_{1a}/ (H_2B_{1a}+H_2B_{1b}) (The ratio by area) (%)	≥90.0	98.4
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 of 3 and 8 calculated on the water , alcohol , formamide and residual solvent free basis.

注：第 3、8 项以无水、乙醇、甲酰胺、残留溶剂计。

Conclusion: Complies with USP 2021

结论：符合美国药典 2021

Reported by: 周双 **Reviewed by:** 王艳敏

Date of Release: 2021.11.25 **Approved by QA:** 蔡丽萍

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