

## North China Pharmaceutical Group Aino Co., Ltd.

## CERTIFICATE OF ANALYSIS

NO.: HAN-1001-out-7

Product name: 产品名称:	Ivermectin 伊维菌素原药	Manuf. Date 生产日期:	2021.10.13
Batch No.批号:	I20211010	Expiration date 失效日期:	2023.10
Quantity 数量:	122.463Kg		

## 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 <sub>4</sub> B <sub>1a</sub> isomers and $\Delta^{2,3}$ H <sub>2</sub> B <sub>1a</sub> (%)	≤2.5	1.3
8a-oxo- H <sub>2</sub> B <sub>1a</sub> (%)	≤1	ND
Avermectin B <sub>1a</sub> (%)	≤0.7	0.18
Any other Individual impurity (%)	≤0.5	0.31
The sum of all unidentified Impurity (%)	≤1	0.69
The sum of all related compounds (%)	≤4	2.2
5. Limit of alcohol (%) 乙醇	≤5.0	4.0
Limit of formamide (%) 甲酰胺	≤3.0	2.3
6. Water (%) 水分	≤1.0	0.09
7. Residue on ignition (%) 炽灼残渣	≤0.1	0.07
8. Assay 含量		
The content of (H <sub>2</sub> B <sub>1a</sub> +H <sub>2</sub> B <sub>1b</sub> ) (%)	95.0-102.0	97.4
H <sub>2</sub> B <sub>1a</sub> / (H <sub>2</sub> B <sub>1a</sub> +H <sub>2</sub> B <sub>1b</sub> ) (The ratio by area) (%)	≥90.0	98.1
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。

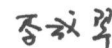
Conclusion: Complies with USP 2021

结论: 符合美国药典 2021

Reported by:



Reviewed by:



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Approved by QA:



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