



# CERTIFICADO DE ANÁLISIS (COA)

Producto: Ivermectina

CAS N°: 70288-86-7

## Certificate of Analysis for Ivermectin

批号 Batch No	yw20210935	代表数量 Quantity	200kg	生产日期 MFG.Date	2021.09.22
检测日期 Test Date	2021.09.24	报告日期 Report Date	2021.09.24	有效期 Expiry Date	2023.09.21
执行标准 Reference	EP9				

检测 Tests	标准规定 Specification	结果 Result
外观 Appearance	白色或微黄色结晶性粉末 White or yellowish-crystalline powder	白色结晶性粉末 White-crystalline powder
鉴别 Identification	IR 与CRS标准品的图谱应一致 Corresponds with that of CRS standard	一致 Complies
	HPLC H <sub>2</sub> B <sub>1a</sub> 和H <sub>2</sub> B <sub>1b</sub> 峰保留时间与标准品一致 The retention time for H <sub>2</sub> B <sub>1a</sub> Corresponds with that of CRS standard	一致 Complies
水分 water	≤1.0 %	0.3
溶液外观(澄清度和颜色) Appearance of solution	澄清, 溶液颜色不深于BY <sub>7</sub> Clear and not more intensely colored than BY <sub>7</sub>	Clear
干品含量 Assay(Basis on drying)	95.0 %~102.0 %	95.8
H <sub>2</sub> B <sub>1a</sub> /(H <sub>2</sub> B <sub>1a</sub> +H <sub>2</sub> B <sub>1b</sub> )	≥90.0 %	97.7
相关物质 Related substances	单一杂质 (RRT1.3-1.5), ≤2.5 % Individual impurities(RRT1.3-1.5)≤2.5 %	2.2
	其它单一杂质, ≤1% Any other individual impurities≤1%	0.57 0.22 0.33 0.10 0.63 0.22
	杂质总和≤5 %	4.3
	检测限≤0.05 % Disregard limit≤0.05 %	0.05
乙醇 Ethanol	≤5.0 %	4.3
甲酰胺 Formamide	≤3.0 %	2.8
重金属 (以Pb计) Heavy metal	≤0.002 %	<0.001
硫酸灰分 Sulphated ash	≤0.1 %	0.05
比旋度 (以干基, 无溶剂计) Specific optical rotation(anhydrous and solvent-free substance)	-17°~-20°	-18.1°
检测结果 Conclusion	本产品符合“EP9”标准 Complies with the requirements of EP9	
报告人 Analyst	审核人 Reviewed by	批准人 Approved by

贮藏条件: 遮光, 密闭, 在干燥处保存。 storage: in an airtight container

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