

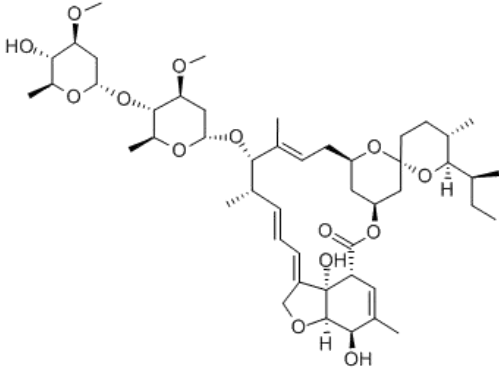


Wuhan HengHeDa Pharm Co., Ltd

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Wuhan Economic& Technological Development Zone, Wuhan, China

CERTIFICATE OF ANALYSIS

Product name	Ivermectin		
CAS NO	70288-86-7		
Molecular formula	C ₄₈ H ₇₄ O ₁₄		
Molecular weight	875.09		
Quantity	100KG		
Batch NO	HHD20230418		
Production date	2023.04.18		
Expiry Date	2025.04.17		
Test based on enterprise standard			
Test Item	Specification	Result	
Appearance	White or yellowish-white crystalline powder,slightly hygroscopic.	Yellowish-white crystalline powder, slight hygroscopic.	
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in alcohol(96percent).	Qualified	
Identification	IR	Corresponds to that of CRS standard	Qualified
	HPLC	The retention time for H ₂ B1 _a and H ₂ B1 _b in the chromatogram obtained with the test solution corresponds to those of standard preparation	Qualified
Appearance of solution	Clear and not more intensely colored than BY ₇	Clear	
Specific optical rotation (anhydrous and solvent-free substance) °	-20~-17	-18.3	
Related substances (%)	Individual impurity(RRT1.3-1.5)≤2.5	I-1:<0.05 K:20	

	Any other impurity ≤ 1	C: <0.05 J: 0.17 D: <0.05 E: 0.31	A: 0.44 H: 0.34 F: <0.05 I-2: 0.17
	Total ≤ 5	3.4	
	Disregard limit: 0.05		
Ethanol and Formamide (%)	Ethanol ≤ 5.0	4.1	
	Formamide ≤ 3.0	2.5	
Catalyst (ug/g)	≤ 1	N.D	
Water (%)	≤ 1.0	0.25	
Sulphated ash (%)	≤ 0.1	0.04	
Heavy Metal (%)	≤ 0.002	<0.002	
Assay (%) (HPLC, on dry basis)	$H_2B1a / (H_2B1a + H_2B1b) \geq 90.0$	99.7	
	$95.0 \leq H_2B1a + H_2B1b \leq 102.0$	96.8	
Conclusion	Complies with the requirements of EP10.0		

Storage	Store in cool & dry place, keep away from strong light and heat.
Shelf life	2 years when properly stored.
Conclusion: This product complies with above specification	

Inspector
Shen Wu

Director
King Yang

