



XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD

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CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	201905016	Quantity	750kgs
Manufacturing Time	Mar. 18.2020	Expiry Date	Mar.18.2022	Test Date	Apr 2, 2020
Specification	EP9.0				
Tests		Specification		Results	
Appearance		While or yellowish-white crystalline powder		Qualified	
Solubility		Practically insoluble in water. freely soluble in methylene chloride, soluble in alcohol (96%)		Qualified	
Identification	IR	Corresponds with that of CRS standard		Qualified	
	HPLC	The retention time for H2B1a and H2B1b corresponds with that of standard preparation		Qualified	
Appearance of solution		Clear and not more intensely colored than BY7		Qualified	
Specific optical rotation (anhydrous and solvent-free substance)		-17~-20		-18.2	
Related substances (%)		Individual impurities(RRT1.3-1.5)≤2.5		I-I:<0.05; K:2.1	
		Any other individual impurities≤1		C: 0.07 A: 0.27 J: 0.20 H: 0.16 D:0.08 F: 0.07 E: 0.57 I-2:0.14 RRT 1.09:0.06	
		Total≤5		3.7	
		Disregard limit ≤0.05		0.05	
Ethanol and Formamide(%)		Ethanol≤5.0		3.7	
		Formamide ≤3.0		2.6	
Water (%)		≤1.0		0.12	
Sulphated ash (%)		≤0.1		0.08	
Cat (ug/g)		≤1.0		<1	
Assay(%)		H2B1a(H2B1a+H2B1b)≥90.0		97.5	
(HPLC. On dry basis)		95.0≤H2B1a+H2B1b≤102.0		96.1	
Conclusion		Conforms With USP40			

QC MANAGER: 王翠月

INSPECTOR: 杨思远

