



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

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CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Batch No	2021061201	Quantity	750kgs
Manufacturing Time	Jun.12.2021	Expiry Date	Jun.12.2023	Test Date	Jun,12,2021
Specification	USP40				
Tests		Specification			Results
Appearance		White 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			1-1:<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 1-2:0.14 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

