



CERTIFICATE OF ANALYSIS

Product Name	Ivermectin	Manufacture Date	April 15, 2022
Batch No.	LYPH220415	Certificate Date	April 17, 2022
Batch Quantity	580KG	Expiration Date	April 14, 2024
Items	Specifications	Results	
Appearance	White or yellowish-white crystalline powder, slightly hygroscopic	Complies	
Solubility	Practically insoluble in water, freely soluble in methylene chloride, soluble in alcohol	Complies	
Identification	IR	Corresponds with that of CRS standard	
	HPLC	The retention time for H ₂ B1 _a and H ₂ B1 _b in chromatogram obtained with the best solution corresponds to those of standard preparation	
Appearance of solution	Clear and not more intensely colored than BY ₇	Complies	
Specific optical rotation (anhydrous and solvent-free substance)	-20~-17°	-17.5°	
Related substances(%)	Individual impurities(BRT1.3-1.5)≤2.5	I-1:<0.05 K:2.1	
	Any other impurities≤1	C:0.05 A:0.58 J:0.21 H:0.31 D:0.05 F:<0.05 E:0.53 I-2:0.17 RTS1.09:0.08	
	Total≤5	4.2	
	Disregard limit: 0.05		
Ethanol and Formamide(%)	Ethanol≤5.0	3.7	
	Formamide≤3.0	2.4	
Heavy metal(%)	≤0.002	<0.002	
Water(%)	≤1.0	0.24	
Catalyst(ug/g)	≤1	<1	
Sulphated ash(%)	≤0.1	0.06	
Assay(%) (HPLC, on dry basis)	H ₂ B1 _a /(H ₂ B1 _a +H ₂ B1 _b) ≥90.9	98.3	
	95.0≤H ₂ B1 _a +H ₂ B1 _b ≤102.0	96.2	
Conclusion	Complies with the requirements of EP 9.0		

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