

CERTIFICATE OF ANALYSIS

Product Name	IVERMECTIN IP		
A.R. No.	FP260029	Mfg. Dt.	FEB-2026
Batch No.	HLS/IVR/202601	Retest Dt./Exp.Dt.	JAN-2030
Quantity	202.05 KG	Release Date	16/02/2026

SR. NO.	TEST	SPECIFICATION	RESULTS
1.	Description	A White or yellowish-white crystalline powder, slightly hygroscopic.	Complies
2.	Solubility	Freely soluble in dichloromethane, soluble in ethanol; practically insoluble in water.	Complies
3.	Identification		
	A: By IR Spectroscopy	IR spectrum of the sample should be concordant with the IR spectrum of Ivermectin WRS.	Complies
	B: Retention time by HPLC	The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).	Complies
4.	Appearance of solution	A 2.0 per cent w/v solution in toluene is clear and not more intensely coloured than reference solution BYS7.	Complies
5.	Specific Optical rotation	Between -20° to -17°	-18.03°
6.	Sulphated Ash	NMT 0.1%	0.05%
7.	Water content	NMT 1.0%	0.56%
8.	Related Substance by HPLC		
	Individual Impurities (RRT 1.3 to 1.5)	NMT 2.5%	1.27%
	Any other impurities	NMT 1.0%	0.60%
	Total Impurities	NMT 5.0%	2.49%
9.	Ethanol and formamide by Gas chromatography		
	Ethanol	NMT 5.0%	0.07%
	Formamide	NMT 3.0%	0.12%
10.	Assay by HPLC	H ₂ B _{1a} + H ₂ B _{1b} : (95% to 102%)	98.46%
		H ₂ B _{1a} / (H ₂ B _{1a} + H ₂ B _{1b}): NLT 90%	98.05%
11.	Additional test		
	Heavy metals	NMT 20 ppm	Complies

Storage: Keep material away from sunlight and moisture. Store at room temperature.

Conclusion: The material complies / does not comply as per above specification.

Prepared By: Jinal Patel

Checked By: Aditya Rathore

Approved By: Chirag Shah

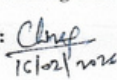
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