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HORSTER LIFE SCIENCE PVT. LTD.

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CERTIFICATE OF ANALYSIS

Product Name	IVERMECTIN USP		
A.R. No.	FP260078	Mfg. Dt.	MAY-2026
Batch No.	HLS/IVR/202602	Retest Dt./Exp. Dt.	APR-2030
Quantity	205.02 KG	Release Date	07/05/2026

SR. NO.	TEST	SPECIFICATION	RESULTS
1.	Description	White to yellowish-white crystalline powder, Slightly Hygroscopic.	Complies
2.	Solubility	Freely soluble in Methanol and in Methylene chloride, Soluble in Acetone and in Acetonitrile, Practically insoluble in hexane and 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 retention times of the component H ₂ B _{1a} peak and the component H ₂ B _{1b} peak in the chromatogram of sample solution should be correspond to that of chromatogram of the Standard solution in the test of Assay by HPLC.	Complies
4.	Specific rotation (On the water, alcohol and formamide free basis)	Between -17° to -20°	-17.11°
5.	Water content	NMT 1.0%	0.42%
6.	Residue on Ignition	NMT 0.1%	0.05%
7.	Limit		
	Alcohol	NMT 5.0%	0.040%
	Formamide	NMT 3.0%	0.123%
8.	Related Compound by HPLC		
	Sum of H ₄ B _{1a} and Δ ^{2,3} H ₂ B _{1a} isomer (at RRT 1.3 to 1.4)	NMT 2.5%	1.23%
	8a-oxo-H ₂ B _{1a} (at RRT 0.7)	NMT 1.0%	0.37%
	Avermectin B _{1a} (at RRT 0.5)	NMT 0.7%	0.58%
	Any other individual Impurity	NMT 0.5%	0.25%
	All unidentified Impurity	NMT 1.0%	0.64%
	Total Impurities	NMT 4.0%	3.01%
9.	Assay by HPLC		
	H ₂ B _{1a} + H ₂ B _{1b} (Calculated on the anhydrous and alcohol-formamide free basis)	95% to 102%	100.30%
	H ₂ B _{1a} / (H ₂ B _{1a} + H ₂ B _{1b})	NLT 90%	98.50%
10.	Additional test		
	Residual solvents(ppm)	Toluene < 890 Methanol < 300	20.1 196.0
	Appearance of solution	Clear and not more intensely colored than BY ₇	Complies
	Heavy metals (%)	NMT 0.002% (20ppm)	Complies
	Melting Point	153°C TO 157°C	154.6°C

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

Conclusion: The material complies as per above specification.

Prepared By: Jinal Patel

Jinal

Sign. & Date: 07/05/2026

Checked By: Aditya Rathore

Aditya

Sign. & Date: 07/05/2026

Approved By: Chirag Shah

Chirag

Sign. & Date: 07/05/2026