Letco Medical, LLC.

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CERTIFICATE OF ANALYSIS

Letco Item:	697246	697247	697248	697249		
Letco Lot:	2406260005	2406260006	2406260007	2406260008		

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Ivermectin USP	4025021N231208	December 19, 2023	December 18, 2026

TEST	SPECIFICATION	RESULT	METHOD
Appearance	White to yellowish-white crystalline powder	White crystalline powder	Visual
Identification A	Infrared spectrum corresponds to the reference standard.	Conforms	USP<197K>
Identification B	The retention time of the component H_2B_{1a} peak and the component H_2B_{1b} peak in the chromatogram of the Assay preparation correspond to the chromatogram of the Standard preparation, as obtained in the Assay.	Conforms	USP Monograph
Residue on Ignition	Not More Than 0.1%	0.0%	USP<281>
Water Content	Not More Than 1.0%	0.1%	USP<921>
Specific Rotation	-17° to -20°, calculated on the anhydrous, ethanol- and formamide- free basis.	-19°	USP<781S>
Related Compounds			
RRT 1.3 to 1.4 ♦	Not More Than 2.5%	1.03%	USP Monograph
RRT 0.7 ♦♦	Not More Than 1%	< 0.05%	USP Monograph
RRT 0.5 ♦♦♦	Not More Than 0.7%	0.21%	USP Monograph
Other Individual Impurity	Not More Than 0.5%	0.29%	USP Monograph
Total Unidentified Impurities	Not More Than 1%	0.5%	USP Monograph
Total Impurities	Not More Than 4%	2.0%	USP Monograph
Assay			
H_2B_{1a} Component	Not Less Than 90.0%	98.9%	USP Monograph
H_2B_{1b} Component	Not More Than 5.0%	0.1%	USP Monograph
Total	95.0% to 100.5% (H_2B_{1a} + H_2B_{1b}), calculated on the anhydrous and ethanol-, and formamide- free basis.	99.0%	USP Monograph
Limit of Ethanol & Formamide			
Ethanol	Not More Than 5.0%	4.5%	Mfr. In-house GC
Formamide	Not More Than 3.0%	2.4%	Mfr. In-house GC

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

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CERTIFICATE OF ANALYSIS

Letco Item:	697246	697247	697248	697249		
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ADDITIONAL INFORMATION

Letco Medical performed identification testing of this material using a validated method.

♦ : H_4B_{1a} isomers, $\Delta^{2,3}H_2B_{1a}$ and 24-ethyl-ivermectin B_{1a}
♦♦ : 8a-oxo- H_2B_{1a} and an impurity with the relative molecular mass of 891
♦♦♦ : Avermectin B_{1a}

Manufacturer Final Batch Disposition : Approved

LETCO QA REVIEW: _____

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