



Letco Medical, LLC.

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<b>CERTIFICATE OF ANALYSIS</b>		

<b>Letco Item:</b>	697246	697247	697248			
<b>Letco Lot:</b>	2501150038	2501150039	2501150040			

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Ivermectin USP	4025021N241002	October 7, 2024	October 6, 2027

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 <sub>2</sub> B <sub>1a</sub> peak and the component H <sub>2</sub> B <sub>1b</sub> 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>
<b>Related Compounds</b>			
RRT 1.3 to 1.4 ♦	Not More Than 2.5%	0.88%	USP Monograph
RRT 0.7 ♦♦	Not More Than 1%	< 0.05%	
RRT 0.5 ♦♦♦	Not More Than 0.7%	0.16%	
Other Individual Impurity	Not More Than 0.5%	0.31%	
Total Unidentified Impurities	Not More Than 1%	0.5%	
Total Impurities	Not More Than 4%	1.7%	
<b>Assay</b>			
H <sub>2</sub> B <sub>1a</sub> Component	Not Less Than 90.0%	98.7%	USP Monograph
H <sub>2</sub> B <sub>1b</sub> Component	Not More Than 5.0%	0.4%	
Total	95.0% to 100.5% (H <sub>2</sub> B <sub>1a</sub> + H <sub>2</sub> B <sub>1b</sub> ), calculated on the anhydrous and ethanol-, and formamide- free basis.	99.1%	
<b>Limit of Ethanol &amp; Formamide</b>			
Ethanol	Not More Than 5.0%	4.0%	Mfr. In-house GC
Formamide	Not More Than 3.0%	2.2%	

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



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<b>CERTIFICATE OF ANALYSIS</b>		

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ADDITIONAL INFORMATION
<p><i>Letco Medical performed identification testing of this material using a validated method.</i></p> <p>◆ : H<sub>4</sub>B<sub>1a</sub> isomers, Δ<sup>2,3</sup>H<sub>2</sub>B<sub>1a</sub> and 24-ethyl-ivermectin B<sub>1a</sub>  ◆◆ : 8a-oxo- H<sub>2</sub>B<sub>1a</sub> and an impurity with the relative molecular mass of 891  ◆◆◆ : Avermectin B<sub>1a</sub></p> <p>Manufacturer Final Batch Disposition : Approved</p> <p>This product was manufactured by Zhejiang Hisun Pharmaceutical Co., Ltd., 46 Waisha Road, Jiaojiang District, Taizhou, Zhejiang 318000, China (CHN)</p>

LETCO QA REVIEW: \_\_\_\_\_

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