



Letco Medical, LLC.

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<b>CERTIFICATE OF ANALYSIS</b>		

<b>Letco Item:</b>	697246	697247	697946	697248	697290	
<b>Letco Lot:</b>	25D09-B07-001835	25D09-B07-001836	25D09-B07-004721	25D09-B07-001837	25D09-B07-005021	

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Ivermectin USP	4025021N241101	November 10, 2024	November 9, 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%	1.28%	USP Monograph
RRT 0.7 ♦♦	Not More Than 1%	< 0.05%	
RRT 0.5 ♦♦♦	Not More Than 0.7%	0.05%	
Other Individual Impurity	Not More Than 0.5%	0.30%	
Total Unidentified Impurities	Not More Than 1%	0.7%	
Total Impurities	Not More Than 4%	2.2%	
<b>Assay</b>			
H <sub>2</sub> B <sub>1a</sub> Component	Not Less Than 90.0%	98.1%	USP Monograph
H <sub>2</sub> B <sub>1b</sub> Component	Not More Than 5.0%	0.6%	
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.	98.7%	
<b>Limit of Ethanol &amp; Formamide</b>			
Ethanol	Not More Than 5.0%	4.3%	

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