



Letco Medical, LLC.

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November 12, 2024	00	1 of 1
<b>CERTIFICATE OF ANALYSIS</b>		

<b>Letco Item</b>	691436	691437	691438	691439	695705	
<b>Letco Lot</b>	2412200022	2412200023	2412200024	2412200025	2412200026	

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Biotin USP	KXVHUSP240926-2	September 26, 2024	September 25, 2027

TEST	SPECIFICATION	RESULT	METHOD
Appearance	White or off-white powder	Conforms	USP
Identification	1) A: 2) B: 3)C:	Conforms	USP
Assay	98.5% ~ 101.0%	99.0%	USP/EP
Impurities	Individual impurity: ≤ 1.0%	0.62%	USP
	Total impurities: ≤ 2.0%	0.76%	
Specific rotation	+89° ~ +93°	+ 90.5°	USP
Melting range	229°C - 232°C	230.0 – 231.3°C	Mfr. In house
Loss on drying	≤ 0.5%	0.16%	EP
Bulk density	≈ 0.35 g/cm <sup>3</sup>	Conforms	Mfr. In House
Sulfate ash	≤ 0.1%	0.06%	EP
Heavy metals	Pb: ≤ 0.5 ppm	Conforms	ICP/AAS
	As: ≤ 1 ppm	Conforms	
	Cd: ≤ 1 ppm	Conforms	
	Hg: ≤ 0.1 ppm	Conforms	
Particle size	100% through 80 mesh	Conforms	Mfr. In house
Microbials test	Total plate count: ≤ 1000 cfu/g	Conforms	CP-2020
	Yeast and mold: ≤ 100 cfu/g	Conforms	
	Salmonella: Negative	Negative	
	E. Coli: Negative	Negative	
	S. Aureus: Negative	Negative	
Total Coli: ≤ 50 cfu/g	Negative		
Solubility	Very slightly soluble in water	Conforms	USP

ADDITIONAL INFORMATION
Molecular Wt: C <sub>10</sub> H <sub>16</sub> N <sub>2</sub> O <sub>3</sub> S Molecular Wt: 244.31 CAS NO: 58-85-5 Manufacturer Conclusion: It Complies With updated USP43/EP Standard.

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

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