



MTC Industries, Inc.

Nutraceuticals, Foodceuticals, and Pharmaceuticals

CERTIFICATE OF ANALYSIS

PRODUCT NAME:	D-Biotin	BATCH NO:	CS1-2305023
MANUFACTURE DATE:	05/12/2023	EXPIRATION DATE:	05/11/2027
Ref. pharmacopoeia(s)	USP2022		

TEST ITEMS	SPECIFICATION	RESULTS	METHOD
Description and solubility	Practically white, crystalline powder. Very slightly soluble in water and in alcohol; insoluble in other common organic solvents	Conform	Visual Perception
Odor	Characteristics	Characteristic	
Identification	To match with the reference IR spectrum	Conform	A: Infrared Absorption
	Meet the requirements	Conform	B: Specific Optical Rotation
	The retention time of the major peak of the sample. Solution corresponds to that of the standard solution, as obtained in the assay.	Conform	C: HPLC
Assay	97.5% - 102.0%	98.8%	HPLC
Optical rotation	+89° -- +93°	+90.3°	USP <781S>
Related Compounds			
1. Individual Impurity	≤ 1.0%	0.10%	HPLC
2. Total Impurities	≤ 2.0%	0.15%	HPLC
Loss on Drying	≤ 1.0%	0.05%	USP <731>
Residue on ignition	≤ 1.0%	0.05%	USP <281>
Residual solvents			USP <467>
Toluene	≤ 890ppm	< 20ppm	
Alcohol	≤ 5000ppm	< 100ppm	
Melting Point	229~232°C	231.4-231.9°C	USP <741>
Heavy Metals	≤ 10ppm	<10ppm	USP <231>
Lead	≤ 0.5mg/kg	<0.5mg/kg	AAS
Arsenic	≤ 1.0mg/kg	<0.5mg/kg	AAS
Cadmium	≤ 0.5mg/kg	<0.5mg/kg	AAS
Mercury	≤ 0.1mg/kg	<0.05mg/kg	AAS
Particle size	100% through #40 Mesh	Pass	
	NLT 90% through #200 Mesh	90.4%	

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Bulk density	≥0.4 g/ml	0.52g/ml	USP<616>
Tapped density	≥0.8 g/ml	1.02g/ml	USP<616>
Microbiological			
Total Plate Count	< 1000cfu/g	<10cfu/g	USP<2021>
Yeast and Mold	< 100cfu/g	<10cfu/g	USP<2021>
Staphylococcus	Negative	Negative	USP<2022>
E. Coli	Negative	Negative	USP<2022>
Salmonella spp	Negative	Negative	USP<2022>



PACKING AND STORAGE: Store in tight, light resistant containers, avoid exposure to direct sunlight, moisture, excessive heat.

CONCLUSION: This batch complies with the specification of USP2022.

The information contained herein is to the best of our knowledge correct. The data outlined and the statements made are intended only as source of information. No warranties expressed or implied are made on the basis of this information. It is suggested that you evaluate the product on a laboratory scale prior to use in a finished product. The information contained herein should not be construed as permission for violation of patent rights.

QC Approved by: Yanyan QA Approved by: Diaping Date: 05/24/2023