上海诺创生物科技有限公司
Shanghai ZNC Biotechnology Co., Ltd.
Tel: 86-21-68453907
Fax: 86-21-58356660
Email: info@zncbio.com
Website: www.zncbio.com

CERTIFICATE OF ANALYSIS

Product Name:	D-Biotin	Specification	USP42
Batch Number:	20230815	Batch Qty	120KGS
Manufacture Date:	2022-08-15	Retesting date:	2025-08-14

ITEMS	SPECIFICATION	RESULTS
Appearance	Practically white, crystalline powder	Conforms
Identification-IR	Consistent with the reference IR Spectrum	Conforms
Specific Rotation	+89 °to +93 °	+90.2 °
Melting range(℃)	229℃~232℃	229.6℃~230.6℃
Particle Size	90% Pass 80 mesh	Conforms
Retention Time	Retention time of the major peak corresponds to that of the standard solution.	Conforms
Ash	Max.0.1%	0.06%
Related compounds		
-Individual impurity	Max.1.0%	0.1%
-Total impurities	Max.2.0%	0.1%
Assay	97.5%~102.0%	99.7%
Heavy Metals		
-Lead	Max. 0.5mg/kg	<0.5mg/kg
-Cadmium	Max. 0.5mg/kg	<0.5mg/kg
-Arsenic	Max.0.5mg/kg	<0.5mg/kg
-Mercury	Max. 0.1mg/kg	<0.1mg/kg
Microbials		
-Total Aerobic Microbial Count	NMT 1000CFU/g	<1000CFU/g
-Total Yeasts and Moulds Count	NMT 100CFU/g	<100CFU/g
-E. Coli	Negative/1g	Negative
-Salmonella	Negative/10g	Negative
-S.Aureus	Negative	Negative
Conclusion:	This batch complies with USP42 and additional requirements for heavy metals and microbials.	
Storage	Store in tight containers.	

Shawn	Rick	Whip
Analyst	Approved	Header of QC