



CERTIFICATE OF ANALYSIS

Product name: Biotin

Batch No.: BN22111023

Manufacturing date	Nov 22, 2022	Reporting date	Nov 27, 2022
Retest date	Nov 21, 2025	Article No.	10102
Package	5 kg per tin	Package size	Φ250 × 350 (mm)
Ref. pharmacopoeia(s)	USP2022	Quantity	30 kg

Test Item	Specification	Method	Result
Description	Practically white, crystalline powder.	USP2022	Comply
Identification			
-IR	Consistent with the Reference IR spectrum	USP2022	Comply
-Specific rotation	+89° ~ +93°	USP2022	+90.7°
-Retention time	Retention time of the major peak corresponds to that of the standard solution	USP2022	Comply
Related Compounds			
-Individual impurity	≤1.0%	USP2022	0.16%
-Total impurities	≤2.0%	USP2022	0.16%
Assay	97.5% ~ 102.0%	USP2022	100.1%
Heavy metals			
Lead	≤0.5 mg/kg	ICP-OES, in-house	<0.5 mg/kg
Cadmium	≤0.5 mg/kg	ICP-OES, in-house	<0.5 mg/kg
Arsenic	≤0.5 mg/kg	ICP-OES, in-house	<0.5 mg/kg
Mercury	≤0.1 mg/kg	ICP-OES, in-house	<0.1 mg/kg
Microbials			
Total Aerobic Microbial Count	NMT 100 cfu/g	ChP2020	<100 cfu/g
Total Yeasts and Moulds Count	NMT 10 cfu/g	ChP2020	<10 cfu/g
E. Coli	Negative	ChP2020	Negative
Salmonella	Negative	ChP2020	Negative
S. Aureus	Negative	ChP2020	Negative
Conclusion: This batch complies with the specification of USP2022 and additional requirements for heavy metals and microbials.			
Remark: Store in tight containers.			

Reported by: 刘勤东

Approved by: