

CERTIFICATE OF ANALYSIS

Product Name	Biotin
Batch No	BN24061009
Manufacturing Date	Jun 12, 2024
Retest Date	Jun 11, 2027
Ref. pharmacopoeia(s)	USP2023

Identification

Test Item	Specification	Result	Method
IR	Consistent with the Reference IR spectrum	Comply	USP2023
Specific rotation	+89° ~ +93°	+90.5°	USP2023
Retention time	Retention time of the major peak corresponds to that of the standard solution	Comply	USP2023

Physical & Chemical Tests

Test	Specification	Result	Method
Description	Practically white, crystalline powder	Comply	USP2023
Loss on drying	≤1.0%	0.02%	EP11

Related Compounds

Test	Specification	Result	Method
Individual impurity	≤1.0%	0.05%	USP2023
Total impurities	≤2.0%	0.05%	USP2023

Assay

Test	Specification	Result	Method
Biotin	99.0% ~ 102.0%	99.8%	USP2023

Heavy Metals

Test	Specification	Result	Method
Lead	≤0.5 mg/kg	<0.5 mg/kg	ICP-OES, in-house
Cadmium	≤0.5 mg/kg	<0.5 mg/kg	ICP-OES, in-house
Arsenic	≤0.5 mg/kg	<0.5 mg/kg	ICP-OES, in-house
Mercury	≤0.1 mg/kg	<0.1 mg/kg	ICP-OES, in-house

Microbials

Test	Specification	Result	Method
Total Aerobic Microbial Count	NMT 100 cfu/g	<100 cfu/g	ChP2020
Total Yeasts and Moulds Count	NMT 10 cfu/g	<10 cfu/g	ChP2020
E. Coli	Negative	Negative	ChP2020
Salmonella	Negative	Negative	ChP2020
S. Aureus	Negative	Negative	ChP2020

Conclusion: This batch complies with the specification of USP2023 and additional requirements for heavy metals and microbials.

Remark: Store in tight containers.

Bulk density: 0.51 g/mL.

Tapped density: 0.94 g/mL.

Particle size: 100.0% Through 100 mesh.