江西天新药业股份有限公司
JIANGXI TIANXIN PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS

Product name: Biotin **Batch No.:** BN24111006

Manufacturing date	Nov 2, 2024	Reporting date	Nov 8, 2024
Retest date	Nov 1, 2027	Article No.	10102
Package	1 kg per bag	Package size	/
Ref. pharmacopoeia(s)	USP2024	Quantity	50 kg

Test Item	Specification	Method	Result
Description	Practically white, crystalline powder.	USP2024	Comply
Identification			
-IR	Consistent with the Reference IR spectrum	USP2024	Comply
-Specific rotation	+89° ~ +93°	USP2024	+91°
-Retention time	Retention time of the major peak corresponds to that of the standard solution	USP2024	Comply
Related Compounds			
-Individual impurity	≤1.0%	USP2024	0.13%
-Total impurities	≤2.0%	USP2024	0.13%
Assay	97.5% ~ 102.0%	USP2024	99.7%
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 USP2024 and additional requirements for heavy metals and microbials.***

Remark: Store in tight containers.

Reported by: 刘勤芹 **Approved by:**

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RESIDUAL SOLVENT STATEMENT

We, Jiangxi Tianxin Pharmaceutical Co., Ltd., hereby confirm that no solvent is used or produced after the Biotin purification process manufactured by us. We also certify that the level of residual solvents of this product conforms to the requirements of **ICH Q3C** (*ICH Harmonised Tripartite Guideline - Impurities: Guideline For Residual Solvents*).

Signature: 王映平

Name: Wang Yingping

Designation: Vice Quality Manager

Date: Jan 1, 2023

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