



浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name: Biotin

Batch number	CS1-2409029	Test No.	CP2409164
Expiry date	Sep.20,2028	Report date	Oct.23,2024
Manufacturing date	Sep.21,2024	Submitted date	Sep.28,2024
Package	10kg per carton	Batch size	300 Kg
Ref. pharmacopoeia(s)	USP43/ EP9/FCCX	Quantity	100 Kg

Test Items	Method	Specification	Results
Description and solubility	Visual	Practically white, crystalline powder. Very slightly soluble in water and in alcohol; insoluble in other common organic solvents.	Complies
Identification:			
A. Infrared absorption	USP<197>	To match with the reference IR spectrum	Complies
B. Specific optical rotation	USP<781S>	Meet the requirements	Complies
C. HPLC	USP	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies
Assay	USP<621> HPLC	97.5%-102.0%	98.7%
Related Compounds:			
1. Individual impurity	HPLC	NMT 1.0%	0.06%
2. Total impurities	HPLC	NMT 2.0%	0.08%
Residual Solvents(Toluene)	USP<467>	≤890ppm	<20ppm
Optical Rotation	USP<781S>	+89° - +93°	+90.7°
Total plate count	USP<2021>	<1000Cfu/g	<10 Cfu/g
Yeast and Mold	USP<2021>	<100Cfu/g	<10 Cfu/g
Escherichia coli	USP<2022>	Negative	Negative
Salmonella	USP<2022>	Negative	Negative
Staphylococcus Aureus	USP<2022>	Negative	Negative
Lead	USP<251>	≤2mg/kg	<0.5mg/kg
Arsenic	USP<211>	≤1 mg/kg	<0.5mg/kg
Cadmium	USP<851>	≤1 mg/kg	<0.5mg/kg
Mercury	USP<261>	≤0.1 mg/kg	<0.05mg/kg





浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

CERTIFICATE OF ANALYSIS

Product name: Biotin

Batch number	CS1-2409029	Test No.	CP2409164
Expiry date	Sep.20,2028	Report date	Oct.23,2024
Manufacturing date	Sep.21,2024	Submitted date	Sep.28,2024
Package	10kg per carton	Batch size	300 Kg
Ref. pharmacopoeia(s)	USP43/ EP9/FCCX	Quantity	100 Kg

Test Items		Method	Specification	Results
EP9	Characters	Visual	White or almost white,crystalline powder	White powder
	Identification: A.IR	EP(2.2.24)	To match with the reference IR spectrum	Complies
	B.TLC	EP(2.2.27)	Meets EP9 requirement	Complies
	C. Color reaction	EP	The bromine water is decolourised	Complies
	Appearance of solution	EP(2.2.1)(2.2.2)	Clear and colourless	Complies
	Specific optical rotation	EP(2.2.7)	+89° - +93°	+90.7°
	Related substances	EP(2.2.27)	Meets EP9 requirement	Complies
	Heavy metals	EP(2.4.8)	≤10ppm	<10ppm
	Loss on drying	EP(2.2.32)	≤1.0%	0.02%
	Sulfated ash	EP(2.4.14)	≤0.1%	0.04%
	Assay	EP(2.2.20)Titration	98.5%-101.0%	99.7%
FCCX	Description	Visual	A white crystalline powder	White powder
	Identification: A.IR	Appendix IIIC	To match with the reference IR spectrum	Complies
	B. Color reaction	FCCX	The bromine water is decolourised	Complies
	Lead	Appendix IIIB	≤2mg/kg	<0.5mg/kg
	Melting Range	Appendix IIB	229~232°C	230.5~230.8°C
	Optical(Specific)Rotation	Appendix IIB	+89° - +93°	+90.7°
	Appearance of solution		Clear and colourless	Complies
	Assay	Titration	97.5%-100.5%	99.6%

Conclusion: This batch complies with the specification of USP43/EP9/FCCX

Reported by: 余, 机

QA: 杨肖娜

Add:No.789,Renmin East Road ,Tiantai, Zhejiang ,China
P.C:317200

Tel:+86-576-83993696 /83881111
Fax:+86-576-83993701