



Product name: Biotin

Batch number	CS1-2012007	Test No.	8022020313
Expiry date	Nov.30,2023	Report date	Dec.07,2020
Manufacturing date	Dec.01,2020	Submitted date	Dec.05,2020
Package	5kg per carton 10kg per carton	Batch size	300 Kg
Ref. pharmacopoeia(s)	USP42/EP9/FCCX	Quantity	25 Kg

Test Items	Method	Specification	Results	
USP42	Description and solubility	Visual	Practically white, crystalline powder Very slightly soluble in water and in insoluble in other common organic	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	
	Assay	USP<621>HPLC	In the Assay. 97.5%-102.0%	Complies 99.2%
	Related Compounds:			
	1. Individual impurity	HPLC	NMT 1.0%	0.06%
	2. Total impurities	HPLC	NMT 2.0%	0.06%
	Residual Solvents (Toluene)	USP<467>	≤890ppm	<20ppm
Optical Rotation	USP<781S>	+89° - +93°	+90.7°	
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 EP 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°	+90.8°
	Related substances	EP(2.2.27)	Meets EP requirement	Complies
	Heavy metals	EP(2.4.8)	≤10ppm	<10ppm
	Loss on drying	EP(2.2.32)	≤1.0%	0.08%
	Sulfated ash	EP(2.4.14)	≤0.1%	0.04%
Assay	EP(2.2.20) Titration	98.5%-101.0%	99.5%	



浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

**CERTIFICATE OF ANALYSIS**



K alchem International, Inc  
Compounding Chemicals You Can Trust

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Test Items	Method	Specification	Results
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	$\leq 2$ mg/kg	<0.5mg/kg
Melting Range	Appendix IIB	229-232°C	231.5°C
Optical(Specific)Rotation	Appendix IIB	+89°-+93°	+90.8°
Appearance of solution		Clear and colourless	Complies
Assay	Titration	97.5%-100.5%	99.5%

**Conclusion:** This batch complies with the specification of USP42/EP9/FCCX

Reported by:

QA Manager:

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

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