

METAPHARMACEUTICAL

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09/09/2022



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	CS1-2202011	Test No.	2022047
Expiry date	Feb.02,2025	Report date	Feb.11,2022
Manufacturing date	Feb.03,2022	Submitted date	Feb.09,2022
Package	1kg per carton	Batch size	300 Kg
Ref. pharmacopoeia(s)	EP9	Quantity	1 Kg

Test Items		Specification	Results
Characters		A white or almost white, crystalline powder or colourless crystals	A white crystalline powder
Identification	A: IR spectrophotometry	To match with the reference IR spectrum	Conform
	B: Examine the chromatograms obtained in the test for related substances	The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution	Conform
	C: Color reaction	The bromine water is decolourised	Conform
Appearance of solution		Clear and colourless	Conform
Specific optical rotation		+89°~+93°	+90.7°
Related substances		Meets EP requirement	Conform
Heavy metals		≤10ppm	<10ppm
Loss on drying		≤1.0%	0.04%
Sulphated ash		≤0.1%	0.06%
Assay		98.5%~101.0%	99.7%
Conclusion: This batch complies with the specification of EP9			

Report by: 许挺

QA manager: 唐生

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

P.C: 317200

Tel: +86-576-83993696 / 83881111

Fax: +86-576-83993731