



浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

28/08/2023

CERTIFICATE OF ANALYSIS

Product name: Biotin

Batch number	CS1-2306006	Test No.	CP2306049
Expiry date	May 30,2027	Report date	Jun.12,2023
Manufacturing date	May 31,2023	Submitted date	Jun.10,2023
Package	10kg per carton	Batch size	300.2 Kg
Ref. pharmacopoeia(s)	EP9	Quantity	10 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%	0.05%
Sulphated ash		≤0.1%	0.05%
Assay		98.5%~101.0%	99.6%
Conclusion: This batch complies with the specification of EP9			

Report by: 孙晓

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