



浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

19/12/2024

CERTIFICATE OF ANALYSIS

Product name: Biotin

Batch number	CS1-2410036	Test No.	CP2410165
Expiry date	Oct.21.2028	Report date	Oct.30.2024
Manufacturing date	Oct.22.2024	Submitted date	Oct.28.2024
Package	20kg per drum	Batch size	140 Kg
Ref. pharmacopoeia(s)	EP9	Quantity	20 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%	0.03%
Sulphated ash		≤0.1%	0.04%
Assay		98.5% ~ 101.0%	99.8%
Conclusion: This batch complies with the specification of EP9			

Report by:

QA:

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