



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:D-Biotin

Batch number	CS1-2501022	Test No.	CP2501065
Expiry date	Jan.11,2029	Report date	Jan.25,2025
Manufacturing date	Jan.12,2025	Submitted date	Jan.22,2025
Package	10kg per carton	Batch size	300 Kg
Ref. pharmacopoeia(s)	USP2024	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	HPLC	97.5%-102.0%	99.0%
Related Compounds:			
1.Individual impurity	HPLC	NMT 1.0%	0.78%
2.Total impurities	HPLC	NMT 2.0%	0.82%
Optical Rotation	USP<781S>	+89°-+93°	+90.6°
Residual Solvents:			
Toluene	USP<467>	≤890ppm	<20ppm
Ethanol	USP<467>	≤5000ppm	<50ppm
Conclusion:	This batch complies with the specification of USP2024		

QC:

QA:

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