



ZHEJIANG NHU PHARMACEUTICAL CO.,LTD

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Certificate of Analysis

Date: May.27,2021

Product	:	D-Biotin
Batch NO.	:	0521040018
Quantity	:	20KGS
Manufacture Date	:	Apr.16,2021
Analysis Date	:	Apr.18,2021
Expiry Date	:	Apr.15,2024
Product Code	:	SPVH01

Result of Analysis:

Test Items	Standards	Results
Appearance	White or off-white crystalline powder	Conform
Identification	A. Infrared Absorption	Conform
	C. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution ,as obtained in the Assay.	Conform
Specific Rotation	+89°~ +93°	+90.3°
Organic volatile impurity	Meets USP requirement	Conform
Assay (HPLC)	97.5%~100.5%	99.8%
Loss on Drying	≤0.5%	0.06%
Heavy Metal	≤10 mg/kg	<10 mg/kg
Related substances	Individual impurity not more than 1,0 %;	Conform
	total impurities not more than 2,0%	Conform

Conclusion: Conforms to USP43

Reporter:

胡晓琴

Inspector:

段子庄

Approved:

