

## Certificate of Analysis

Product Name: Biotin pure

Standard: USP37/EP8

Origin: China

Ref. Pharmacopoeia (s): USP37/EP8

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
USP37	Identification:		
	A: Infrared absorption	USP<197>	To match with the reference IR spectrum
	B: Specific optical rotation	USP<781S>	Meet the requirements
	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.
Assay	HPLC	97.5%-100.5%	98.7%
Related Compounds:			
1. Individual impurity	HPLC	NMT1.0%	0.47%
2. Total impurity	HPLC	NMT2.0%	0.47%
Optical Rotation	USP<781S>	+89° -+93°	+90.3%
Characters	Visual	White or almost white, crystalline powder	White powder
Identification: A. IR	EP (2.2.24)	To match with the reference IR spectrum	Complies
B. TLC	EP (2.2.27)	Meets EP requirement	Complies
C. Color reaction	EP	The bromine water is decolourised	Complies
Appearance of solution	EP	Clear and colourless	Complies
Specific optical rotation	(2.2.1)(2.2.2)	+89° -+93°	+90.3°
Related substances	EP (2.2.7)	Meets EP requirement	Complies
Heavy metals	EP (2.2.27)	≤10 ppm	<10ppm
Loss on drying	EP (2.4.8)	≤1.0%	0.11%
Sulfated ash	EP (2.2.32)	≤0.1%	0.07%
Assay	EP (2.4.14)	98.5%-101.0%	99.3%
	Titration		
Conclusion: This batch complies with the specification of USP37/EP8.			

**Biotin pure COA**