

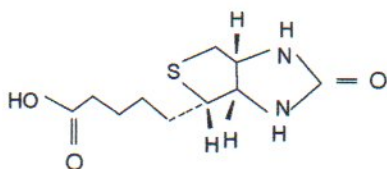
## SPECIFICATION OF D-BIOTIN

**Product:** BIOTIN , D-BIOTIN, (VITAMIN H)

**CAS NO.:** 58-85-5

**Structural formula:** C<sub>10</sub>H<sub>16</sub>N<sub>2</sub>O<sub>3</sub>S

**Structure:**



浙江圣达生物药业股份有限公司  
ZHEJIANG SHENGDA  
BIO-PHARM CO., LTD.

洪霞  
Authorised Signature

**Molecular weight:** 244.31

**Characters:** A white or almost white, crystalline powder or colourless crystals, very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in dilute solutions of alkali hydroxides.

Specification	Certified	Test method
Appearance	White, crystalline powder	/
Solution 1% in 0.1 N NaOH (EP)	Clear and colourless	/
Melting range(FCC)	229-232°C (with decomposition)	FCC<Appendix IIB>
Specific optical rotation (USP/EP/FCC)	+89° to +93° (on dry material)	EP<2.2.7>/USP<781S>/FCC<Appendix IIB>
Identification (USP/EP/FCC)	Conforms	EP<2.2.24>/USP<197K>
Related substances (EP)	Conforms to Ph. Eur. Requirements	EP<2.2.27>
Individual impurity (USP)	NMT 1.0%	HPLC
Total impurities (USP)	NMT 2.0%	HPLC
Sulphated ash (EP)	NMT 0.1%	EP<2.4.14>
Heavy metals (EP)	NMT 10ppm	EP<2.4.8>
Lead (FCC)	NMT 2ppm	FCC<Appendix IIIB>

Specification	Certified	Test method
Cadmium	NMT 1ppm	USP<851>
Mercury	NMT 0.1ppm	USP<261>
Arsenic	NMT 1ppm	USP<211>
Loss on drying (EP)	NMT 1.0%	EP<2.2.32>
Residual solvents(USP)	Toluene ≤ 890ppm	USP<467>
Total plate count	<1000 cfu/g	USP<2021>
Yeast and Mold	<100 cfu/g	USP<2021>
E.Coli	Negative	USP<2022>
Salmonella	Negative	USP<2022>
Staphylococcus aureus	Negative	USP<2022>
Assay(USP)	97.5%-102.0%(on dry base)	HPLC
Assay(FCC)	97.5%-100.5%(on dry base)	Titration
Assay(EP)	98.5%-101.0%(on dry base)	Titration

**Packaging and Storage:** Store protected from light. D-Biotin is fairly stable to air and heat. The shelf life is 36 months from the date of production when stored in tight containers at room temperature.

**Uses:** Food /Feed additives

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