



## SPECIFICATION

<b>Product name</b>	<b>D-Biotin Pure</b>
<b>Product code</b>	<b>SPVH01</b>
<b>Production site</b>	<b>Zhejiang NHU Pharmaceutical</b>
<b>Description</b>	
Ingredients	D-Biotin
Synonym	Vitamin H; Biotin; 1H-thieno[3,4-d]imidazole-4-pentanoic acid
Formula	C <sub>10</sub> H <sub>16</sub> N <sub>2</sub> O <sub>3</sub> S
CAS No	58-85-5
<b>Properties</b>	
Shelf life	36 months after production date in unopened original packaging
Aspect	A white or almost white, crystalline powder or colourless crystals, clear and colourless of 10g/l in 4 g/l solution of sodium hydroxide
Assay (Titration, 0,1 N NaOH)	98,5 % - 101 %
Assay (HPLC)	97,5 % - 102 %
Loss on drying	≤ 0,2 %
Solubility	Very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in diluted solutions of alkali hydroxydes.
Identification	A EP 9.4: IR B EP 9.4: TLC C EP 9.4: Reaction with bromine water C USP: (HPLC) The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay
Specific optical rotation	+ 89° – + 93 ° (EP 9.4, USP, FCC)
Melting point	229 °C – 232 °C (FCC)
Sulphated ash	≤ 0,1 %
Particle size	100 % through 60 mesh/423,33 µm
<b>Heavy metals</b>	
Arsenic (As)	≤ 1 mg/kg
Lead (Pb)	≤ 0,5 mg/kg
Cadmium (Cd)	≤ 0,5 mg/kg
Mercury (Hg)	≤ 0,1 mg/kg



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### Microbiological specs

Total plate count ≤ 1000 CFU/g  
Mould and Yeast ≤ 100 CFU/g

Related substances EP 9.4: TLC: Any impurity obtained in test sol. (a) shall not be more intense than that in ref (b) (0,5 %) and at most one of ref (c) (0,25 %)  
USP: HPLC: Individual impurity not more than 1,0 %; total impurities not more than 2,0 %  
Organic volatile impurity Meets USP requirements

### Handling

Usage For food and cosmetic applications

Stability The product is stable to air, heat and light. It is stable in water for drinking for at least 24 hours when used properly.

Storage Store in a tight container in a dry place.

Transport instructions See our latest safety data sheet

The product complies with EP 9.4, USP and FCC.

### NHU Life Science GmbH

