

SPECIFICATION

Product name D-Biotin
Product code SPVH01
Production site Zhejiang NHU Pharmaceutical
Trade name D-Biotin pure Food Grade (USP2022/EP9.4)

Description

Ingredients D-Biotin pure
Synonym Vitamin H; Biotin;
1H-Thieno[3,4-d]imidazole-4-pentanoic acid
Formula C₁₀H₁₆N₂O₃S
CAS No 58-85-5

Properties

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 sodiumhydroxide
Assay (Titration, 0,1 N NaOH) 98,5 % - 101 %
Assay (HPLC) 97,5 % - 102 %
Loss on drying max. 0,2 %
Solubility Very slightly soluble in water and in alcohol, practically insoluble in acetone. It dissolves in diluted solutions of alkali hydroxides

Identification
A Ph. Eur.: IR
B Ph. Eur.: TLC
C Ph. Eur.: 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 ° (Ph. Eur., USP, FCC)
Melting point 229 °C – 232 °C (FCC)
Sulphated ash max. 0,1 %

Heavy metals

Arsenic (As) max. 1 mg/kg
Lead (Pb) max. 0,5 mg/kg
Cadmium (Cd) max. 0,5 mg/kg
Mercury (Hg) max. 0,1 mg/kg

Microbiological specs

Total plate count	≤ 1000 CFU/g
Mould and Yeast	≤ 100 CFU/g
E. coli	Negative (in 1 g)
Salmonella spp.	Negative (in 25 g)

Related substances	Ph. Eur.: 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

Stability The product is stable to air, heat and light

Storage Store in a tight container in a dry place

Usage For cosmetic and food industry, product can also be used as feed additive which consists of Biotin (3a880)
dosage in feed: as per latest version of European feedstuff law

Transport instructions See our latest safety data sheet

NHU EUROPE GmbH