

SPECIFICATION D-Biotin pure Food Grade (USP43/EP9.4)

Production unit

Zhejiang NHU Pharmaceutical

Description

Ingredients

D-Biotin pure

Synonym

Vitamin H; Biotin;

1H-Thieno[3,4-d]imidazole-4-pentanoic acid

Formula

C₁₀H₁₆N₂O₃S

Product code

SPVH01

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

max. 10 mg/kg

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

D-Biotin pure/SPVH01/üa und fgg 010722/av