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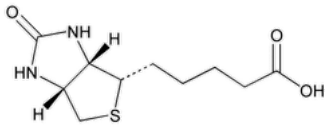
Biotin



$C_{10}H_{16}N_2O_3S$ 244.31

1*H*-Thieno[3,4-*d*]imidazole-4-pentanoic acid, hexahydro-2-oxo-, [3a*S*-(3aα,4β,6aα)]-;

(3a*S*,4*S*,6a*R*)-Hexahydro-2-oxo-1*H*-thieno[3,4-*d*]imidazole-4-valeric acid CAS RN®: 58-85-5; UNII: 6SO6U10H04.

DEFINITION

Biotin contains NLT 97.5% and NMT 102.0% of biotin ($C_{10}H_{16}N_2O_3S$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

• **B.** It meets the requirements in *Specific Tests* for *Optical Rotation⟨781S⟩, Specific Rotation*.

• **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer solution: Dissolve 1 g of sodium perchlorate monohydrate in 500 mL of water, add 1 mL of phosphoric acid, and dilute with water to 1000 mL.

Mobile phase: Acetonitrile and *Buffer solution* (8.5:91.5)

Diluent: Acetonitrile and water (1:4)

Standard solution: 0.1 mg/mL of USP Biotin RS in *Diluent*. Sonicate if necessary to dissolve.

Sample solution: 0.1 mg/mL of Biotin in *Diluent*. Sonicate if necessary to dissolve.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 15-cm; 3-µm packing L7

Flow rate: 1.2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of biotin ($C_{10}H_{16}N_2O_3S$) in the portion of Biotin taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Biotin RS in the *Standard solution* (mg/mL)

C_U = concentration of Biotin in the *Sample solution* (mg/mL)

Acceptance criteria: 97.5%–102.0%

IMPURITIES

• **Related Compounds**

Buffer solution, Mobile phase, Diluent, Standard solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Measure the peak responses of the *Sample solution*.

Calculate the percentage of each impurity in the portion of Biotin taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_T = sum of the peak responses of all the peaks from the *Sample solution*

Acceptance criteria

Individual impurity: NMT 1.0%

Total impurities: NMT 2.0%

SPECIFIC TESTS

• **Optical Rotation,** *Specific Rotation*⟨781S⟩

Sample solution: 20 mg/mL in 0.1 N sodium hydroxide

Acceptance criteria: +89° to +93°

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Store in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Biotin RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BIOTIN	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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