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Biotin Capsules

DEFINITION
Biotin Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of biotin ($C_{10}H_{16}N_2O_3S$).

IDENTIFICATION
• **A.** 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: 0.05 mg/mL of USP Biotin RS in *Diluent*. Sonicate, if necessary, to dissolve.

Sample solution: Weigh NLT 20 Capsules in a tared weighing bottle. Open the Capsules, without the loss of shell material, and transfer the contents to a 100-mL beaker. Remove any contents adhering to the empty shells by washing, if necessary, with several portions of ether. Discard the washings, and dry the Capsule shells with the aid of a current of dry air until the odor of ether is no longer perceptible. Weigh the empty Capsule shells in the tared weighing bottle, and calculate the average net weight per Capsule. Transfer a portion of the Capsule contents, equivalent to a nominal amount of 5 mg of biotin to a 100-mL volumetric flask, add 60 mL of water, and shake in a water bath at 65° for 20 min. Sonicate for 5 min, shake by mechanical means for 15 min, and cool to room temperature. Add 20 mL of acetonitrile, dilute with water to volume, and filter.

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 Capsules 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 = nominal concentration of biotin in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS
• **Dissolution ⟨711⟩**

Buffer solution: 0.02 N anhydrous disodium hydrogen phosphate adjusted with phosphoric acid to a pH of 7.4

Medium: *Buffer solution*; 500 mL

Apparatus 1: 100 rpm

Time: 1 h

Standard solution: Dissolve a suitable amount of USP Biotin RS in *Buffer solution* to obtain a concentration similar to that expected in the *Sample solution*.

Sample solution: Withdraw a portion of the solution under test, pass through a suitable filter, and use the pooled sample as the test specimen.

Analysis: Proceed as directed in the *Assay*, making any necessary adjustments.

Calculate the percentage of the labeled amount of biotin ($C_{10}H_{16}N_2O_3S$) dissolved:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = labeled amount of biotin (µg/Capsule)

Tolerances: NLT 75% (Q) of the labeled amount of biotin ($C_{10}H_{16}N_2O_3S$) is dissolved.

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant 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 CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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