Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Dec-2013
Document Type: USP Monographs
DocId: GUID-F9A08AA7-BF7E-464F-952F-DD00F13B57E4_1_en-US
DOI: https://doi.org/10.31003/USPNF_M7499_01_01
DOI Ref: h43qy

Biotin Tablets

DEFINITION
Biotin Tablets 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: Transfer a portion equivalent to 5 mg of biotin from NLT 30 finely powdered Tablets 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 Tablets 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 2: 75 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/Tablet)

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 TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 38(5)

Current DocID: GUID-F9A08AA7-BF7E-464F-952F-DD00F13B57E4_1_en-US

DOI: https://doi.org/10.31003/USPNF_M7499_01_01

DOI ref: h43qy