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Add the following:

▲Biotin Compounded Oral Suspension

DEFINITION

Biotin Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of biotin ($C_{10}H_{16}N_2O_3S$).

Prepare Biotin Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Biotin powder	1 g
Vehicle: 1:1 mixture of Ora-Plus[a] and Ora-Sweet,[a] a sufficient quantity to make	100 mL

[a] Perrigo Pharmaceuticals, Allegan, MI.

Place the *Biotin powder* in a suitable container and triturate to a fine powder. Add a small amount of *Vehicle* and mix well to form a smooth paste. Add a sufficient amount of *Vehicle* to make the mortar contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Mix well.

ASSAY

• **Procedure**

Solution A: Add 1 g of sodium perchlorate monohydrate to 500 mL of water. Add 1 mL of phosphoric acid and then an additional 500 mL of water.

Mobile phase: Acetonitrile and *Solution A* (8.5: 91.5)

Diluent: Acetonitrile and water (20:80)

Standard solution: 0.1 mg/mL of USP Biotin RS in *Diluent*

Sample solution: Transfer 1.0 mL of Oral Suspension into a 100-mL volumetric flask, and add *Diluent* to volume. Pass through a filter of 0.22-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 200 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing L7

Flow rate: 1.2 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for biotin is about 11.8 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of biotin ($C_{10}H_{16}N_2O_3S$) in the portion of Oral Suspension taken:

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

r_U = peak response of biotin from the *Sample solution*

r_S = peak response of biotin 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%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.7–4.7

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Biotin RS

▲2S *(USP41)*

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

Topic/Question	Contact	Expert Committee
BIOTIN COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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