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Add the following:

▲Hydrochlorothiazide Compounded Oral Suspension

DEFINITION

Hydrochlorothiazide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$).

Prepare Hydrochlorothiazide Compounded Oral Suspension 2.5 mg/mL and 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

For Hydrochlorothiazide Compounded Oral Suspension Containing 2.5 mg/mL

Hydrochlorothiazide powder	0.25 g
Ora-Blend,[a] a sufficient quantity to make	100 mL

[a] Perrigo, Allergan, MI.

For Hydrochlorothiazide Compounded Oral Suspension Containing 10 mg/mL

Hydrochlorothiazide powder	1 g
Ora-Blend,[a] a sufficient quantity to make	100 mL

[a] Perrigo, Allergan, MI.

Place the *Hydrochlorothiazide powder* in a suitable container and triturate to a fine powder. Add a small amount of *Ora-Blend* and mix well to form a smooth paste. Add a sufficient amount of *Ora-Blend* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 80 mM of monobasic sodium phosphate monohydrate adjusted with phosphoric acid to a pH of 2.9

Solution B: Methanol and water (20:80)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	80	20
6	80	20
6.5	50	50
11.5	50	50

Time (min)	Solution A (%)	Solution B (%)
12	80	20
17	80	20

Standard solution: Transfer 20 mg of USP Hydrochlorothiazide RS to a 200-mL volumetric flask. Add 40 mL of methanol and sonicate for 20 min. Dilute with water to volume and mix.

Sample solution

For Oral Suspension 2.5 mg/mL: Transfer 2 mL of Oral Suspension to a 50-mL volumetric flask, add 10 mL of methanol, and sonicate for 20 min. Dilute with water to volume and mix. Centrifuge an aliquot for 10 min and transfer the supernatant to an HPLC vial.

For Oral Suspension 10 mg/mL: Transfer 1 mL of Oral Suspension to a 100-mL volumetric flask, add 20 mL of methanol, and sonicate for 20 min. Dilute with water to volume and mix. Centrifuge an aliquot for 10 min and transfer the supernatant to an HPLC vial.

Chromatographic system

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

Mode: LC

Detector: UV 227 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Temperatures

Autosampler: 4°

Column: 25°

Flow rate: 2.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for hydrochlorothiazide is about 4.8 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 hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$) 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 hydrochlorothiazide from the *Sample solution*

r_S = peak response of hydrochlorothiazide from the *Standard solution*

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

C_U = nominal concentration of hydrochlorothiazide 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 in a refrigerator or at controlled room temperature.

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded, when stored in a refrigerator or at controlled room temperature

• **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 Hydrochlorothiazide RS▲ (USP 1-May-2020)

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

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

Chromatographic Database Information: Chromatographic Database

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