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Add the following:

▲Chlorothiazide Compounded Oral Suspension

DEFINITION

Chlorothiazide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of chlorothiazide ($C_7H_6ClN_3O_4S_2$).

Prepare Chlorothiazide Compounded Oral Suspension 50 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Chlorothiazide tablets,[a] equivalent to	5 g of chlorothiazide
Ora-Blend,[b] a sufficient quantity to make	100 mL

[a] Chlorothiazide 500-mg tablets, Mylan Pharmaceuticals, Inc., Morgantown, WV.

[b] Perrigo Pharmaceuticals, Allegan, MI.

Place the *Chlorothiazide tablets* 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 the contents stepwise and quantitatively into a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume. Mix well.

ASSAY

• **Procedure**

Solution A: 92.5 mM monobasic sodium phosphate monohydrate adjusted with phosphoric acid to a pH of 2.9

Mobile phase: Methanol and *Solution A* (20:80)

Standard solution: Transfer 20 mg of USP Chlorothiazide RS to a 200-mL volumetric flask and dissolve in about 20 mL of methanol. Add water to bring to final volume.

Sample solution: Transfer 1.0 mL of Oral Suspension into a 50-mL volumetric flask, and add methanol to volume. Transfer 1.0 mL of the resultant solution into a 10-mL volumetric flask, and add water to bring to final volume.

Chromatographic system

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

Mode: LC

Detector: UV 227 nm

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

Flow rate: 2.0 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for chlorothiazide is about 4.4 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 chlorothiazide ($C_7H_6ClN_3O_4S_2$) 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 chlorothiazide from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.9–4.9

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 Chlorothiazide RS▲ (USP 1-May-2019)

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

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

Chromatographic Database Information: Chromatographic Database

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