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Spironolactone and Hydrochlorothiazide Compounded Oral Suspension

DEFINITION
Spironolactone and Hydrochlorothiazide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$) and hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$).
Prepare an oral suspension containing 5 mg/mL of spironolactone and 5 mg/mL of hydrochlorothiazide as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Spironolactone and Hydrochlorothiazide tablets ^a equivalent to	500 mg of spironolactone and 500 mg of hydrochlorothiazide
Vehicle: a 1:1 mixture of Ora-Sweet ^b (regular or sugar-free) and Ora-Plus, ^b a sufficient quantity to make	100 mL

- ^a Spironolactone and hydrochlorothiazide 25-mg/25-mg tablets, Mylan Pharmaceutical Inc., Morgantown, WV.
^b Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Spironolactone and Hydrochlorothiazide tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a spironolactone and hydrochlorothiazide liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Mobile phase: Methanol and water (70:30). Filter and degas.
Standard solution: 0.1 mg/mL of [USP Spironolactone RS](#) and 0.1 mg/mL of [USP Hydrochlorothiazide RS](#) in methanol
Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.1 mg/mL of spironolactone and 0.1 mg/mL of hydrochlorothiazide from Oral Suspension and methanol. Centrifuge.
Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)
Mode: LC
Detector: UV 254 nm
Column: 4.6-mm × 25-cm; 5-μm packing L1
Flow rate: 1.0 mL/min
Injection volume: 20 μL
System suitability
Sample: *Standard solution*
[NOTE—The retention times for hydrochlorothiazide and spironolactone are about 3.5 and 7.4 min, respectively.]
Suitability requirements
Relative standard deviation: NMT 2.0% for spironolactone and NMT 2.0% for hydrochlorothiazide for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$) in the portion of Oral Suspension taken:

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 Spironolactone RS](#) in the *Standard solution* (mg/mL)

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

Calculate the percentage of the labeled amount of hydrochlorothiazide ($C_7H_8ClN_3O_4S_2$) in the portion of Oral Suspension taken by the same formula, changing the terms to refer to hydrochlorothiazide.

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH (791):** 3.8–4.8

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded, when stored in a refrigerator or controlled at 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 Spironolactone RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

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