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# Spironolactone Compounded Oral Suspension

**DEFINITION**

***Change to read:***

Spironolactone Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of spironolactone ($C_{24}H_{32}O_4S$).

Prepare Spironolactone Compounded Oral Suspension 5 mg/mL in Ora-Blend as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

| | |
|---|---|
| Spironolactone tablet(s)[a] equivalent to | 500 mg |
| Ora-Blend,[b] a sufficient quantity to make | 100 mL |

[a] Spironolactone 25-mg tablet, Qualitest Pharmaceuticals, Huntsville, AL.

[b] Perrigo Pharmaceuticals, Allegan, MI.

Crush the *Spironolactone tablet(s)* to a fine powder, and pass through a 40-mesh sieve. Wet the powder with a small amount of *Ora-Blend*, and triturate to make a smooth paste. Add the *Ora-Blend* to make the mortar contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume ▲and▲ (USP 1-May-2021) mix well.

▲Prepare Spironolactone Compounded Oral Suspension 5 mg/mL in SuspendIt as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

| | |
|---|---|
| Spironolactone powder | 1.25 g |
| SuspendIt,[a] a sufficient quantity to make | 250 mL |

[a] PCCA, Houston, TX.

Place the *Spironolactone powder* in a suitable container and triturate to a fine powder. Add a small amount of *SuspendIt*, and mix well to form a smooth paste. Add a sufficient amount of *SuspendIt* to make a liquid that is pourable. Transfer contents stepwise and quantitatively to a calibrated container using additional amounts of the *SuspendIt*. Add a sufficient amount of *SuspendIt* to bring to final volume, and mix well.▲

(USP 1-May-2021)

**ASSAY**

***Change to read:***

• **Procedure ▲1: Oral Suspension in Ora-Blend▲** (USP 1-May-2021)

**Mobile phase:** Mix 435 mL of water with 2.7 mL of phosphoric acid and 50 mL of methanol. Combine the solution with 515 mL of acetonitrile and mix well. Filter and degas.

**Standard solution:** 0.2 mg/mL of USP Spironolactone RS in *Mobile phase*

**Sample solution:** Shake each bottle of Oral Suspension thoroughly. Transfer 1.0 mL of Oral Suspension into a 25-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well to dissolve.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 238 nm

**Column:** 4.6-mm × 25-cm; 5-µm packing L11

**Flow rate:** 1.0 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—The retention time for spironolactone is about 10.7 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 spironolactone ($C_{24}H_{32}O_4S$) 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 spironolactone from the *Sample solution*

$r_S$ = peak response of spironolactone from the *Standard solution*

$C_S$ = concentration of ▲USP Spironolactone RS▲ (USP 1-May-2021) in the *Standard solution* (mg/mL)

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

**Acceptance criteria:** 90.0%–110.0%

***Add the following:***

▲• **PROCEDURE 2: ORAL SUSPENSION IN SUSPENDIT**

**Solution A:** 30 mM sodium phosphate monobasic adjusted with phosphoric acid to a pH of 2.9

**Mobile phase:** Acetonitrile and *Solution A* (45:55)

**Standard solution:** 0.0075 mg/mL of spironolactone prepared from USP Spironolactone RS in *Mobile phase*

**Sample solution:** Shake each bottle of Oral Suspension thoroughly. Transfer 0.015 mL of Oral Suspension into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix well to dissolve. Sonicate for 5 min.

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 240 nm

**Column:** 2.1-mm × 10-cm; 5-µm packing L1

**Flow rate:** 0.8 mL/min

**Injection volume:** 20 µL

**System suitability**

**Sample:** *Standard solution*

[NOTE—The retention time for spironolactone is about 5.2 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 spironolactone ($C_{24}H_{32}O_4S$) 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 spironolactone from the *Sample solution*

$r_S$ = peak response of spironolactone 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)

**Acceptance criteria:** 90.0%–110.0%▲ (USP 1-May-2021)

**SPECIFIC TESTS**

***Change to read:***

• **pH** ⟨791⟩

▲**Oral Suspension in Ora-Blend:** 3.6–4.6

**Oral Suspension in SuspendIt:** 4.8–5.8▲ (USP 1-May-2021)

**ADDITIONAL REQUIREMENTS**

***Change to read:***

• **Packaging and Storage:** Package in tight, light-resistant containers. Store ▲in a refrigerator▲ (USP 1-May-2021) 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*.

***Change to read:***

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored ▲in a refrigerator▲ (USP 1-May-2021) or at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Spironolactone RS

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

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

**Chromatographic Database Information:** Chromatographic Database

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