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Ursodiol Compounded Oral Suspension

Change to read:

DEFINITION
Ursodiol Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of ursodiol ($C_{24}H_{40}O_4$).

Prepare Ursodiol Compounded Oral Suspension 50 mg/mL ▲in Ora-Sweet SF and Ora-Plus▲ (USP 1-Dec-2021) as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Ursodiol tablets[a] equivalent to	5 g of ursodiol
Vehicle: a 1:1 mixture of Ora-Sweet[b] (sugar-free) and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Urso 250-mg tablets, Axcan Pharma U.S. Inc., Birmingham, AL.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Ursodiol 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 ursodiol 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.

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

Ursodiol powder	5 g
Acesulfame potassium	0.5 g
Steviol glycosides 95%	0.5 g
SuspendIt,[a] a sufficient quantity to make	100 mL

[a] PCCA, Houston, TX.

Place the *Ursodiol powder, Acesulfame potassium*, and *Steviol glycosides 95%* 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 the remainder of the *SuspendIt*. Add a sufficient amount of *SuspendIt* to bring to final volume, and mix well.

Prepare Ursodiol Compounded Oral Suspension 100 mg/mL in SuspendIt as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Ursodiol powder	10 g
Acesulfame potassium	0.5 g
Steviol glycosides 95%	0.5 g

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SuspendIt,[a] a sufficient quantity to make	100 mL

[a] PCCA, Houston, TX.

Place the *Ursodiol powder, Acesulfame potassium*, and *Steviol glycosides 95%* 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 the remainder of the *SuspendIt*. Add a sufficient amount of *SuspendIt* to bring to final volume, and mix well.▲ (USP 1-Dec-2021)

ASSAY

Change to read:

• **Procedure 1: ▲Oral Suspension in Ora-Sweet SF and Ora-Plus▲** (USP 1-Dec-2021)

Mobile phase: Methanol and 0.01 M dihydrogen potassium phosphate buffer (75:25). Adjust with dilute phosphoric acid to a pH of 5.25. Filter and degas.

Standard solution: 1.25 mg/mL of USP Ursodiol RS in methanol

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 1.25 mg/mL of ursodiol from Oral Suspension and methanol, and centrifuge.

Chromatographic system

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

Mode: LC

Detector: UV 201 nm

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

Column temperature: 40°

Flow rate: 1.2 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for ursodiol is about 7 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ursodiol ($C_{24}H_{40}O_4$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

Add the following:

▲• **Procedure 2: Oral Suspension in SuspendIt**

Mobile phase: Methanol and 1 mg/mL of acetic acid (58:42)

Standard stock solution: 10 mg/mL of USP Ursodiol RS in methanol

Standard solution: Transfer 1 mL of the *Standard stock solution* into a 10-mL volumetric flask, and dilute with *Mobile phase* to volume to create a 1-mg/mL solution of ursodiol.

Sample solution: Prepare the appropriate solution as follows.

For 50 mg/mL: Shake the bottle of Oral Suspension thoroughly. Transfer 0.1 mL of Oral Suspension into a 5-mL volumetric flask, dissolve with 1 mL of methanol, dilute with *Mobile phase* to volume, and mix well. Transfer into HPLC vials, taking care not to transfer any globular-gelled SuspendIt.

For 100 mg/mL: Shake the bottle of Oral Suspension thoroughly. Transfer 0.1 mL of Oral Suspension into a 10-mL volumetric flask, dissolve with 1 mL of methanol, dilute with *Mobile phase* to volume, and mix well. Transfer into HPLC vials, taking care not to transfer any globular-

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gelled SuspendIt.

Chromatographic system

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

Mode: LC

Detector: Refractive index

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

Flow rate: 0.8 mL/min

Injection volume: 30 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for ursodiol is about 6.1 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 ursodiol ($C_{24}H_{40}O_4$) 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 ursodiol from the *Sample solution*

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

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

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

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

SPECIFIC TESTS

Change to read:

• **pH** ⟨791⟩

▲**Oral Suspension in Ora-Sweet SF and Ora-Plus:** 4.0–5.0

Oral Suspension in SuspendIt: 4.5–5.5▲ (USP 1-Dec-2021)

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

Change to read:

• **BEYOND-USE DATE**

▲**Oral Suspension in Ora-Sweet SF and Ora-Plus:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator

Oral Suspension in SuspendIt: NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature▲ (USP 1-Dec-2021)

• **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 Ursodiol RS

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

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

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