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Add the following:

▲Leflunomide Compounded Oral Suspension

DEFINITION

Leflunomide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of leflunomide ($C_{12}H_9F_3N_2O_2$).

Prepare Leflunomide Compounded Oral Suspension 20 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Leflunomide powder	2000 mg
Vehicle: 1:1 mixture of Ora-Plus[a] and Ora-Sweet,[a] a sufficient quantity to make	100 mL

[a] Perrigo, Allegan, MI.

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

[**Caution—**Leflunomide is a hazardous drug and must be handled accordingly.]

ASSAY

• **Procedure**

Mobile phase: Add 350 mL of acetonitrile to 650 mL of water. Add 5 mL of trimethylamine and adjust with phosphoric acid to a pH of 4.0.

Standard solution: 0.5 mg/mL of USP Leflunomide RS in methanol

Sample solution: Transfer 0.625 mL of Oral Suspension into a 25-mL volumetric flask, and add methanol to volume. Pass through a filter of 0.22-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 260 nm

Column: 2.1-mm × 5-cm; 1.6-µm packing L1

Temperatures

Autosampler: 10°

Column: 20°

Flow rate: 0.39 mL/min

Injection volume: 1 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for leflunomide is about 8.6 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 leflunomide ($C_{12}H_9F_3N_2O_2$) 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 leflunomide from the *Sample solution*

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

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

C_U = nominal concentration of leflunomide 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 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 state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Leflunomide RS

▲2S *(USP41)*

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

Topic/Question	Contact	Expert Committee
LEFLUNOMIDE 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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