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Add the following:

▲Chlorambucil Compounded Oral Suspension

DEFINITION

Chlorambucil Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of chlorambucil ($C_{14}H_{19}Cl_2NO_2$).

Prepare Chlorambucil Compounded Oral Suspension 2 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Chlorambucil tablets,[a] equivalent to	200 mg of chlorambucil
Vehicle: a 1:1 mixture of Ora Plus[b] and Ora-Sweet,[b] a sufficient quantity to make	100 mL

[a] Chlorambucil 2-mg tablets, GlaxoSmithKline, Research Triangle Park, NC.

[b] Perrigo, Allegan, MI.

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

ASSAY

• **Procedure**

Solution A: 0.2% (v/v) glacial acetic acid in water

Mobile phase: Methanol and *Solution A* (65:35)

Standard solution: 0.2 mg/mL of USP Chlorambucil RS in methanol

Sample solution: Transfer 1.0 mL of Oral Suspension into a 10-mL volumetric flask, add methanol to volume, and filter. [Note—The *Standard solution* and the *Sample solution* must be used within 6 h of preparation.]

Chromatographic system

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

Mode: LC

Detector: UV 258 nm

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

Temperatures

Autosampler: 15°

Column: 40°

Flow rate: 2.0 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for chlorambucil is about 3.6 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 chlorambucil ($C_{14}H_{19}Cl_2NO_2$) 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 chlorambucil from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.5–4.5

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator.

• **Beyond-Use Date:** NMT 14 days after the day on which it was compounded when stored 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 Chlorambucil RS

▲ (USP 1-May-2020)

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

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

Chromatographic Database Information: Chromatographic Database

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