

Add the following:

Hydrocortisone Compounded Oral Suspension

DEFINITION
Hydrocortisone Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of hydrocortisone ($C_{21}H_{30}O_5$).
Prepare Hydrocortisone Compounded Oral Suspension, 2 mg/mL, as follows¹ (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Hydrocortisone powder	200 mg
Ora-Blend ^a a sufficient quantity to make	100 mL

^a Perrigo, Allegan, MI.

Place the *Hydrocortisone powder* in a suitable container. Add a small amount of *Ora-Blend* and mix well to form a smooth paste. Add a sufficient amount of *Ora-Blend* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume and mix well.

ASSAY

• **PROCEDURE**

- Solution A:** A solution of 5.44 g/L of potassium phosphate dibasic in water, adjusted with phosphoric acid to a pH of 7.5. Pass through a polyvinyl difluoride filter of 0.22-µm pore size.
- Solution B:** Methanol and acetonitrile (50:50)
- Diluent:** Methanol and water (20:80)
- Mobile phase:** See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
2	70	30
4	60	40
10	55	45
14	30	70
18	30	70
20	70	30
26	70	30

Standard solution: 0.1 mg/mL of [USP Hydrocortisone RS](#) in *Diluent*. Sonicate for 10 min and vortex.

Sample solution: Vortex the bottle for 2 min, then allow 1 min for the bubbles to dissipate. Transfer about 2 mL of Oral Suspension into a plastic cup. Draw 1 mL of Oral Suspension into a wide bore micropipette, wipe the outside of the pipette tip, and transfer the sample slowly into a 20-mL volumetric flask. Rinse the pipette tip three times using the *Diluent* and transfer the contents into the volumetric flask. Dilute with *Diluent* to volume. Vortex for 2 min and sonicate for 5 min. Vortex for 2 min. Pass through a filter of 0.22-µm pore size and transfer into an HPLC vial after discarding the first 3 mL.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

- Mode:** LC
- Detector:** UV 254 nm
- Column:** 4.6-mm × 15-cm; 5-µm packing L7
- Temperatures**
 - Autosampler:** 4°
 - Column:** 30°
- Flow rate:** 1 mL/min
- Injection volume:** 20 µL

System suitability

- Sample:** *Standard solution*
- [NOTE—The retention time for hydrocortisone is about 11.9 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 hydrocortisone ($C_{21}H_{30}O_5$) in the portion of Oral Suspension taken:

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

- r_U = peak response of hydrocortisone from the *Sample solution*
- r_S = peak response of hydrocortisone from the *Standard solution*
- C_S = concentration of [USP Hydrocortisone RS](#) in the *Standard solution* (mg/mL)
- C_U = nominal concentration of hydrocortisone in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- pH (791):** 3.8–4.8
- Appearance:** Cloudy, white suspension with visible particulates

ADDITIONAL REQUIREMENTS

- PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- 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 indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.
- USP REFERENCE STANDARDS (11):**
[USP Hydrocortisone RS](#) ▲ (USP 1-May-2024)

¹ This formulation meets the requirements in [Antimicrobial Effectiveness Testing \(51\)](#).

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

Topic/Question	Contact	Expert Committee
HYDROCORTISONE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding  Documents Document Sharing Hub