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Add the following:

^Cyclophosphamide Compounded Oral Suspension

DEFINITION

Cyclophosphamide Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of cyclophosphamide ($C_7H_{15}Cl_2N_2O_2P$).

Prepare Cyclophosphamide Compounded Oral Suspension 20 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Cyclophosphamide capsules, ^a equivalent to	2 g of cyclophosphamide
Ora-Blend, ^b a sufficient quantity to make	100 mL

- ^a Cyclophosphamide 50-mg capsules, Roxane Laboratories, Inc., Columbus, OH.
- ^b Perrigo, Allegan, MI.

Empty the *Cyclophosphamide capsules* into a suitable container and triturate to a fine powder. 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 container contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *Ora-Blend*. Add sufficient *Ora-Blend* to bring to final volume. Mix well.

[CAUTION—Cyclophosphamide is a hazardous drug and must be handled accordingly.]

ASSAY

• PROCEDURE

Mobile phase: Add 2.34 g of monobasic potassium phosphate to 780 mL of water. Adjust with 6 N potassium hydroxide to a pH of 7.0. Add 220 mL of acetonitrile. Pass the solution through a filter of 0.22-µm pore size.

Standard solution: 0.4 mg/mL of cyclophosphamide prepared from [USP Cyclophosphamide RS](#) in water

Sample solution: Transfer 1.0 mL of Oral Suspension into a 50-mL volumetric flask and bring to final volume with water. Pass through a filter of 0.45-µm pore size.

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

Mode: LC
Detector: UV 205 nm
Column: 3.0-mm × 15-cm; 3-µm packing L1
Temperatures
Autosampler: 5°
Column: 45°

Flow rate: 0.5 mL/min
Injection volume: 5 µL

System suitability
Sample: *Standard solution*
[NOTE—The retention time for cyclophosphamide is about 8.1 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 cyclophosphamide ($C_7H_{15}Cl_2N_2O_2P$) 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 cyclophosphamide from the *Sample solution*

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

C_S = concentration of [USP Cyclophosphamide RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH** (791): 3.6–4.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator.
 - **BEYOND-USE DATE:** NMT 30 days after the date on which it was compounded when stored 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 Cyclophosphamide RS](#)
- ▲2S (USP41)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

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