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Chloroquine Phosphate Compounded Oral Suspension

DEFINITION

Chloroquine Phosphate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of chloroquine phosphate ($C_{18}H_{26}ClN_3 \cdot 2H_3PO_4$).

Prepare Chloroquine Phosphate Compounded Oral Suspension 15 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Chloroquine Phosphate tablets[a] equivalent to	1.5 g of chloroquine phosphate
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus[b], a sufficient quantity to make	100 mL

[a] Aralen 500-mg tablets, Sanofi-Winthrop, NY.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Chloroquine Phosphate 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 chloroquine phosphate 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.

ASSAY

• **Procedure**

Buffer solution: 20 mM 1-heptanesulfonic acid adjusted to a pH of 3.4

Mobile phase: Acetonitrile and *Buffer solution* (34:66). Filter and degas.

Standard solution: 150 µg/mL of USP Chloroquine Phosphate RS in *Mobile phase*

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 1.0 mL of the Oral Suspension into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 340 nm

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

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for chloroquine phosphate is about 9.4 min.]

Suitability requirements

Relative standard deviation: NMT 2% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chloroquine phosphate ($C_{18}H_{26}ClN_3 \cdot 2H_3PO_4$) 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 Chloroquine Phosphate RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of chloroquine phosphate in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–5.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature

• **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 Chloroquine Phosphate RS

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

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

Chromatographic Database Information: Chromatographic Database

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