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Chloroquine Phosphate Tablets

DEFINITION

Chloroquine Phosphate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of chloroquine phosphate ($C_{18}H_{26}ClN_3 \cdot 2H_3PO_4$).

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)

Standard solution: 7.5 µg/mL of USP Chloroquine Phosphate RS in water

Sample solution: Nominally 7.5 µg/mL of chloroquine phosphate from a filtered solution of finely powdered Tablets in water

Instrumental conditions

Mode: UV

Wavelength range: 329–343 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the absorbance ratio:

$$\text{Result} = A_{343}/A_{329}$$

A_{343} = absorbance of the *Sample solution* at 343 nm

A_{329} = absorbance of the *Sample solution* at 329 nm

Acceptance criteria: The peak maxima and minima of the *Sample solution* correspond to those of the *Standard solution*; the absorbance ratio is 1.00–1.15.

• **B.**

Sample solution: 20 mL of a filtered 1-mg/mL chloroquine phosphate solution from finely powdered Tablets in water

Analysis 1: To the *Sample solution* add 5 mL of trinitrophenol TS.

Acceptance criteria 1: A yellow precipitate is formed.

Analysis 2: Filter, wash the precipitate with water until the last washing is colorless, and dry over silica gel. [**Caution—**Picrates may explode.]

Acceptance criteria 2: The precipitate melts at 205°–210°.

• **C.** The retention time of the chloroquine peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: 6.8 g/L of monobasic potassium phosphate in water. Add 1.0 mL of perchloric acid to each 1 L of solution, adjust with phosphoric acid to a pH of 2.5, and pass through a filter of 0.45-µm pore size.

Mobile phase: Methanol and *Buffer* (22:78)

System suitability solution: 0.15 mg/mL of USP Amodiaquine Hydrochloride RS and 0.15 mg/mL of USP Chloroquine Phosphate RS in water

Standard solution: 0.15 mg/mL of USP Chloroquine Phosphate RS in water

Sample solution: Nominally 0.15 mg/mL of chloroquine phosphate in water prepared as follows. Transfer nominally 7.5 mg of chloroquine phosphate from finely powdered Tablets (NLT 20) to a 50-mL volumetric flask, and dissolve in and dilute with water to volume. Sonicate for 20 min. Pass 10 mL through a nylon filter of 0.2-µm pore size, discarding the first 4 mL, and use 2 mL for the *Analysis*.

Chromatographic system

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

Mode: LC

Detector: UV 224 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for chloroquine phosphate and amodiaquine hydrochloride are 1.0 and 1.3, respectively.]

Suitability requirements

Resolution: NLT 1.5 between amodiaquine hydrochloride and chloroquine phosphate

Tailing factor: NMT 1.5 for the amodiaquine and chloroquine peaks

Relative standard deviation: NMT 2.0% for the amodiaquine and chloroquine peaks

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 Tablets 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* (mg/mL)

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

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **DISSOLUTION ⟨711⟩**

Medium: Water; 900 mL

Apparatus 2: 100 rpm

Time: 45 min

Detector: UV

Analytical wavelength: 343 nm

Standard solution: USP Chloroquine Phosphate RS in *Medium*

Sample solution: Dilute with *Medium* to a concentration that is similar to the *Standard solution*.

Tolerances: NLT 75% (*Q*) of the labeled amount of chloroquine phosphate ($C_{18}H_{26}ClN_3 \cdot 2H_3PO_4$) is dissolved.

• **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Amodiaquine Hydrochloride RS

USP Chloroquine Phosphate RS

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

Topic/Question	Contact	Expert Committee
CHLOROQUINE PHOSPHATE TABLETS	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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