

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Nov-2020
 Document Type: USP Monographs
 DocId: GUID-D348694A-F089-4CAE-A044-91A4F9677E55_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M69080_02_01
 DOI Ref: 22p7i

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Primaquine Phosphate Tablets

DEFINITION

Primaquine Phosphate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$).

IDENTIFICATION

Change to read:

- **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-Aug-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

PROCEDURE

Mobile phase: [Acetonitrile](#), [tetrahydrofuran](#), [trifluoroacetic acid](#), and [water](#) (9:1:0.1:90)

Standard solution: 0.4 mg/mL of [USP Primaquine Phosphate RS](#) in *Mobile phase*. Sonicate with intermittent shaking to dissolve, if necessary.

System suitability stock solution: 0.4 mg/mL of [USP Primaquine Related Compound A RS](#) in *Mobile phase*

System suitability solution: Transfer 1.0 mL of *System suitability stock solution* to a 10-mL volumetric flask, and dilute with *Standard solution* to volume.

Sensitivity solution: 0.2 µg/mL of [USP Primaquine Phosphate RS](#) from *Standard solution* ▲in *Mobile phase*▲ (USP 1-Aug-2020)

Sample stock solution: Transfer a quantity of Tablets (NLT 20), accurately counted and weighed, to a 500-mL volumetric flask. Add 300 mL of *Mobile phase*, then sonicate and shake for 15 min. Add 150 mL of *Mobile phase*, then sonicate and shake for 15 min. Dilute with *Mobile phase* to volume, and filter.

Sample solution: ▲Nominally▲ (USP 1-Aug-2020) 0.4 mg/mL of primaquine phosphate in *Mobile phase* from the *Sample stock solution*

Chromatographic system

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

Mode: LC

Detector: UV 265 nm. ▲For *Identification A*, use a diode array detector in the range of 220–400 nm.▲ (USP 1-Aug-2020)

Column: 4.6-mm × 75-mm; 3-µm packing [L7](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: ▲NLT▲ (USP 1-Aug-2020) 3 times the retention time of primaquine

System suitability

Samples: *Standard solution*, *System suitability solution*, and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.5 between primaquine phosphate and primaquine related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0% for primaquine phosphate, *Standard solution*

Signal-to-noise ratio: NLT 10 for the primaquine peak, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$) 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 Primaquine Phosphate RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of primaquine phosphate in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: [0.01 N hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 60 min

Solution A: 961 mg of [sodium 1-pentanesulfonate](#) and 1 mL of [glacial acetic acid](#) in 400 mL of [water](#)

Mobile phase: [Methanol](#) and *Solution A* (3:2)

Sample solution: Pass a portion of the solution under test through an appropriate filter.

Standard solution: [USP Primaquine Phosphate RS](#) in *Medium* in a concentration similar that of the *Sample solution*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the ▲percentage of the labeled▲ (USP 1-Aug-2020) amount of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$) dissolved.

$$\text{▲Result} = (r_u/r_s) \times (C_s/L) \times V \times D \times 100$$

r_u = peak response of primaquine from the *Sample solution*

r_s = peak response of primaquine from the *Standard solution*

C_s = concentration of [USP Primaquine Phosphate RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*, if applicable▲ (USP 1-Aug-2020)

Tolerances: NLT 80% (Q) of the labeled amount of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Mobile phase, Standard solution, System suitability solution, Sensitivity solution, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Analysis

Sample: *Sample solution*

Calculate the percentage of each impurity in the portion of Tablets taken: