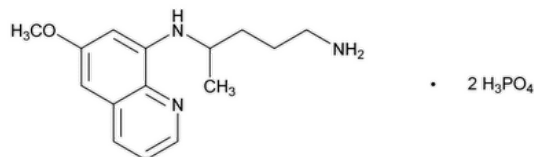


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-A98BAA35-5F09-4702-B2AD-185DF228D443_6_en-US
 DOI: https://doi.org/10.31003/USPNF_M69050_06_01
 DOI Ref: ct67r

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Primaquine Phosphate



$C_{15}H_{21}N_3O \cdot 2H_3PO_4$ 455.34

1,4-Pentanediamine, N^4 -(6-methoxy-8-quinolyl)-, ($\pm$)-, phosphate (1:2);

($\pm$)-8-[(4-Amino-1-methylbutyl)amino]-6-methoxyquinoline phosphate (1:2) CAS RN®: 63-45-6; UNII: H0982HF78B.

DEFINITION

Primaquine Phosphate contains NLT 97.0% and NMT 102.0% of primaquine phosphate ($C_{15}H_{21}N_3O \cdot 2H_3PO_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020) : Meets the requirements
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\), Chemical Identification Tests, Phosphate, Pyrophosphates](#): The residue obtained by ignition meets the requirements.
- **C.** 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*. [NOTE—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 the *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 the *Standard solution*

Sample solution: 0.4 mg/mL of Primaquine Phosphate in *Mobile phase*. [NOTE—Sonicate with intermittent shaking to dissolve, if necessary.]

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

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

Flow rate: 1.5 mL/min

Injection volume: 10 µL

Run time: ▲NLT ▲2S (USP41) 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 and primaquine related compound A, *System suitability solution*

Relative standard deviation: NMT 1.0% for primaquine, *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 Primaquine Phosphate taken:

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

 r_U = peak response of primaquine phosphate from the *Sample solution* r_S = peak response of primaquine phosphate from the *Standard solution* C_S = concentration of [USP Primaquine Phosphate RS](#) in the *Standard solution* (mg/mL) C_U = concentration of Primaquine Phosphate in the *Sample solution* (mg/mL)**Acceptance criteria:** 97.0%–102.0% on the dried basis**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 Primaquine Phosphate taken:

$$\text{Result} = (r_U/r_S) \times 100$$

 r_U = peak response of each impurity from the *Sample solution* r_S = peak response of primaquine phosphate from the *Sample solution***Acceptance criteria:** See [Table 1](#). Disregard any impurity peak less than 0.05%.**Table 1**

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
▲Methoxyquinolinamine ^a ▲ _{2S} (USP41)	0.24	0.20
▲Phthalhydrazide ^b ▲ _{2S} (USP41)	0.29	0.60
Primaquine related compound A ^c	0.80	2.0
Primaquine	1.0	—
Secaquine ^d	1.8	0.80
Any other individual impurities	—	0.20
Total impurities	—	3.0

^a 6-Methoxyquinolin-8-amine.^b 2,3-Dihydrophthalazine-1,4-dione.▲_{2S} (USP41)^c 8-[(4-Aminopentyl)amino]-6-methoxyquinoline.^d N³-(6-Methoxyquinolin-8-yl)pentane-1,3-diamine.