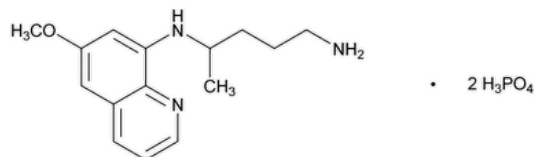


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## Primaquine Phosphate



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

1,4-Pentanediamine,  $N^4$ -(6-methoxy-8-quinolinyl)-, ( $\pm$ )-, 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 <sup>a</sup> ▲ <sub>2S</sub> (USP41) | 0.24                    | 0.20                         |
| ▲Phthalhydrazide <sup>b</sup> ▲ <sub>2S</sub> (USP41)      | 0.29                    | 0.60                         |
| Primaquine related compound A <sup>c</sup>                 | 0.80                    | 2.0                          |
| Primaquine                                                 | 1.0                     | —                            |
| Secaquine <sup>d</sup>                                     | 1.8                     | 0.80                         |
| Any other individual impurities                            | —                       | 0.20                         |
| Total impurities                                           | —                       | 3.0                          |

<sup>a</sup> 6-Methoxyquinolin-8-amine.

<sup>b</sup> 2,3-Dihydrophthalazine-1,4-dione.▲<sub>2S</sub> (USP41)

<sup>c</sup> 8-[(4-Aminopentyl)amino]-6-methoxyquinoline.

<sup>d</sup> N<sup>3</sup>-(6-Methoxyquinolin-8-yl)pentane-1,3-diamine.

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)

**Analysis:** Dry at 105° for 2 h.

**Acceptance criteria:** NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed, light-resistant containers.

- [USP REFERENCE STANDARDS \(11\)](#)

[USP Primaquine Phosphate RS](#)

[USP Primaquine Related Compound A RS](#)

8-[(4-Aminopentyl)amino]-6-methoxyquinoline.



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

| Topic/Question             | Contact                                                                     | Expert Committee          |
|----------------------------|-----------------------------------------------------------------------------|---------------------------|
| PRIMAQUINE PHOSPHATE       | <a href="#">Documentary Standards Support</a>                               | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | SM12020 Small Molecules 1 |

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