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Monobasic Potassium Phosphate

KH_2PO_4 136.09
Phosphoric acid, monopotassium salt;
Monopotassium phosphate CAS RN[®]: 7778-77-0.

DEFINITION

Monobasic Potassium Phosphate, dried at 105° for 4 h, contains NLT 98.0% and NMT 100.5% of monobasic potassium phosphate (KH_2PO_4).

IDENTIFICATION

- **A.** [IDENTIFICATION TESTS—GENERAL, Potassium \(191\)](#).

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

- **B.** [IDENTIFICATION TESTS—GENERAL, Phosphate \(191\)](#).

Sample solution: 50 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Sample solution: Transfer 5 g of Monobasic Potassium Phosphate, previously dried, to a 250-mL beaker. Add 100 mL of water and 5.0 mL of 1 N hydrochloric acid VS, and stir until the assay specimen is completely dissolved.

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 1 N sodium hydroxide VS

Endpoint detection: Potentiometrically

Analysis: Slowly titrate the excess acid in the *Sample solution*, stirring constantly, with *Titrant* to the inflection point occurring at about pH 4 (V_{S1}). Continue the titration with *Titrant* until the inflection point occurring at about pH 8.8 is reached (V_{S2}).

Calculate the percentage of monobasic potassium phosphate (KH_2PO_4) in the sample taken:

$$\text{Result} = \{[(V_{S2} - V_{S1}) \times N \times F]/W\} \times 100$$

V_{S2} = *Titrant* volume consumed by the *Sample solution* to the second inflection point (mL)

V_{S1} = *Titrant* volume consumed by the *Sample solution* to the first inflection point (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 0.1361 g/mEq

W = weight of monobasic potassium phosphate taken to prepare the *Sample solution* (g)

Acceptance criteria: 98.0%–100.5% on the previously dried basis

IMPURITIES

Change to read:

- [ARSENIC \(211\), Procedures, Procedure 1](#)  (CN 1-JUN-2023) : NMT 3 µg/g

Change to read:

- ▲ [LEAD \(251\), Procedures, Procedure 1](#) ▲ (CN 1-JUN-2023)

Test preparation: 1 g in 20 mL of water

Acceptance criteria: NMT 5 µg/g

• **LIMIT OF FLUORIDE**

[NOTE—Prepare and store all solutions in plastic containers.]

Buffer solution: 294 mg/mL of sodium citrate dihydrate

Standard stock solution: 1.1052 mg/mL of [USP Sodium Fluoride RS](#)

Standard solution: Dilute 20.0 mL of *Standard stock solution* and 50.0 mL of *Buffer solution* with water to 100 mL. Each mL of this solution contains 100 µg of fluoride ion.

Sample solution: Transfer 2.0 g of Monobasic Potassium Phosphate to a beaker containing a plastic-coated stirring bar. Add 20 mL of water and 2.0 mL of hydrochloric acid, and stir until dissolved. Add 50.0 mL of *Buffer solution* and sufficient water to make 100 mL.

Electrode system: Use a fluoride-specific ion-indicating electrode and a silver–silver chloride reference electrode connected to a pH meter capable of measuring potentials with a minimum reproducibility of ±0.2 mV (see [pH \(791\)](#)).

Analysis

Standard response line: Transfer 50.0 mL of *Buffer solution* and 2.0 mL of hydrochloric acid to a beaker, and add water to make 100 mL.

Add a plastic-coated stirring bar, insert the electrodes into the solution, stir for 15 min, and read the potential, in mV. Continue stirring, and at 5-min intervals add 100, 100, 300, and 500 µL of *Standard solution*, reading the potential 5 min after each addition. Plot the logarithms of the cumulative fluoride ion concentrations (0.1, 0.2, 0.5, and 1.0 µg/mL) versus potential, in mV.

Rinse and dry the electrodes, insert them into the *Sample solution*, stir for 5 min, and read the potential in mV. From the measured potential and the *Standard response line* determine the concentration, C (in µg/mL), of fluoride ion in the *Sample solution*.

Calculate the content of fluoride in the portion of Monobasic Potassium Phosphate taken:

$$\text{Result} = (V \times C)/W$$

V = volume of the *Sample solution* (mL)

C = concentration of fluoride ion, determined from the *Standard response line*, in the *Sample solution* (µg/mL)

W = weight of Monobasic Potassium Phosphate taken to prepare the *Sample solution* (g)

Acceptance criteria: NMT 10 µg/g

SPECIFIC TESTS

• **INSOLUBLE SUBSTANCES**

Sample solution: 10 g in 100 mL of hot water

Analysis: Filter the *Sample solution* through a tared filtering crucible, wash the insoluble residue with hot water, and dry at 105° for 2 h.

Acceptance criteria: NMT 20 mg (0.2%)

• **LOSS ON DRYING (731)**

Analysis: Dry a sample at 105° for 4 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

• **USP REFERENCE STANDARDS (11).**

[USP Sodium Fluoride RS](#)

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

Topic/Question	Contact	Expert Committee
MONOBASIC POTASSIUM PHOSPHATE	Documentary Standards Support	SE2020 Simple Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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