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Tribasic Sodium Phosphate

Na_3PO_4(anhydrous) 163.94
Trisodium phosphate, monohydrate 181.96
Phosphoric acid, trisodium salt, dodecahydrate;
Trisodium phosphate, dodecahydrate 380.13 CAS RN®: 10101-89-0.
Anhydrous CAS RN®: 7601-54-9.

DEFINITION

Tribasic Sodium Phosphate is anhydrous or contains one to twelve molecules of water of hydration. Na_3PO_4 (anhydrous) and $Na_3PO_4 \cdot H_2O$ (monohydrate) contain NLT 97.0% of Na_3PO_4, calculated on the ignited basis. $Na_3PO_4 \cdot 12H_2O$ (dodecahydrate) contains NLT 92.0% of Na_3PO_4, calculated on the ignited basis.

IDENTIFICATION

• **A. Identification Tests—General, *Sodium* ⟨191⟩ and *Phosphate* ⟨191⟩:** A solution (1 in 20) meets the requirements.

ASSAY

• **Procedure**

Sample: 5.5 g of Tribasic Sodium Phosphate, on the anhydrous basis

Blank: 100.0 mL of 1 N hydrochloric acid, accurately measured

Titrimetric system

(See *Titrimetry* ⟨541⟩.)

Mode: Residual titration

Titrant: 1 N sodium hydroxide VS

Endpoint detection: Potentiometric

Analysis: Transfer the *Blank* to a 400-mL beaker, and titrate with the *Titrant* to the endpoint at a pH of 7.0. Record as the volume consumed, and designate as *A*. Transfer the *Sample* to a 400-mL beaker, add 100.0 mL of 1 N hydrochloric acid, and stir until dissolved. Pass a stream of carbon dioxide-free air, in fine bubbles, through the solution for 30 min to expel carbon dioxide, covering the beaker loosely to prevent any loss by spraying. Wash the cover and sides of the beaker with a few mL of water.

Titrate the excess acid potentiometrically with the *Titrant* to the inflection point at a pH of 4. Record the buret reading, and designate as *B*. Protect the solution from carbon dioxide absorbed from the air, and continue the titration with 1 N sodium hydroxide VS to the inflection point at a pH of 8.8. Record the buret reading, and designate as *C*.

Calculate the amount of *Titrant* consumed by the *Sample* to the first inflection point, correcting for the *Blank* ($V_1 = A - B$) and the amount of *Titrant* consumed by the *Sample* between the two inflection points ($V_2 = C - B$). If V_1 is equal to or greater than $2V_2$, calculate the amount of Na_3PO_4 in the portion of *Sample* taken:

$$D = V_2 \times N \times F$$

V_2 = volume of *Titrant* consumed between the two inflection points (mL)

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

F = equivalency factor, 163.9 mg/mEq

If V_1 is less than $2V_2$, calculate the amount of Na_3PO_4 in the portion of *Sample* taken:

$$D = (V_1 - V_2) \times N \times F$$

V_1 = volume of the *Titrant* consumed to the first inflection point, correcting for the *Blank* (mL)

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

F = equivalency factor, 163.9 mg/mEq

Calculate the percentage of Na_3PO_4 on the ignited basis in the portion of Tribasic Sodium Phosphate taken:

$$\text{Result} = [10/(100 - L)] \times (D/W)$$

L = percentage calculated in the test for *Loss on Ignition ⟨733⟩*

D = amount of Na_3PO_4 found (mg)

W = weight of the *Sample* (g)

Acceptance criteria: NLT 97.0% of Na_3PO_4 on the ignited basis. $Na_3PO_4 \cdot 12H_2O$ (dodecahydrate) contains NLT 92.0% of Na_3PO_4 on the ignited basis.

IMPURITIES

• **Loss on Ignition ⟨733⟩**

Sample: 2 g

Analysis: Dry the *Sample* at 110° for 5 h, and then ignite at 800° for 30 min.

Acceptance criteria: The anhydrous form loses NMT 2.0% of its weight, the monohydrate loses 8.0%–11.0% of its weight, and the dodecahydrate loses 45.0%–57.0% of its weight.

Change to read:

• ▲**Arsenic ⟨211⟩**, *Procedures, Procedure 1*▲ (CN 1-Jun-2023)

Test preparation: Dissolve a portion equivalent to 1.0 g of anhydrous tribasic sodium phosphate in 35 mL of water.

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NMT 3 ppm

SPECIFIC TESTS

• **Insoluble Substances**

Sample solution: Dissolve a portion equivalent to 10.0 g of anhydrous tribasic sodium phosphate in 100 mL of hot water.

Analysis: Filter the *Sample solution* through a tared filtering crucible. [Note—Do not use glass.] Wash the insoluble residue with hot water, and dry at 105° for 2 h.

Acceptance criteria: The weight of the residue so obtained does not exceed 20 mg (0.2%).

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. No storage requirements specified.

• **Labeling:** Label it to indicate whether it is anhydrous, the monohydrate, or the dodecahydrate.

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

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

Chromatographic Database Information: Chromatographic Database

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