Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: USP Monographs
DocId: GUID-319DE716-0AF3-46EA-8FFB-4DE499B8433A_4_en-US
DOI: https://doi.org/10.31003/USPNF_M77027_04_01
DOI Ref: 9k3td

Dibasic Sodium Phosphate

$Na_2HPO_4 \cdot 12H_2O$ 358.14
$Na_2HPO_4 \cdot 7H_2O$ 268.07
$Na_2HPO_4 \cdot 2H_2O$ 177.99
$Na_2HPO_4 \cdot H_2O$ 159.94
Na_2HPO_4 141.96

Phosphoric acid, disodium salt, dodecahydrate;
Disodium hydrogen phosphate, dodecahydrate CAS RN®: 10039-32-4.
Phosphoric acid, disodium salt, heptahydrate;
Disodium hydrogen phosphate heptahydrate CAS RN®: 7782-85-6.
Phosphoric acid, disodium salt, dihydrate;
Disodium hydrogen phosphate, dihydrate CAS RN®: 10028-24-7.
Phosphoric acid, sodium salt, monohydrate;
Disodium hydrogen phosphate, monohydrate CAS RN®: 118830-14-1.
Phosphoric acid, disodium salt, hydrate;
Disodium hydrogen phosphate hydrate CAS RN®: 10140-65-5.
Anhydrous CAS RN®: 7558-79-4.

DEFINITION

Dibasic Sodium Phosphate is dried or contains one, two, seven, or twelve molecules of water of hydration. It contains NLT 98.0% and NMT 100.5% of Na_2HPO_4, calculated on the dried basis.

IDENTIFICATION

- **A. Identification Tests—General, *Sodium*⟨191⟩**

  Sample solution: Equivalent to 1 part of Na_2HPO_4 in 30

  Acceptance criteria: The solution meets the requirements.

- **B. Identification Tests—General, *Phosphate*⟨191⟩**

  Sample solution: Equivalent to 1 part of Na_2HPO_4 in 30

  Acceptance criteria: The solution meets the requirements.

ASSAY

- **Procedure**

  Sample: Equivalent to 2.5 g of Na_2HPO_4

  Sample solution: Transfer the *Sample* to a 250-mL beaker. Add 50 mL of water and 40.0 mL of 1 N hydrochloric acid, and stir until dissolved.

  Blank: Transfer 40.0 mL of 1 N hydrochloric acid to a 250-mL beaker. Add 50 mL of water.

  Analysis: Titrate the *Blank* with 1 N sodium hydroxide VS, and record the volume of 1 N sodium hydroxide VS consumed. Titrate the excess acid in the *Sample solution* potentiometrically with 1 N sodium hydroxide VS to the inflection point at about pH 4, and record the buret reading. Subtract this buret reading from that of the *Blank*, and designate the volume of 1 N sodium hydroxide VS resulting from this subtraction as *A*. Continue the titration with 1 N sodium hydroxide VS to the inflection point at about pH 8.8, record the buret reading, and calculate the volume (*B*) of 1 N sodium hydroxide required in the titration between the two inflection points (pH 4–8.8). Where *A* is equal to or less than *B*, each mL of the volume *A* of 1 N sodium hydroxide is equivalent to 142.0 mg of Na_2HPO_4. Where *A* is greater than *B*, each mL of the volume ($2B - A$) of 1 N sodium hydroxide is equivalent to 142.0 mg of Na_2HPO_4.

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

IMPURITIES

• **Insoluble Substances**

Sample solution: Equivalent to 5.0 g of Na_2HPO_4 in 100 mL of hot water

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

Acceptance criteria: NMT 20 mg (NMT 0.4%)

• **Chloride and Sulfate,** *Chloride*⟨221⟩

Sample: Equivalent to 0.5 g of Na_2HPO_4

Acceptance criteria: Shows no more chloride than corresponds to 0.42 mL of 0.020 N hydrochloric acid (NMT 0.06%)

• **Chloride and Sulfate,** *Sulfate*⟨221⟩

Sample: Equivalent to 0.1 g of Na_2HPO_4

Acceptance criteria: Shows no more sulfate than corresponds to 0.2 mL of 0.020 N sulfuric acid (NMT 0.2%)

Change to read:

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

Test preparation: Equivalent to 187.5 mg of Na_2HPO_4 in 35 mL of water

Acceptance criteria: NMT 16 ppm

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩**:** Dry a sample at 130° to constant weight.

Acceptance criteria: See *Table 1*.

Table 1

Hydrate Form	Acceptance Criteria
Dried	NMT 5.0%
Monohydrate	10.3%–12.0%
Dihydrate	18.5%–21.5%
Heptahydrate	43.0%–50.0%
Dodecahydrate	55.0%–64.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

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

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

Topic/Question	Contact	Expert Committee
DIBASIC SODIUM PHOSPHATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 29(5)

Current DocID: GUID-319DE716-0AF3-46EA-8FFB-4DE499B8433A_4_en-US

DOI: https://doi.org/10.31003/USPNF_M77027_04_01

DOI ref: 9k3td