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Dibasic Calcium Phosphate Tablets

DEFINITION

Dibasic Calcium Phosphate Tablets contain NLT 92.5% and NMT 107.5% of the labeled amount of dibasic calcium phosphate dihydrate ($CaHPO_4 \cdot 2H_2O$).

[NOTE—An equivalent amount of Dibasic Calcium Phosphate with less water of hydration may be used in place of $CaHPO_4 \cdot 2H_2O$ in preparing Dibasic Calcium Phosphate Tablets.]

IDENTIFICATION

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

  Sample solution: A filtered portion of the *Sample solution* from the *Assay*

  Acceptance criteria: Meets the requirements

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

  Sample solution: A filtered portion of the *Sample solution* from the *Assay*, neutralized with ammonium hydroxide

  Acceptance criteria: Meets the requirements

ASSAY

- **Procedure**

  Sample solution: Transfer a portion of powder, equivalent to 1 g of dibasic calcium phosphate dihydrate, from NLT 20 powdered Tablets, to a 100-mL volumetric flask containing 15 mL of hydrochloric acid and 10 mL of water. Heat on a steam bath, with occasional mixing, to dissolve the dibasic calcium phosphate, but not longer than 30 min. Cool, add water to volume, and mix. If the solution is not clear, filter, discarding the first 10 mL of the filtrate.

  Blank: Water

  Titrimetric system

  (See *Titrimetry* ⟨541⟩.)

  Mode: Direct titration

  Titrant: 0.05 M edetate disodium VS

  Indicator: Hydroxy naphthol blue

  Endpoint detection: Visual

  Analysis: Transfer 25.0 mL of the *Sample solution* to a 250-mL beaker equipped with a magnetic stirrer. With constant stirring, add, in the order named, 0.5 mL of triethanolamine, 300 mg of *Indicator*, and from a 50-mL buret, about 23 mL of *Titrant*. Add sodium hydroxide solution (45 in 100) until the initial red color changes to clear blue. Continue to add it dropwise until the color changes to violet, and add an additional 0.5 mL. The pH is 12.3–12.5. Continue the titration dropwise with the *Titrant* to the appearance of a clear blue endpoint that persists for NLT 60 s. Perform a blank determination.

  Calculate the percentage of the labeled amount of dibasic calcium phosphate dihydrate ($CaHPO_4 \cdot 2H_2O$) in the portion of Tablets taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

  V_S = *Titrant* volume consumed by the *Sample solution* (mL)

  V_B = *Titrant* volume consumed by the *Blank* (mL)

  M = actual molarity of the *Titrant* (mM/mL)

  F = equivalency factor, 172.08 mg/mM

  W = nominal weight of dibasic calcium phosphate dihydrate in the *Sample solution* taken for *Analysis* (mg)

  Acceptance criteria: 92.5%–107.5%

PERFORMANCE TESTS

- **Dissolution ⟨711⟩**

  Medium: 0.1 N hydrochloric acid; 900 mL

  Apparatus 2: 75 rpm

  Time: 45 min

  Standard solution: Solution having a known concentration of calcium in *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium* if necessary

Instrumental conditions

(See *Atomic Absorption Spectroscopy* ⟨852⟩.)

Mode: Atomic absorption spectrophotometry

Analytical wavelength: 422.7 nm

Lamp: Calcium hollow-cathode

Flame: Air-acetylene

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the concentration of calcium (Ca) in the *Sample solution* in comparison with a *Standard solution*.

Calculate the percentage of the labeled amount of dibasic calcium phosphate dihydrate ($CaHPO_4 \cdot 2H_2O$) dissolved:

$$\text{Result} = (A_U/A_S) \times (C_S \times D \times V/L) \times (M_r/A_r) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of calcium in the *Standard solution* (mg/mL)

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

M_r = molecular weight of dibasic calcium phosphate, 172.08

A_r = atomic weight of calcium, 40.08

Tolerances: NLT 75% (Q) of the labeled amount of dibasic calcium phosphate dihydrate ($CaHPO_4 \cdot 2H_2O$) is dissolved.

• **Uniformity of Dosage Units** ⟨905⟩**:** Meet the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** The quantity of dibasic calcium phosphate stated in the labeling is in terms of dibasic calcium phosphate dihydrate ($CaHPO_4 \cdot 2H_2O$).

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

Topic/Question	Contact	Expert Committee
DIBASIC CALCIUM PHOSPHATE TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

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