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Calcium Sulfate

CaSO₄ 136.14
CaSO₄ · 2H₂O 172.17
Sulfuric acid, calcium salt (1:1);
Calcium sulfate (1:1) CAS RN®: 7778-18-9.
Dihydrate CAS RN®: 10101-41-4.

DEFINITION

Calcium Sulfate is anhydrous or contains two molecules of water of hydration. It contains NLT 98.0% and NMT 101.0% of CaSO₄, calculated on the dried basis.

IDENTIFICATION

- **A. IDENTIFICATION TESTS—GENERAL, Calcium(191).**
Sample solution: Dissolve 200 mg by warming in a mixture of 4 mL of 3 N hydrochloric acid and 16 mL of water.
Acceptance criteria: Meets the requirements
- **B. IDENTIFICATION TESTS—GENERAL, Sulfate(191).**
Sample solution: Dissolve 200 mg by warming in a mixture of 4 mL of 3 N hydrochloric acid and 16 mL of water.
Acceptance criteria: Meets the requirements

ASSAY

- **PROCEDURE**
Sample: Dissolve 300 mg of Calcium Sulfate in 100 mL of water and 4 mL of 3 N hydrochloric acid. Boil, if necessary, to dissolve, and cool before titrating.
Titrimetric system
(See [Titrimetry\(541\).](#))
Mode: Direct titration
Titrant: 0.05 M edetate disodium VS
Endpoint detection: Visual
Analysis: While stirring, preferably with a magnetic stirrer, add to the *Sample solution*, in the order named, 0.5 mL of triethanolamine, 300 mg of hydroxy naphthol blue, and, from a 50-mL buret, 30 mL of 0.05 M edetate disodium VS. Add sodium hydroxide solution (45 in 100) until the initial red color changes to clear blue, continue to add 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 0.05 M edetate disodium VS to the appearance of a clear-blue endpoint that persists for NLT 60 s.
Calculate the percentage of Calcium Sulfate (CaSO₄) in the Sample taken:

$$\text{Result} = [(V \times M \times F)/W] \times 100$$

- V* = volume of *Titrant* consumed by the *Sample* (mL)
M = actual molarity of the *Titrant* (mM/mL)
F = equivalency factor, 136.14 mg/mM
W = weight of the *Sample* (mg)

Acceptance criteria: 98.0%–101.0% on the dried basis

IMPURITIES

Change to read:

- **▲Iron(241), Procedures, Procedure 1▲** (CN 1-JUN-2023)
Sample solution: Dissolve 100 mg in 8 mL of 3 N hydrochloric acid, and dilute with water to 47 mL.
Acceptance criteria: NMT 100 ppm

SPECIFIC TESTS

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

Samples: Neat

Analysis: Dry a sample at a temperature NLT 250° to constant weight.

Acceptance criteria: NMT 1.5% for the anhydrous form and 19.0%–23.0% for the dihydrate

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **LABELING:** Label it to indicate whether it is anhydrous or the dihydrate.

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

Topic/Question	Contact	Expert Committee
CALCIUM SULFATE	Documentary Standards Support	SE2020 Simple Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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