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Calamine

Iron oxide (Fe_2O_3), mixture with zinc oxide;
Calamine (pharmaceutical preparation)
CAS RN®: 8011-96-9.

DEFINITION

Calamine is Zinc Oxide with a small proportion of ferric oxide, and contains, after ignition, NLT 98.0% and NMT 100.5% of zinc oxide (ZnO).

IDENTIFICATION

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

  Sample: 1 g

  Analysis: Treat the *Sample* with 10 mL of 3 N hydrochloric acid, and filter.

  Acceptance criteria: The filtrate meets the requirements.

- **B.**

  Sample: 1 g

  Analysis: Add 10 mL of 3 N hydrochloric acid to the *Sample*, heat to boil, and filter.

  Acceptance criteria: The filtrate assumes a reddish color upon the addition of ammonium thiocyanate TS.

ASSAY

- **Procedure**

  Sample solution: Digest 1.5 g of freshly ignited Calamine in 50.0 mL of 1 N sulfuric acid VS, applying gentle heat until no further solution occurs. Filter the mixture, and wash the residue on the filter with hot water until the last washing is neutral to litmus paper. To the combined filtrate and washings add 2.5 g of ammonium chloride. Cool, and add methyl orange TS.

  Titrimetric system

  Mode: Back titration

  Titrant: 1 N sodium hydroxide VS

  Endpoint detection: Visual

  Analysis: Titrate the excess sulfuric acid in the *Sample solution* with *Titrant*. Each mL of 1 N sulfuric acid comsumed is equivalent to 40.69 mg of zinc oxide (ZnO).

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

IMPURITIES

Change to read:

- ▲**Arsenic ⟨211⟩, *Procedures, Procedure 1*▲** (CN 1-Jun-2023) **:** NMT 8 ppm

- **Calcium**

  Sample: 1 g

  Analysis: Digest the *Sample* in 25 mL of 3 N hydrochloric acid for 30 min, filter to remove the insoluble ferric oxide, and add 6 N ammonium hydroxide to the filtrate until the precipitate first formed is redissolved, then add 5 mL more of 6 N ammonium hydroxide. To 10 mL of this solution add 2 mL of ammonium oxalate TS.

  Acceptance criteria: NMT a slight turbidity is produced.

- **Calcium or Magnesium**

  Analysis: To another 10-mL portion of the solution prepared in the test for *Calcium*, add 2 mL of dibasic sodium phosphate TS.

  Acceptance criteria: NMT a slight turbidity is produced.

- **Lead**

  Sample: 1 g

  Analysis: Add 15 mL of water to the *Sample*, stir, then add 3 mL of glacial acetic acid, and warm on a steam bath until dissolved. Filter, and add 5 drops of potassium chromate TS.

  Acceptance criteria: No turbidity is produced.

SPECIFIC TESTS

- **Acid-Insoluble Substances**

Sample: 2.0 g

Analysis: Dissolve the *Sample* in 50 mL of 3 N hydrochloric acid. If an insoluble residue remains, collect it on a tared filter, wash with water, and dry at 105° for 1 h. Cool, and weigh.

Acceptance criteria: NMT 40 mg (2.0%)

• **Alkaline Substances**

Sample: 1.0 g

Analysis: Digest the *Sample* with 20 mL of water on a steam bath for 15 min, filter, and add 2 drops of phenolphthalein TS.

Acceptance criteria: If a red color is produced, NMT 0.20 mL of 0.10 N sulfuric acid is required to discharge it.

• **Loss on Ignition** ⟨733⟩

Sample: 2 g

Analysis: Ignite the *Sample* at 500° to constant weight.

Acceptance criteria: NMT 2.0%

• **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
CALAMINE	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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