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Change to read:

Zinc Oxide [▲]Compounded _▲ (USP 1-May-2019) Ointment

DEFINITION

Change to read:

Zinc Oxide [▲]Compounded _▲ (USP 1-May-2019) Ointment contains NLT 18.5% and NMT 21.5% of zinc oxide (ZnO).

Prepare Zinc Oxide [▲]Compounded _▲ (USP 1-May-2019) Ointment as follows.

Zinc Oxide	200 g
Mineral Oil	150 g
White Ointment	650 g
To make	1000 g

Levigate the *Zinc Oxide* with the *Mineral Oil* to a smooth paste, and incorporate the *White Ointment* [see [General Notices, 5.20.20 Added Substances \(Excipients and Ingredients\) in Official Products](#)].

IDENTIFICATION

- **A.** The residue obtained in the Assay is yellow when hot and white when cool.

ASSAY

Change to read:

• PROCEDURE

Sample solution: Weigh 700 mg of Ointment in a porcelain crucible, heat gently until melted, and continue heating, gradually raising the temperature until the mass is thoroughly charred. Ignite the mass until the residue is uniformly yellow, and cool. Dissolve the residue in 10 mL of 2 N sulfuric acid, warming if necessary to dissolve.

Titrimetric system

[▲](See [Titrimetry \(541\)](#).) _▲ (USP 1-May-2019)

Mode: Direct titration

Titrant: 0.05 M edetate disodium VS

Endpoint detection: Visual

Analysis: Transfer the *Sample solution* to a beaker, and rinse the crucible with small portions of water until the combined solution and rinsings measure 50 mL. Add 15 mL of ammonia–ammonium chloride buffer TS and 1 mL of eriochrome black TS, and titrate with *Titrant* until the solution is blue in color. Each milliliter of *Titrant* is equivalent to 4.069 mg of zinc oxide (ZnO).

Acceptance criteria: 18.5%–21.5%

PERFORMANCE TESTS

- [MINIMUM FILL \(755\)](#): Meets the requirements

SPECIFIC TESTS

• CALCIUM, MAGNESIUM, AND OTHER FOREIGN SUBSTANCES

Sample: Heat 2 g gently until melted, and continue heating, gradually raising the temperature until the mass is thoroughly charred. Ignite the mass until the residue is uniformly yellow.

Analysis 1: To the *Sample* add 6 mL of 3 N hydrochloric acid.

Acceptance criteria 1: No effervescence occurs.

Analysis 2: Heat the mixture obtained in *Analysis 1* on a steam bath for 10–15 min.

Acceptance criteria 2: NMT a trace of insoluble residue remains.

Analysis 3: Filter the solution from *Analysis 2*, dilute with water to 10 mL, add 6 N ammonium hydroxide until the precipitate first formed redissolves, and add 2 mL each of ammonium oxalate TS and dibasic sodium phosphate TS.

Acceptance criteria 3: NMT a slight turbidity is produced in 5 min.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in well-closed containers, and avoid prolonged exposure to temperatures exceeding 30°.

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

Topic/Question	Contact	Expert Committee
ZINC OXIDE COMPOUNDED OINTMENT	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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