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Bland Lubricating Ophthalmic Ointment

DEFINITION

Bland Lubricating Ophthalmic Ointment is a sterile ointment of white petrolatum and mineral oil. It may contain Lanolin, Modified Lanolin, or Lanolin Alcohols. It may also contain a suitable antimicrobial preservative.

SPECIFIC TESTS

• **APPEARANCE**

Analysis: Transfer a portion of it to a suitable test tube, and examine the sample in front of a light source.

Acceptance criteria: The sample appears translucent.

• **STERILITY TESTS (71):** Meets the requirements

• **ACIDITY OR ALKALINITY**

Sample solution: Transfer 20.0 g of Ophthalmic Ointment to a 400-mL beaker. Add 100 mL of a mixture of [neutralized alcohol](#) and [water](#) (1 in 2), agitate thoroughly, and gradually heat to boiling. Boil for 10 min.

Analysis: To the *Sample solution* add 1 mL of [phenolphthalein TS](#), and rapidly titrate with vigorous agitation with either [0.1 N sodium hydroxide VS](#) (from a colorless alcohol–water layer to a sharp pink endpoint) or [0.1 N hydrochloric acid VS](#) (from a pink alcohol–water layer to a colorless endpoint).

Acceptance criteria: NMT 0.40 mL of 0.1 N hydrochloric acid VS or 0.1 N sodium hydroxide VS is required to produce the color change.

• **COLOR**

Analysis: Examine the extruded Ophthalmic Ointment for color.

Acceptance criteria: Colorless to light yellow

• **OTHER REQUIREMENTS:** It meets the requirements for *Particulate and Foreign Matter* in [Ophthalmic Products—Quality Tests \(771\)](#), [Drug Product Quality, Universal Tests, Particulate and Foreign Matter](#).

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in suitable collapsible ophthalmic ointment tubes.

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

Topic/Question	Contact	Expert Committee
BLAND LUBRICATING OPHTHALMIC OINTMENT	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](#)

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