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Topical Light Mineral Oil

DEFINITION
Topical Light Mineral Oil is Light Mineral Oil that has been suitably packaged.

- IDENTIFICATION**
Change to read:
- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F ▲](#) (CN 1-MAY-2020)
 - **B.** It meets the requirements in *Specific Tests* for [Viscosity—Capillary Methods \(911\)](#).

- SPECIFIC TESTS**
- [SPECIFIC GRAVITY \(841\)](#): 0.818–0.880
 - [VISCOSITY—CAPILLARY METHODS \(911\)](#): 3.0–34.4 mm² · s^{−1} for kinematic viscosity, measured with a capillary viscometer at 40 ± 0.1°
 - **ACIDITY**
Sample: 10 mL
Analysis: Add 20 mL of boiling water to the *Sample*, and shake vigorously for about 1 min. Allow to cool, and draw off the separated water. To 10 mL of the filtered aqueous layer add 0.1 mL of phenolphthalein TS.
Acceptance criteria: The solution does not produce a pink color. NMT 1.0 mL of 0.01 N sodium hydroxide is required to produce a pink color.
 - **SOLID PARAFFIN**
Sample: Topical Light Mineral Oil that has been dried previously in a beaker at 105° for 2 h and cooled to room temperature in a desiccator over silica gel
Analysis: Fill a tall, cylindrical, standard oil-sample bottle of colorless glass of 120-mL capacity with the *Sample*. Insert the stopper, and immerse the bottle in a mixture of ice and water for 4 h.
Acceptance criteria: The *Sample solution* is sufficiently clear that a black line 0.5 mm in width, on a white background, held vertically behind the bottle, is clearly visible.

- ADDITIONAL REQUIREMENTS**
- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers. No storage requirements specified.
 - **LABELING:** Label it to indicate the name and quantity of any substance added as a stabilizer, and label packages intended for direct use by the public to indicate that it is not intended for internal use.
 - [USP REFERENCE STANDARDS \(11\)](#)
[USP Mineral Oil RS](#)

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

Topic/Question	Contact	Expert Committee
TOPICAL LIGHT MINERAL OIL	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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