Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-198F770E-F8C4-4FF8-88EB-8C1C095E3318_2_en-US
DOI: https://doi.org/10.31003/USPNF_M54081_02_01
DOI Ref: m6gbg

Mineral Oil

DEFINITION

Mineral Oil is a purified mixture of liquid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

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⟩.

IMPURITIES

• **Limit of Polycyclic Aromatic Hydrocarbons**

Dimethyl sulfoxide: Use spectrophotometric grade dimethyl sulfoxide.

***n*-Hexane:** Use *n*-hexane that has been washed by being shaken previously twice with one-fifth its volume of *Dimethyl sulfoxide*.

Standard solution: 7.0 µg/mL of USP Naphthalene RS in isooctane (2,2,4-trimethylpentane)

Standard blank: 2,2,4-Trimethylpentane

Sample solution: Transfer 25.0 mL of Mineral Oil and 25 mL of *n-Hexane* to a 125-mL separator, and mix. [Note—Use no lubricants other than water on the stopcock, or use a separator equipped with a suitable polymeric stopcock.]

Add 5.0 mL of *Dimethyl sulfoxide*, and shake the mixture vigorously for 1 min. Allow to stand until the lower layer is clear, transfer the lower layer to another 125-mL separator, add 2 mL of *n-Hexane*, and shake vigorously. Use the lower layer.

Sample blank: *Dimethyl sulfoxide* that has been shaken previously vigorously for 1 min with *n-Hexane* in the ratio of 5 mL of *Dimethyl sulfoxide* to 25 mL of *n-Hexane*

Instrumental conditions

Mode: UV

Analytical wavelengths

Standard solution: 275 nm

Sample solution: 260–350 nm

Cell: 1 cm

Analysis

Samples: *Standard solution, Standard blank, Sample solution,* and *Sample blank*

Acceptance criteria: The absorbance at any wavelength in the specified range of the *Sample solution* is NMT one-third of the absorbance of the *Standard solution*.

SPECIFIC TESTS

• **Specific Gravity ⟨841⟩:** 0.845–0.905

• **Viscosity—Capillary Methods ⟨911⟩:** 34.5–150.0 $mm^2 \cdot s^{-1}$ 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 to produce a pink color.

• **Readily Carbonizable Substances Test ⟨271⟩**

Sample: 5 mL

Standard solution: In a glass-stoppered test tube that previously has been rinsed with hot nitric acid (see *Cleaning Glass Apparatus* ⟨1051⟩), mix 3 mL of ferric chloride CS, 1.5 mL of cobaltous chloride CS, and 0.5 mL of cupric sulfate CS then overlaid with 5 mL of Mineral Oil.

Analysis: Place the *Sample* in a glass-stoppered test tube that previously has been rinsed with hot nitric acid (see *Cleaning Glass Apparatus* ⟨1051⟩), then rinsed with water, and dried. Add 5 mL of sulfuric acid containing 94.5%–94.9% of H_2SO_4, and heat in a boiling water bath for 10 min. After the test tube has been in the bath for 30 s, remove it quickly, and while holding the stopper in place, give three vigorous, vertical shakes over an amplitude of about 5 in. Repeat every 30 s. Do not keep the test tube out of the bath longer than 3 s for each shaking period. At the end of 10 min from the time when first placed in the water bath, remove the test tube.

Acceptance criteria: The oil portion of the *Sample* may turn hazy, but it remains colorless or shows a slight pink or yellow color, and the acid portion of the *Sample* does not become darker than the *Standard solution*.

- **Solid Paraffin**

Sample: 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 in an ice bath for 4 h.

Acceptance criteria: The *Sample* is sufficiently clear that a black line 0.5 mm in width, on a white background, held vertically behind the bottle, is clearly visible.

- **Limit of Sulfur Compounds**

Solution A: Saturated solution of lead(II) oxide in sodium hydroxide (200 mg/mL)

Sample: 4.0 mL

Analysis: Combine the *Sample*, 2 mL of dehydrated alcohol, and 2 drops of *Solution A*, heat at 70° for 10 min with frequent shaking, and cool.

Acceptance criteria: No dark brown color develops.

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.
- **USP Reference Standards** ⟨11⟩

USP Mineral Oil RS

USP Naphthalene RS

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 33(5)

Current DocID: GUID-198F770E-F8C4-4FF8-88EB-8C1C095E3318_2_en-US

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