Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-6A8116E6-B749-489B-A3DF-A04E95927A40_2_en-US
DOI: https://doi.org/10.31003/USPNF_M60740_02_01
DOI Ref: g7w64

Paraffin

CAS RN®: 8002-74-2.

DEFINITION

Paraffin is a purified mixture of solid saturated hydrocarbons obtained from petroleum. It may contain suitable antioxidants.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197F**▲ (CN 1-May-2020)

Sample: Use a thin film of melted specimen.

Analysis: Ensure complete melting to avoid doublet peaks that may be observed at wavenumbers at about 1460 and 730 cm^{-1}.

Acceptance criteria: Meets the requirements

• **B.** It meets the requirements in *Specific Tests* for *Congealing Temperature* ⟨651⟩.

IMPURITIES

• **Limit of Sulfur Compounds**

Sample: 4.0 g

Analysis: To the *Sample* add 2 mL of dehydrated alcohol, and add 2 drops of a clear saturated solution of lead(II) oxide in sodium hydroxide solution (200 mg/mL). Heat the mixture at 70° for 10 min with frequent shaking, and cool.

Acceptance criteria: No dark brown color develops.

• **Limit of Polycyclic Aromatic Hydrocarbons**

Dimethyl sulfoxide: Use spectrophotometric grade dimethyl sulfoxide.

Standard solution: 7.0 µg/mL of USP Naphthalene RS in *Dimethyl sulfoxide*. Determine the absorbance of this solution at 278 nm using *Dimethyl sulfoxide* as the blank.

Sample: 0.50 g

Instrumental conditions

(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)

Mode: UV

Wavelength range: 260–350 nm

Cell: 1 cm

Analysis: Dissolve the *Sample* in 25 mL of *n*-heptane, place in a 125-mL separator with unlubricated ground-glass parts (stopper, stopcock), and mix. Add 5.0 mL of *Dimethyl sulfoxide*, and shake the mixture vigorously for 1 min. Allow to stand until two clear layers are formed. Transfer the lower layer to another 125-mL separator, add 2 mL of *n*-heptane, and shake the mixture vigorously. Allow to stand until two clear layers are formed. Separate the lower layer, and determine its absorbance using as the blank *Dimethyl sulfoxide* that previously has been shaken vigorously for 1 min with *n*-heptane in the ratio of 5 mL of *Dimethyl sulfoxide* to 25 mL of *n*-heptane.

Acceptance criteria: The absorbance at any wavelength in the specified range is not greater than one-third of the absorbance, at 278 nm, of the *Standard solution*.

SPECIFIC TESTS

• **Congealing Temperature** ⟨651⟩**:** 47°–65°

• **Acidity**

Sample: 15 g

Analysis: Introduce the *Sample* into a suitable separator, add 30 mL of boiling water, and shake vigorously for about 1 min. Allow to cool, and draw off the separated water. To 10 mL of the filtrated 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 M sodium hydroxide is subsequently required to change the color of the indicator to pink.

- **Alkalinity**

Sample: 10 mL of the filtrated aqueous layer obtained from the test for *Acidity*

Analysis: To the *Sample* add 0.1 mL of methyl red TS2.

Acceptance criteria: The solution produces a yellow color. NMT 0.5 mL of 0.01 M hydrochloric acid is subsequently required to change the color of the indicator to red.

- **Readily Carbonizable Substances ⟨271⟩**

Standard solution: A mix of 3 mL of ferric chloride CS, 1.5 mL of cobaltous chloride CS, and 0.50 mL of cupric sulfate CS, overlaid with 5 mL of mineral oil

Sample: 5 mL, at a temperature just above the melting point

Analysis: Use a clean, dry, heat-resistant, glass-stoppered test tube, 140 ± 2 mm in length with an outside diameter between 14.5 and 15.0 mm, and calibrated at the 5- and 10-mL liquid levels. The capacity of the tube with the stopper inserted is between 13.6 and 15.6 mL.[1] Place the *Sample* in the test tube, add 5 mL of sulfuric acid (94.5%–94.9% of H_2SO_4), and heat in a water bath at 70° for 10 min. When 5 min have elapsed, and at each successive min thereafter, remove the tube from the bath, place a finger over the stopper, and give the tube three vigorous vertical shakes over an amplitude of about 12 cm, returning the tube to the bath within 3 s after the time when it was removed therefrom.

Acceptance criteria: At the end of 10 min from the time the tube was placed in the bath, the acid (lower layer) has no more color than the *Standard solution*. If the sulfuric acid remains dispersed in the molten paraffin, the color of the emulsion is not darker than that of the *Standard solution* when shaken vigorously.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in light resistant, well-closed containers, and avoid exposure to excessive heat.
- **Labeling:** Label it to indicate the name and quantity of any antioxidants.
- **USP Reference Standards ⟨11⟩**

USP Naphthalene RS
USP Paraffin RS

[1] A suitable test tube is available from Kimble Kontes. Item number: 34-19426. Description: Nessler Tube. Contact: phone 800-682-6644, fax 856-692-6644, e-mail customglass@kimkon.com.

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

Topic/Question	Contact	Expert Committee
PARAFFIN	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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

Current DocID: GUID-6A8116E6-B749-489B-A3DF-A04E95927A40_2_en-US
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