Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: NF Monographs
DocId: GUID-329E3F83-0F98-4C36-95A8-F38152CBC682_4_en-US
DOI: https://doi.org/10.31003/USPNF_M60745_04_01
DOI Ref: mya8w

Synthetic Paraffin

DEFINITION

Synthetic Paraffin is synthesized by the Fischer-Tropsch process from carbon monoxide and hydrogen, which are catalytically converted to a mixture of paraffin hydrocarbons; the lower molecular weight fractions are removed by distillation, and the residue is hydrogenated and further treated by percolation through activated charcoal. This mixture may be fractionated into its components by a solvent separation method, using a suitable synthetic isoparaffinic petroleum hydrocarbon solvent. It may contain NMT 0.005% of a suitable antioxidant.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F.**▲ (CN 1-May-2020) A thin film of it, cast from a melt onto a cesium bromide plate, exhibits a pair of very strong IR absorption peaks between 2840 cm^{-1} and 3000 cm^{-1}, a pair of moderately strong peaks between 1430 cm^{-1} and 1490 cm^{-1}, a pair of medium peaks between 720 cm^{-1} and 750 cm^{-1}, and only weak peaks at any other wavenumbers.

IMPURITIES

• **Limit of Oil Content**

Analysis: Follow ASTM Method D721-68, “Standard Test Method for Oil Content of Petroleum Waxes” (Reapproved 1987).[1]

Acceptance criteria: NMT 0.5%

SPECIFIC TESTS

• **Absorptivity**

Sample solution: Transfer 50–100 mg to a 100-mL volumetric flask. Dissolve in decahydronaphthalene at 88°, dilute with the same solvent at this temperature to volume, and mix.

Blank: Decahydronaphthalene

Instrumental conditions

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

Mode: UV

Analytical wavelength: 290 nm

Cell: 10 cm (jacketed cells maintained at 88°)

Analysis

Samples: *Sample solution* and *Blank*

Determine the absorbance of the *Sample solution*, and calculate the absorptivity.

Acceptance criteria: NMT 0.01

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

• **Labeling:** The labeling indicates its congealing temperature, viscosity, and needle penetration range under the specified conditions.

[1] Available from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

Topic/Question	Contact	Expert Committee
SYNTHETIC 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. Information currently unavailable

Current DocID: GUID-329E3F83-0F98-4C36-95A8-F38152CBC682_4_en-US
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