Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-1C10932B-8F36-4F87-8A83-D79BC52E0E41_1_en-US
DOI: https://doi.org/10.31003/USPNF_M62760_01_01
DOI Ref: ym90t

Petrolatum

DEFINITION

Petrolatum is a purified mixture of semisolid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

IMPURITIES

Inorganic Impurities

- **Residue on Ignition ⟨281⟩**

  Sample: 2 g

  Analysis: Heat the *Sample* in an open porcelain or platinum dish over a Bunsen flame.

  Acceptance criteria: It volatilizes without emitting an acrid odor and yields NMT 0.1% of residue.

Organic Impurities

- **Procedure: Organic Acids**

  Sample solution: 20.0 g of Petrolatum in 100 mL of a 1 in 2 mixture of neutralized alcohol and water. Agitate thoroughly, and heat to boiling.

  Analysis: Add 1 mL of phenolphthalein TS, and titrate rapidly with 0.1 N sodium hydroxide VS, with vigorous agitation to the production of a sharp pink endpoint, noting the color change in the alcohol–water layer.

  Acceptance criteria: NMT 400 µL of 0.1 N sodium hydroxide is required.

SPECIFIC TESTS

- **Color**

  Standard solution: Ferric chloride CS and cobaltous chloride CS (3.8:1.2)

  Sample: 10 g

  Analysis: Melt the *Sample* on a steam bath, and pour 5 mL of the liquid into a clear-glass 15-mm × 150-mm test tube, keeping the petrolatum melted.

  Acceptance criteria: The warm, melted liquid is not darker than 5 mL of the *Standard solution* in a similar tube; the comparison of the two being made in reflected light against a white background, and the petrolatum tube being held directly against the background at such an angle that there is no fluorescence.

- **Specific Gravity ⟨841⟩:** 0.815–0.880 at 60°
- **Melting Range or Temperature, *Class III*⟨741⟩:** 38°–60°
- **Consistency**

  Apparatus: A penetrometer fitted with a polished cone-shaped metal plunger weighing 150 g, having a detachable steel tip of the following dimensions: the tip of the cone has an angle of 30°, the point of the tip is truncated to a diameter of 0.381 ± 0.025 mm, the base of the tip is 8.38 ± 0.05 mm in diameter, and the length of the tip is 14.94 ± 0.05 mm.

  The remaining portion of the cone has an angle of 90°, is 28 mm in height, and has a maximum diameter at the base of 65 mm. The containers for the test are flat-bottom metal cylinders that are 100 ± 6 mm in diameter and NLT 65 mm in height. They are constructed of at least 1.6-mm (16-gauge) metal, and are provided with well-fitting, water-tight covers.

  Sample: Petrolatum

  Analysis: Place the required number of containers in an oven, bring them and a quantity of the *Sample* to a temperature of 82 ± 2.5°, and pour the *Sample* into one or more of the containers, filling to within 6 mm of the rim. Cool to 25 ± 2.5° over a period of NLT 16 h, protected from drafts. Two h before the test, place the containers in a water bath at 25 ± 0.5°. If the room temperature is below 23.5° or above 26.5°, adjust the temperature of the cone to 25 ± 0.5° by placing it in the water bath.

  Without disturbing the surface of the substance under test, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the test substance at a spot 25–38 mm from the edge of the container. Adjust the zero setting and quickly release the plunger, then hold it free for 5 s. Secure the plunger, and read the total penetration from the scale. Make three or more trials, each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm, use a separate container of the test substance for each trial. Read the penetration to the nearest 0.1 mm. Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than ±3%.

Acceptance criteria: The final average of the trials is NLT 10.0 mm and NMT 30.0 mm, indicating a consistency value of 100–300.

- **Alkalinity**

Sample: 35 g

Analysis: Introduce the *Sample* into a suitable beaker, add 100 mL of boiling water, cover, and place on a stirring hot-plate maintained at the boiling point of water. After 5 min, allow the phases to separate. Draw off the separated water into a casserole, wash the petrolatum further with two 50-mL portions of boiling water, and add the washings to the casserole. To the pooled washings, add 1 drop of phenolphthalein TS, and boil.

Acceptance criteria: The solution does not acquire a pink color.

- **Acidity:** If the addition of phenolphthalein TS in the test for *Alkalinity* produces no pink color, add 0.1 mL of methyl orange TS.

Acceptance criteria: No red or pink color is produced.

- **Fixed Oils, Fats, and Rosin**

Sample: 10 g

Analysis: Digest the *Sample* with 50 mL of 5 N sodium hydroxide at 100° for 30 min. Separate the water layer, and acidify it with 5 N sulfuric acid.

Acceptance criteria: No oily or solid matter separates.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.
- **Labeling:** Label it to indicate the name and proportion of any added stabilizer.

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

Topic/Question	Contact	Expert Committee
PETROLATUM	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. 45(3)

Current DocID: GUID-1C10932B-8F36-4F87-8A83-D79BC52E0E41_1_en-US

DOI: https://doi.org/10.31003/USPNF_M62760_01_01

DOI ref: ym90t