Stage 4 Harmonization
Official: August 1, 2025

White Petrolatum

Add the following:

▲Portions of the text that are national *USP* text, and are not part of the harmonized text, are marked with symbols (⧫,⧫) to specify this fact.▲ (USP 1-Aug-2025)

Change to read:

DEFINITION
White Petrolatum is a purified and wholly or nearly decolorized semisolid mixture of hydrocarbons obtained from petroleum. It may contain a suitable ▲antioxidant.▲ (USP 1-Aug-2025)

IDENTIFICATION

Add the following:

▲● **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197F▲ (USP 1-Aug-2025)

Change to read:

● **B. Color**

Sample: 10 g

Standard: ▲Ferric chloride CS and 10 mg/mL of hydrochloric acid (1:9)▲ (USP 1-Aug-2025)

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 white petrolatum melted.

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

Add the following:

▲● **C. Drop Point**

Apparatus: The apparatus (see *Figure 1*) consists of two metal sheaths (A and B) screwed together. Sheath A is fixed to a thermometer. A metal cup is loosely fixed to the lower part of sheath B by means of two tightening bands. Fixed supports 2 mm long determine the exact position of the cup, and in addition are used to center the thermometer. A hole pierced in the wall of sheath B is used to balance the pressure. The draining surface of the cup must be flat, and the edges of the outflow orifice must be at right angles to it. The lower part of the thermometer has the form and size shown in *Figure 1*; it covers a range from 0°–110°, and on its scale a distance of 1 mm represents a difference of 1°. The reservoir of the thermometer has a diameter of 3.5 ± 0.2 mm and a height of 6.0 ± 0.3 mm. The apparatus is placed in the axis of a test tube about 200 mm long and with an external diameter of about 40 mm. It is fixed to the test tube by means of a laterally grooved stopper through which the thermometer passes. The opening of the cup is placed about 15 mm from the bottom of the test tube. The whole device is immersed in a beaker with a capacity of about 1 L, filled with water. The bottom of the test tube is placed about 25 mm from the bottom of the beaker. The water level reaches the upper part of sheath A. A stirrer is used to ensure that the temperature of the water remains uniform. Alternatively, a validated automated method can be used.

Procedure: Heat the substance to be examined at 100°–105° for NMT 10 min, with stirring to ensure uniformity. Warm the metal cup at 100°–105° in an oven, remove it from the oven, place it on a clean plate or ceramic tile, and pour a sufficient quantity of the melted sample into the cup to fill it completely. Allow the filled cup to cool for 30 min on the ceramic tile (25 ± 3°), and place it in a water bath at 24°–26° for a further 30–40 min. Level the surface of the sample with a single stroke of a knife or razor blade, avoiding compression of the sample. Determine the drop point using a starting temperature at least 10° below the expected drop point and increasing the temperature at a rate of 1°/min. Note the temperature at the fall of the first drop. Carry out at least three determinations, each time with a fresh sample of the substance. The difference between the readings must not exceed 3°.

Acceptance criteria: The mean of three readings is the drop point of the substance. The drop point is 35°–70° and does not differ by more than 5° from the value stated on the label.

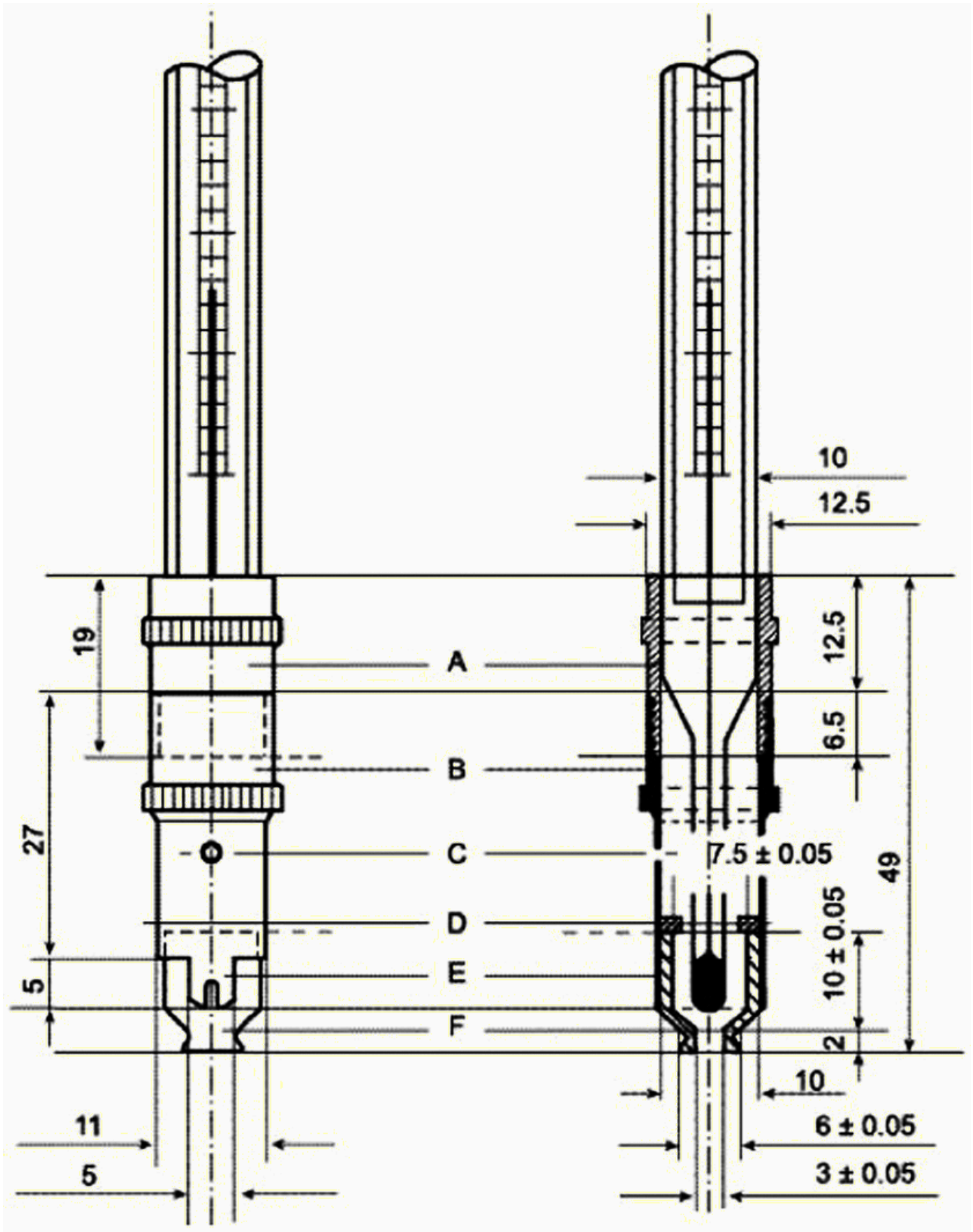

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Figure 1. Apparatus for the determination of drop point. Dimensions in millimeters.

A. Upper metal sheath

B. Lower metal sheath
C. Pressure-balancing hole
D. Fixed supports
E. Tightening bands
F. Metal sample cup▲ (USP 1-Aug-2025)

IMPURITIES

Change to read:

● **Residue on Ignition** ⟨281⟩

Sample: 2 g

Analysis: Heat the *Sample* in an open porcelain or platinum dish: It volatilizes. ▲Then ignite at 600 ± 50° in the presence of sulfuric acid until constant weight.▲ (USP 1-Aug-2025)

Acceptance criteria: ▲▲ (USP 1-Aug-2025)NMT 0.05% of residue

Delete the following:

▲**Organic Impurities**

● **Procedure: Organic Acids**▲ (USP 1-Aug-2025)

Add the following:

▲● **UV Absorbance Limit for Polycyclic Aromatic Hydrocarbons**

Sample solution: 1.0 g of White Petrolatum in 50 mL of hexane that has been previously shaken twice with 10 mL of dimethyl sulfoxide

Reference solution: 6.0 mg/L of USP Naphthalene RS in dimethyl sulfoxide

Analysis: Transfer the *Sample solution* to a 125-mL separating funnel with unlubricated ground-glass parts (stopper, stopcock). Add 20 mL of dimethyl sulfoxide. Shake vigorously for 1 min, and allow to stand until two clear layers are formed. Transfer the lower layer to a second separating funnel. Repeat the extraction with a further 20 mL of dimethyl sulfoxide. Vigorously shake the combined lower layers with 20 mL of hexane for 1 min. Allow to stand until two clear layers are formed. Separate the lower layer, and dilute with dimethyl sulfoxide to 50.0 mL. Measure the absorbance over the range of 265–420 nm, using a path length of 1 cm, and, as compensation liquid, the clear lower layer obtained by vigorously shaking 10 mL of dimethyl sulfoxide with 25 mL of hexane for 1 min. Measure the absorbance of the *Reference solution* at the maximum at 278 nm, using a path length of 1 cm and dimethyl sulfoxide as compensation liquid.

Acceptance criteria: At no wavelength in the range of 265–420 nm does the absorbance of the *Sample solution* exceed one-fourth of the absorbance of the *Reference solution* at 278 nm.▲ (USP 1-Aug-2025)

SPECIFIC TESTS

Delete the following:

▲● **Color**▲ (USP 1-Aug-2025)

Delete the following:

▲● **Specific Gravity** ⟨841⟩▲ (USP 1-Aug-2025)

Delete the following:

▲● **Melting Range or Temperature,** *Class III*⟨741⟩▲ (USP 1-Aug-2025)

Change to read:

● **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 being truncated to a diameter of ▲0.380 ± 0.026▲ (USP 1-Aug-2025) mm, the base of the tip is 8.38 ± 0.05 mm in diameter, and the length of the tip is 14.94 ± ▲0.11▲ (USP 1-Aug-2025) 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, watertight covers.

Sample: White Petrolatum

Analysis: Place the required number of containers in an oven, and bring them and a quantity of *Sample* to a temperature of 82° ± 2.5°. 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 hours 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, 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.▲▲ (USP 1-Aug-2025)

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.

Add the following:

▲● **Acidity or Alkalinity**

Sample: 10 g

Analysis: To the *Sample* add 20 mL of boiling water, and shake vigorously for 1 min. Allow to cool, and decant. To 10 mL of the aqueous layer add 0.1 mL of phenolphthalein TS.

Acceptance criteria: The solution is colorless. NMT 0.5 mL of 0.01 N sodium hydroxide is required to change the color of the indicator to pink or red.▲ (USP 1-Aug-2025)

Delete the following:

▲● **Alkalinity**▲ (USP 1-Aug-2025)

Delete the following:

▲● **Acidity**▲ (USP 1-Aug-2025)

Delete the following:

▲● **Fixed Oils, Fats, and Rosin**▲ (USP 1-Aug-2025)

ADDITIONAL REQUIREMENTS

Change to read:

● ▲▼▲ (USP 1-Aug-2025)**Packaging and Storage:** Preserve in well-closed containers, ▲protected from light.▼▲ (USP 1-Aug-2025)

Change to read:

● ▲ (USP 1-Aug-2025)**Labeling:** Label ▲ (USP 1-Aug-2025) to indicate the name and proportion of any added antioxidant. ▲Label to state the drop point value of the product. ▲ (USP 1-Aug-2025)

Add the following:

▲● **USP Reference Standards** ⟨11⟩

USP White Petrolatum RS

USP Naphthalene RS ▲ (USP 1-Aug-2025)

Petrolatum, White —*see* Petrolatum, White General Monographs

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