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Candelilla Wax

CAS RN®: 8006-44-8.

DEFINITION

Candelilla Wax is the purified wax obtained from the leaves of the candelilla plant, *Euphorbia antisyphilitica* Zucc.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197F

  Sample: Use a thin film of melted *Candelilla Wax*.

  Acceptance criteria: Meets the requirements

- **B.** It meets the requirements of the test in *Specific Tests* for *Melting Range or Temperature ⟨741⟩, Class II*.

IMPURITIES

- **Lead ⟨251⟩, *Procedures, Procedure 1***

  Sample: 3.3 g

  Control: 10 µg of lead from a *Diluted standard lead solution* (1 µg/mL of lead)

  Analysis: Weigh the *Sample* into a porcelain dish, heat on a hot plate until completely charred, then heat in a muffle furnace at 480° for 8 h or overnight, and cool. Cautiously add 5 mL of nitric acid, evaporate to dryness on a hot plate, then heat again in the muffle furnace for exactly 15 min, and cool. Extract the ash with two 10-mL portions of water, filtering each extract into a separator. Leach any insoluble material on the filter with 6 mL of *Ammonium citrate solution*, 2 mL of *Hydroxylamine hydrochloride solution*, and 5 mL of water, adding the filtered washings to the separator. Continue as directed in *⟨251⟩, Procedure*, beginning with "Add 2 drops of phenol red TS", and use 10 mL of *Diluted standard lead solution* for a control.

  Acceptance criteria: The color of the *Sample solution* does not exceed that in the control, corresponding to NMT 3 µg/g.

SPECIFIC TESTS

- **Melting Range or Temperature ⟨741⟩, *Procedures, Procedure for Class II*:** 68°–73°

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Acid Value***

  Sample: 3 g

  Analysis: Weigh the *Sample* in a 250-mL flask, add 50 mL of a mixture of isopropyl alcohol and toluene (5:4), attach the flask to a reflux condenser, and boil gently until the wax is completely dissolved. Examine the solution: no insoluble particles are present. Remove the flask from the condenser, add 1 mL of phenolphthalein TS, and titrate immediately with 0.5 N alcoholic potassium hydroxide VS to a faint, reddish-yellow color. [Note—Do not allow the solution to cool; titrate at a warm temperature after refluxing. After the titration, reserve the solution for use in the test for *Saponification Value*.]

  Calculate the acid value as the number of mg of potassium hydroxide required to neutralize the free acids in 1 g of Candelilla Wax.

  Acceptance criteria: 12–22

Change to read:

- **Fats and Fixed Oils ⟨401⟩, *Procedures, Saponification Value***

  Sample solution: Use the solution from the test for *Acid Value*.

  Analysis: To the *Sample solution* add 15.0 mL of 0.5 N alcoholic potassium hydroxide VS, reflux for 3–4 h, and titrate the excess alkali with 0.5 N hydrochloric acid VS to a yellow-amber color. Perform a blank determination under the same conditions (see ▲*Titrimetry ⟨541⟩, Types of Titrations, Blank Corrections*▲ (CN 1-Aug-2024)). The saponification value is the summation of the ester value so obtained and the acid value obtained above.

  Acceptance criteria: 43–65

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

- **USP Reference Standards ⟨11⟩**

  USP Candelilla Wax RS

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

Topic/Question	Contact	Expert Committee
CANDELILLA WAX	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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