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Hydrogenated Lanolin

CAS RN®: 8031-44-5.

DEFINITION

A mixture of higher aliphatic alcohols, hydrocarbons, and sterols is obtained from the direct high-pressure, high-temperature hydrogenation of lanolin. During the hydrogenation process, the esters and acids present are reduced to the corresponding alcohols. Alcoholic derivatives may be further reduced to hydrocarbons. It may contain antioxidants.

IDENTIFICATION

- **A.**

  Sample: 50 mg

  Analysis: Dissolve the *Sample* in 5 mL of methylene chloride, and add 1 mL of acetic anhydride and 0.1 mL of sulfuric acid.

  Acceptance criteria: A green color is produced.

- **B. Chromatographic Identity**

  Analysis: Proceed as directed in the test for *Chromatographic Profile of Fatty Alcohols, Hydrocarbons, and Sterols* in the *Assay*.

  Acceptance criteria: The retention times of the cetyl alcohol, stearyl alcohol, cholestane, cholestanol, and 24,25-dihydrolanosterol peaks of the *Sample solution* correspond to those of *Standard solution A*, as obtained in the *Assay*.

ASSAY

- **Chromatographic Profile of Fatty Alcohols, Hydrocarbons, and Sterols**

  Standard solution A: 2.5 mg/mL of USP Hydrogenated Lanolin RS in dehydrated alcohol

  Standard solution B: 0.5 mg/mL of cholestane, 0.5 mg/mL of cholestanol, and 0.25 mg/mL of 24,25-dihydrolanosterol in dehydrated alcohol

  Standard solution C: 0.5 mg/mL of USP Cetyl Alcohol RS in dehydrated alcohol. [Note—Vortex or sonification helps standard preparation.]

  Standard solution D: 0.5 mg/mL of USP Stearyl Alcohol RS in dehydrated alcohol. [Note—Vortex or sonification helps standard preparation.]

  Sample solution: 2.5 mg/mL of Hydrogenated Lanolin in dehydrated alcohol

  Chromatographic system

  (See *Chromatography ⟨621⟩, System Suitability*.)

  Mode: GC

  Detector: Flame ionization

  Column: 0.25-mm × 30-m fused-silica capillary; 0.25-µm layer of phase G2

  Temperatures

  Detector: 350°

  Injection port: 325°

  Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
100	—	100	5
100	5	300	15

Carrier gas: Helium

Flow rate: 1 mL/min

Injection volume: 1 µL

System suitability

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Standard solution D*

[NOTE—See *Table 2* for relative retention times.]

Table 2

Component	Relative Retention Time
Cetyl alcohol	1.00
Stearyl alcohol	1.15
Cholestane	1.63
Cholestanol	1.77
24,25-Dihydrolanosterol	1.85

System suitability requirements

Resolution: NLT 30 between cetyl alcohol and stearyl alcohol, *Standard solution A*

Analysis

Samples: *Standard solution A*, *Standard solution B*, *Standard solution C*, *Standard solution D*, and *Sample solution*

Identify the peaks from *Standard solution A*, *Standard solution B*, *Standard solution C*, and *Standard solution D*.

Calculate the percentage of cetyl alcohol (stearyl alcohol, cholestane, cholestanol, or 24,25-dihydrolanosterol) in the portion of Hydrogenated Lanolin taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of cetyl alcohol (stearyl alcohol, cholestane, cholestanol, or 24,25-dihydrolanosterol) from the *Sample solution*

r_S = peak response of cetyl alcohol (stearyl alcohol, cholestane, cholestanol, or 24,25-dihydrolanosterol) from *Standard solution C*, *Standard solution D*, or *Standard solution B*

C_S = concentration of USP Cetyl Alcohol RS (USP Stearyl Alcohol RS, cholestane, cholestanol, or 24,25-dihydrolanosterol) in *Standard solution C*, *Standard solution D*, or *Standard solution B* (mg/mL)

C_U = concentration of Hydrogenated Lanolin in the *Sample solution* (mg/mL)

Acceptance criteria

Sample solution: Chromatogram exhibits a profile similar to that in the chromatogram of *Standard solution A*.

Cetyl alcohol, stearyl alcohol, cholestane, cholestanol, and **24,25-dihydrolanosterol:** See *Table 3*.

Table 3

Name	Acceptance Criteria (%)
Cetyl alcohol	2–15
Stearyl alcohol	0.5–10
Cholestane	2–13
Cholestanol	3–11
24,25-Dihydrolanosterol	3–15

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%, determined on 5.0 g

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 45°–55°. Allow to stand at 20° for 16 h.

• **Fats and Fixed Oils,** *Acid Value* **⟨401⟩:** NMT 1.0, determined on 5.0 g

• **Fats and Fixed Oils,** *Hydroxyl Value* **⟨401⟩:** 140–180

• **Fats and Fixed Oils,** *Saponification Value* **⟨401⟩:** NMT 8.0. Heat under reflux for 4 h.

• **Loss on Drying ⟨731⟩**

Sample: 2.0 g

Analysis: Dry the *Sample* in an oven at 105° for 1 h.

Acceptance criteria: NMT 3.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, protected from light. Do not store above 45°.

• **Labeling:** Label it to indicate the name and amount of the antioxidant added.

• **USP Reference Standards ⟨11⟩**

USP Cetyl Alcohol RS
USP Hydrogenated Lanolin RS
USP Stearyl Alcohol RS

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

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

Chromatographic Database Information: Chromatographic Database

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