Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: NF Monographs
DocId: GUID-3D415227-6228-4780-B0DF-BFD2518BB386_1_en-US
DOI: https://doi.org/10.31003/USPNF_M44340_01_01
DOI Ref: df9qs

Lanolin Alcohols

CAS RN®: 8027-33-6.

DEFINITION

Lanolin Alcohols is a mixture of aliphatic alcohols, triterpenoid alcohols, and sterols, obtained by the hydrolysis of Lanolin. It may contain NMT 0.1% of a suitable antioxidant.

IDENTIFICATION

- **A.**

Sample: 0.5 g

Analysis: Dissolve the *Sample* in 5 mL of chloroform, and add 1 mL of acetic anhydride and 2 drops of sulfuric acid.

Acceptance criteria: A green color is produced.

ASSAY

- **Content of Sterols** (as cholesterol)

Sample: 20 g

Analysis: Melt the *Sample* on a water bath, mix, and allow to cool. Dissolve 100 mg in 12 mL of warm (60°) 90% alcohol. Allow to stand for 18 h, pass through a medium-porosity, sintered-glass filter, and wash the residue with two 15-mL portions of 90% alcohol. Combine the filtrate and washings, add 20 mL of a freshly prepared 1-in-100 solution of digitonin in 90% alcohol, and warm to 60°. Allow to cool, pass through a medium-porosity, sintered-glass filter with the aid of gentle vacuum, wash the residue with 10 mL of 90% alcohol, and dry at 105° to constant weight. Each g of residue is equivalent to 0.239 g of cholesterol.

Acceptance criteria: NLT 30.0% of sterols, calculated as cholesterol

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.15%

- **Copper**

Solution A: 1 mg/mL of sodium diethyldithiocarbamate

Sample: 5.0 g

Control: Add 1 mL of *Solution A* and a few drops of 6 N ammonium hydroxide to 2.5 mL of a 39.3-ppm solution of cupric sulfate. Dilute with water to 50 mL.

Analysis: Heat the *Sample* over a small flame until charred, ignite the residue at 550°, and dissolve the ash in 5 mL of hydrochloric acid, with the aid of heat. Cool, dilute with water, render alkaline with ammonium hydroxide, boil to remove the excess ammonia, add a few drops of bromine TS, boil again, and filter. To the filtrate add 1 mL of *Solution A*, a few drops of 6 N ammonium hydroxide, and sufficient water to bring the volume to 50 mL.

Acceptance criteria: The *Sample* is not darker than the *Control* (5 ppm).

SPECIFIC TESTS

- **Melting Range or Temperature, *Class II* ⟨741⟩:** NLT 56°

- **Acidity and Alkalinity**

Analysis: Boil 10 g with 100 mL of water for 5 min, with frequent stirring. Remove the source of heat, add 0.5 mL of phenolphthalein TS, and stir.

Acceptance criteria: No pink color is produced. Add 0.5 mL of methyl orange TS, and stir: no red color is produced.

- **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 1 h.

Acceptance criteria: NMT 0.5%

- **Fats and Fixed Oils,** *Acid Value* ⟨401⟩**:** NMT 2.0.
- **Fats and Fixed Oils,** *Hydroxyl Value* ⟨401⟩**:** 120–180
- **Fats and Fixed Oils,** *Peroxide Value* ⟨401⟩

  Sample: Take wedge-shaped pieces with bases that contain part of the surface.

  Analysis: Melt the pieces before carrying out the determination. Before adding the 0.5 mL of saturated potassium iodide solution, cool the solution obtained to room temperature.

  Acceptance criteria: NMT 15
- **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩

  Sample: 5 g of molten Lanolin Alcohols

  Analysis: Reflux the *Sample* with the alcoholic potassium hydroxide for 4 h.

  Acceptance criteria: NMT 12

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers, and store at controlled room temperature.
- **Labeling:** Label it to indicate the name and quantity of any antioxidant added.

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

Topic/Question	Contact	Expert Committee
LANOLIN ALCOHOLS	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. PF 34(4)

Current DocID: GUID-3D415227-6228-4780-B0DF-BFD2518BB386_1_en-US

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