U.S. PHARMACOPEIA

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Lanolin Alcohols

» Lanolin Alcohols is a mixture of aliphatic alcohols, triterpenoid alcohols, and sterols, obtained by the hydrolysis of Lanolin. It may contain not more than 0.1 percent of a suitable antioxidant.

Packaging and storage— Preserve in well-closed, light-resistant containers, preferably at controlled room temperature.

Identification— Dissolve 0.5 g in 5 mL of chloroform, and add 1 mL of acetic anhydride and 2 drops of sulfuric acid: a green color is produced.

Melting range, *Class II* ⟨ 741 ⟩ : not below 56°.

Acidity and alkalinity— Boil 10 g with 100 mL of water for 5 minutes, with frequent stirring. Remove the source of heat, add 0.5 mL of phenolphthalein TS, and stir: no pink color is produced. Add 0.5 mL of methyl orange TS, and stir: no red color is produced.

Loss on drying ⟨ 731 ⟩ **—** Dry it at 105° for 1 hour: it loses not more than 0.5% of its weight.

Residue on ignition ⟨ 281 ⟩ : not more than 0.15%.

Copper— Heat 5.0 g over a small flame until charred, ignite the residue at about 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 of ammonia, add a few drops of bromine TS, boil again, and filter. To the filtrate add 1 mL of sodium diethyldithiocarbamate solution (1 in 1000), a few drops of 6 N ammonium hydroxide, and sufficient water to bring the volume to 50 mL. The resulting color is not darker than that produced by adding 1 mL of the sodium diethyldithiocarbamate solution and a few drops of 6 N ammonium hydroxide to 2.5 mL of a 0.00393% solution of cupric sulfate, and diluting with water to 50 mL (5 ppm).

Acid value ⟨ 401 ⟩ : not more than 2.

Saponification value ⟨ 401 ⟩ : not more than 12, a 5-g specimen of molten Lanolin Alcohols being refluxed with the alcoholic potassium hydroxide for 4 hours.

Content of sterols (as cholesterol)— Melt 20 g of Lanolin Alcohols on a water bath, mix, and allow to cool. Dissolve about 100 mg, accurately weighed, in 12 mL of warm (about 60°) 90 percent alcohol. Allow to stand for 18 hours, pass through a medium-porosity, sintered-glass filter, and wash the residue with two 15-mL portions of 90 percent alcohol. Combine the filtrate and washings, add 20 mL of a freshly prepared 1 in 100 solution of digitonin in 90 percent 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 percent alcohol, and dry at 105° to constant weight. Each g of residue is equivalent to 0.239 g of cholesterol: not less than 30.0% of sterols, calculated as cholesterol, is found.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
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