U.S. PHARMACOPEIA

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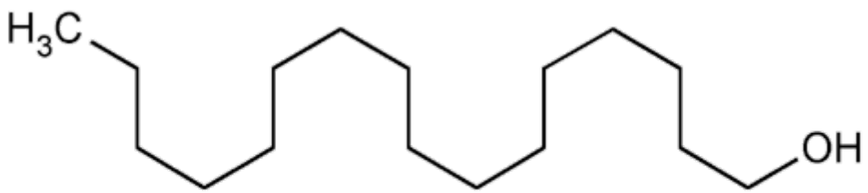
Cetyl Alcohol



$C_{16}H_{34}O$ 242.44

1-Hexadecanol.
1-Hexadecanol [*124-29-8*; *36653-82-4*].

» Cetyl Alcohol contains not less than 90.0 percent of cetyl alcohol ($C_{16}H_{34}O$), the remainder consisting chiefly of related alcohols.

Packaging and storage— Preserve in well-closed containers.

USP Reference standards ⟨ 11 ⟩ **—** *USP Cetyl Alcohol RS*. *USP Stearyl Alcohol RS*.

Identification— The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *System suitability solution,* as obtained in the *Assay.*

Acid value ⟨ 401 ⟩ **:** not more than 2.

Iodine value ⟨ 401 ⟩ **:** not more than 5.

Hydroxyl value— Place about 2 g, accurately weighed, in a dry, glass-stoppered, 250-mL flask, and add 2 mL of pyridine, followed by 10 mL of toluene. To the mixture add 10.0 mL of a solution of acetyl chloride, prepared by mixing 10 mL of acetyl chloride with 90 mL of toluene. Insert the stopper in the flask, and immerse in a water bath heated at 60° to 65° for 20 minutes. Add 25 mL of water, again insert the stopper in the flask, and shake vigorously for several minutes to decompose the excess acetyl chloride. Add 0.5 mL of phenolphthalein TS, and titrate to a permanent pink endpoint with 1 N sodium hydroxide VS, shaking the flask vigorously toward the end of the titration to maintain the contents in an emulsified condition. Perform a blank test with the same quantities of the same reagents and in the same manner. The difference between the number of mL of 1 N sodium hydroxide consumed in the test with the sample and that consumed in the blank test, multiplied by 56.1, and the result divided by the weight, in g, of the Cetyl Alcohol used, represents the hydroxyl value of the Cetyl Alcohol, which is between 218 and 238.

Residual solvents ⟨ 467 ⟩ **:** meets the requirements.
(Official January 1, 2007)

Change to read:
Assay—

System suitability solution— Dissolve accurately weighed quantities of *USP Cetyl Alcohol RS* and *USP Stearyl Alcohol RS* in dehydrated alcohol to obtain a solution having known concentrations of about 9 mg per mL and 1 mg per mL, respectively.

Assay preparation— Dissolve 100 mg of Cetyl Alcohol in 10.0 mL of dehydrated alcohol, and mix.

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)— The gas chromatograph is equipped with a flame-ionization detector and a 3-mm × 2-m column packed with 10% liquid phase G2 on support S1A. The carrier gas is helium. The column temperature is maintained at about 205°, the injection port temperature is maintained at about 275°, and the detector temperature is maintained at about 250°. Chromatograph the *System suitability solution,* and record the peak responses as directed for *Procedure:* the resolution, *R,* between cetyl alcohol and stearyl alcohol is not less than 4.0; and the relative standard deviation for replicate injections, ▲calculated with the area ratio of cetyl alcohol to stearyl alcohol,▲*NF24* is not more than 1.5%.

Procedure— Inject about 2 µL of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the areas for the major peaks. Calculate the percentage of $C_{16}H_{34}O$ in the portion of Cetyl Alcohol taken by the formula:

$$100(r_U / r_S)$$

in which r_U is the peak area for cetyl alcohol obtained from the *Assay preparation;* and r_S is the sum of the areas of all the peaks except the solvent peak.

Auxiliary Information— *Staff Liaison* : Catherine Sheehan, B.Sc., Scientist
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