U.S. PHARMACOPEIA

Search USP29 Go

Cetostearyl Alcohol

» Cetostearyl Alcohol contains not less than 40.0 percent of stearyl alcohol ($C_{18}H_{38}O$), and the sum of the stearyl alcohol content and the cetyl alcohol ($C_{16}H_{34}O$) content is not less than 90.0 percent.

Packaging and storage— Preserve in well-closed containers.

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

Identification— The retention times of the major peaks in the chromatogram of the *Assay preparation* correspond to those in the chromatogram of the *System suitability solution*, as obtained in the *Assay.*

Melting range ⟨ 741 ⟩ **:** between 48° and 55°.

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

Iodine value ⟨ 401 ⟩ **:** not more than 4.

Hydroxyl value ⟨ 401 ⟩ **—** Place about 2 g, accurately weighed, in a dry, glass-stoppered, 250-mL flask, add 2 mL of pyridine, then add 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 with 1 N sodium hydroxide VS to a permanent pink endpoint, shaking the flask vigorously toward the end of the titration in order to maintain the contents in an emulsified condition. Perform a blank determination 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 specimen under test and that consumed in the blank test, multiplied by 56.1, and the result divided by the weight, in g, of the Cetostearyl Alcohol used, represents the hydroxyl value of the Cetostearyl Alcohol. The hydroxyl value is between 208 and 228.

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 alcohol to obtain a solution having a known concentration of about 5 mg of each per mL.

Assay preparation— Dissolve 100 mg of Cetostearyl 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 at about 275°, and the detector temperature 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 is not more than 1.5% ▲for the percentages of $C_{16}H_{34}O$ and $C_{18}H_{38}O$.▲*NF24*

Procedure— Inject about 2 µL of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the areas for the major peaks. Separately calculate the percentages of cetyl alcohol ($C_{16}H_{34}O$) and stearyl alcohol ($C_{18}H_{38}O$) in the portion of Cetostearyl Alcohol taken by the formula:

$$100(r_U / r_S)$$

in which r_U is the peak area obtained from cetyl alcohol or stearyl alcohol; 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
Expert Committee : (EM105) Excipient Monographs 1
USP29–NF24 Page 3309
Pharmacopeial Forum : Volume No. 31(2) Page 494
Phone Number : 1-301-816-8262