

U.S. PHARMACOPEIA

Search USP29

Go

Octyldodecanol

» Octyldodecanol contains not less than 90.0 percent of 2-octyldodecanol, the remainder consisting chiefly of related alcohols.

Packaging and storage— Preserve in tight containers.

USP Reference standards [〈 11 〉](#) — [USP Octyldodecanol RS](#). [USP Stearyl Alcohol RS](#).

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

Acid value [〈 401 〉](#) : not more than 0.5.

Iodine value [〈 401 〉](#) : not more than 8.

Hydroxyl value [〈 401 〉](#) : between 175 and 190.

Saponification value [〈 401 〉](#) : not more than 5.

Organic volatile impurities, Method V [〈 467 〉](#) : meets the requirements.

Solvent: dimethyl sulfoxide.

Residual solvents [〈 467 〉](#) : meets the requirements.

(Official January 1, 2007)

Assay—

System suitability solution— Dissolve accurately weighed quantities of [USP Octyldodecanol RS](#) and [USP Stearyl Alcohol RS](#) in alcohol to obtain a solution having known concentrations of about 9 mg per mL and 1 mg per mL, respectively.

Assay preparation— Dissolve 90 mg of Octyldodecanol in 10.0 mL of alcohol, and mix.

Chromatographic system (see [Chromatography](#) [〈 621 〉](#))—The gas chromatograph is equipped with a flame-ionization detector and a 2-mm × 2-m column packed with 3% liquid phase G2 on support S1A. The carrier gas is nitrogen. The column temperature is programmed as follows. Initially it is equilibrated at about 80 °, then increased at a rate of 6 ° per minute to 300 °. The detector and the injection port temperatures are both

maintained at about 280°. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution, R , between octyldodecanol and stearyl alcohol is not less than 4.0; and the relative standard deviation for replicate injections 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 C₂₀H₄₂O in the portion of Octyldodecanol taken by the formula:

$$100(r_U / r_s),$$

in which r_U is the peak area for octyldodecanol 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](#)

Expert Committee : (EM105) Excipient Monographs 1

USP29–NF24 Page 3382

Phone Number : 1-301-816-8262