Cetostearyl Alcohol

1 Nonproprietary Names

BP: Cetostearyl Alcohol

PhEur: Cetostearyl Alcohol

USP–NF: Cetostearyl Alcohol

2 Synonyms

Alcohol cetylicus et stearylicus; cetearyl alcohol; cetyl stearyl alcohol; *Crodacol CS90*; *DUB SC 20D*; *Kolliwax CSA*; *Lanette O*; *Speziol C16-18 Pharma*; *Tego Alkanol 1618*; *Tego Alkanol 6855*.

3 Chemical Name and CAS Registry Number

Cetostearyl alcohol [67762-27-0] and [8005-44-5]

4 Empirical Formula and Molecular Weight

Cetostearyl alcohol is a mixture of solid aliphatic alcohols consisting mainly of stearyl ($C_{18}H_{38}O$) and cetyl ($C_{16}H_{34}O$) alcohols. The proportion of stearyl to cetyl alcohol varies considerably, but the material usually consists of about 50–70% stearyl alcohol and 20–35% cetyl alcohol, with limits specified in pharmacopeias. The combined stearyl alcohol and cetyl alcohol comprise at least 90% of the material. Small quantities of other alcohols, chiefly myristyl alcohol, make up the remainder of the material.

5 Structural Formula

See Section 4.

6 Functional Category

Emollient; emulsifying agent; viscosity-increasing agent.

7 Applications in Pharmaceutical Formulation or Technology

Cetostearyl alcohol is used in topical pharmaceutical formulations to increase viscosity and act as an emulsifier in both water-in-oil and oil-in-water emulsions. Cetostearyl alcohol will stabilize an emulsion and also act as a co-emulsifier, thus decreasing the total amount of surfactant required to form a stable emulsion.

Cetostearyl alcohol has been used for ocular delivery of methazolamide[1] and as a co-surfactant in conjunction with propylene glycol to increase skin penetration of piroxicam.[2] Controlled-release tablet formulations of etodolac have also been studied using a variety of lipid matrices.[3] *See also* Section 18.

8 Description

Cetostearyl alcohol occurs as white or cream-colored unctuous masses, flakes, pellets or granules. It has a faint, characteristic sweet odor. On heating, cetostearyl alcohol melts to a clear, colorless or pale yellow-colored liquid free of suspended matter.

9 Pharmacopeial Specifications

See Table I. *See also* Section 18.

10 Typical Properties

Boiling point ≈ 300-360°C (degradation temperature)
Density (bulk) ≈ 0.8 g/cm^3 at 20°C.
Solubility Soluble in ethanol (95%), ether, and oil; practically insoluble in water.

Table I: Pharmacopeial specifications for cetostearyl alcohol.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Melting range	49–56°C	48–55°C
Acid value	≤1.0	≤2.0
Iodine value	≤2.0	≤4
Hydroxyl value	208–228	208–228
Saponification value	≤2.0	—
Assay		
of $C_{18}H_{38}O$	≥40.0%	≥40.0%
of $C_{16}H_{34}O$ and $C_{18}H_{38}O$	≥90.0%	≥90.0%

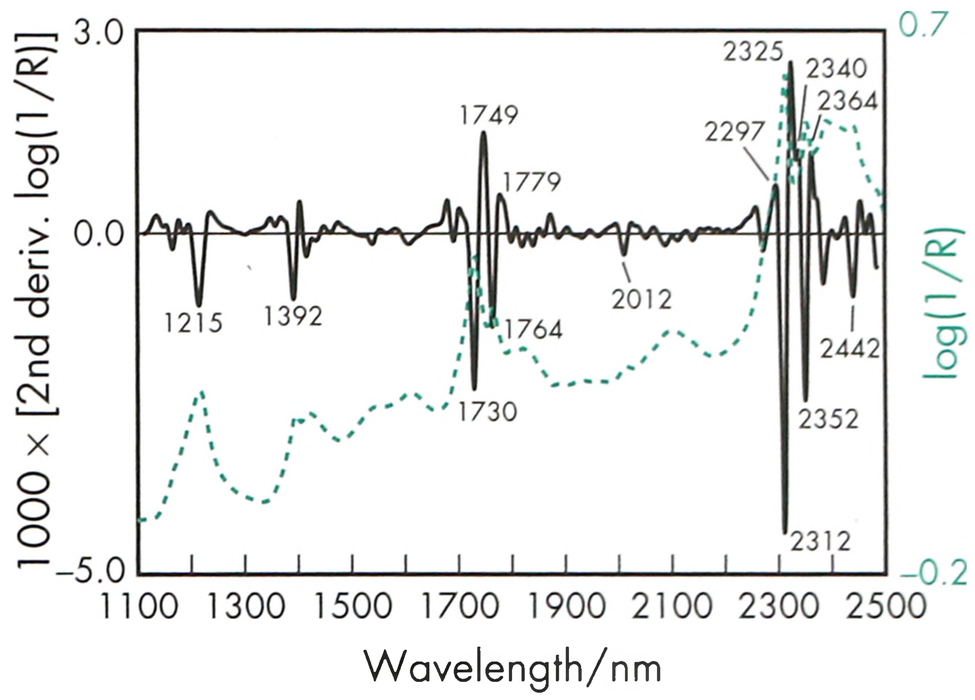

Figure 1: Near-infrared spectrum of cetostearyl alcohol measured by reflectance.

Spectroscopy

NIR spectrum *see* Figure 1.

11 Stability and Storage Conditions

Cetostearyl alcohol is stable under normal storage conditions. It should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

Cetostearyl alcohol is incompatible with strong oxidizing agents and metal salts.

13 Method of Manufacture

Cetostearyl alcohol is prepared by the reduction of the appropriate fatty acids from vegetable and animal sources. Cetostearyl alcohol can also be prepared directly from hydrocarbon sources.

14 Safety

Cetostearyl alcohol is mainly used in topical pharmaceutical formulations and topical cosmetic formulations.

Cetostearyl alcohol is generally regarded as a nontoxic material.[4] Although it is essentially nonirritating, sensitization reactions to cetostearyl, cetyl, and stearyl alcohols[5–10] have been reported.