Oleic Acid

1 Nonproprietary Names

BP: Oleic Acid

PhEur: Oleic Acid

USP–NF: Oleic Acid

2 Synonyms

Acidum oleicum; *Crodolene*; *Crossential 094*; elaic acid; elaidic acid; *Emersol*; extraolein; *Glycon*; *Groco*; *Hy-Phi*; *Industrene*; *Metaupon*; *Neo-Fat*; *cis*-9-octadecenoic acid; 9,10-octadecenoic acid; oleinic acid; *Priolene*.

3 Chemical Name and CAS Registry Number

(*Z*)-9-Octadecenoic acid [112-80-1]

4 Empirical Formula and Molecular Weight

$C_{18}H_{34}O_2$ 282.47

5 Structural Formula

6 Functional Category

Emulsifying agent; penetration enhancer; solubilizing agent.

7 Applications in Pharmaceutical Formulation or Technology

Oleic acid is used as an emulsifying agent in foods and topical pharmaceutical formulations. It has been investigated as a penetration enhancer in transdermal formulations,[1–21] to improve the bioavailability of poorly water-soluble drugs in tablet formulations,[22] and as part of a vehicle in soft gelatin capsules, in topical nanoemulsion,[23,24] lipid-emulsion[25] and microemulsion[26–35] formulations, in oral self-emulsifying drug delivery systems,[36,37] bioadhesive gels,[38] in oral mucoadhesive patches,[39] buccal delivery[40] and in a metered-dose inhaler.[41] It has also been used as a solubilizer[42,43] and as an iontophoresis pre-treatment.[44–46]

The phase behavior of sonicated dispersions of oleic acid has been described,[47] and mechanisms for the topical penetration-enhancing actions of oleic acid have been presented.[48,49] Oleic acid has also been studied as a plasticizer in drug-loaded casein beads,[50] as a phospholipid stabilizer[51] and viscosity enhancer.[52]

8 Description

A yellowish to pale brown, oily liquid with a characteristic lard-like odor and taste. Pure oleic acid is a colorless liquid (above 5-7°).

Oleic acid consists chiefly of (*Z*)-9-octadecenoic acid together with varying amounts of saturated and other unsaturated acids. It may contain a suitable antioxidant.

9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for oleic acid.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	—
Specific gravity	≈0.892	—
Residue on ignition	—	≤1 mg
Total ash	≤0.1%	—
Mineral acids	—	+
Neutral fat or mineral oil	—	—
Fatty acid composition	+	—
Myristic acid	≤5.0%	≤5.0%
Palmitic acid	≤16.0%	≤16.0%
Palmitoleic acid	≤8.0%	≤8.0%
Stearic acid	≤6.0%	≤6.0%
Oleic acid	65.0–88.0%	≥65.0%
Linoleic acid	≤18.0%	≤18.0%
Linolenic acid	≤4.0%	≤4.0%
Fatty acids of chain length greater than C_{18}	≤4.0%	≤4.0%
Acid value	195–204	196–204
Iodine value	89–105	85–105
Peroxide value	≤10.0	≤10.0
Congealing temperature	—	+
From animal sources	—	3–10°C
From vegetable sources	—	10–16°C
Margaric acid	+	—
From animal sources	≤4.0%	—
From vegetable sources	≤0.2%	—
Color of solution	+	—
Assay	65–88%	≥65.0%
Water	—	≤0.4%

10 Typical Properties

Acidity/alkalinity pH = 4.4 (saturated aqueous solution)

Autoignition temperature 363°C

Boiling point 286°C at 13.3 kPa (100 mmHg) (decomposition at 80–100°C)

Density 0.895 g/cm^3

Flash point 189°C

Melting point 6–12°C; pure oleic acid solidifies at 4°C[53]

Refractive index n_D^{26} = 1.4585

Solubility Miscible with benzene, chloroform, ethanol (95%), ether, hexane, and fixed and volatile oils; practically insoluble in water.

Vapor pressure 133 Pa (1 mmHg) at 176.5°C

Viscosity (dynamic) 26 mPa s (26 cP) at 25°C

11 Stability and Storage Conditions

On exposure to air, oleic acid gradually absorbs oxygen, darkens in color, and develops a more pronounced odor. At atmospheric pressure, it decomposes when heated at 80–100°C.

Oleic acid should be stored in a well-filled, well-closed container, protected from light, in a cool, dry place.

12 Incompatibilities

Incompatible with aluminum, calcium, heavy metals, iodine solutions, perchloric acid, and oxidizing agents. Oleic acid reacts with alkalis to form soaps.