Glyceryl Palmitostearate

1 Nonproprietary Names

None adopted.

2 Synonyms

Glycerin palmitostearate; glycerol palmitostearate; 2-[(1-oxohexadecyl)-oxy]-1,3-propanediyl dioctadecanoate and 1,2,3-propane triol; *Precirol ATO 5*.

3 Chemical Name and CAS Registry Number

Octadecanoic acid, 2,3-dihydroxypropyl ester mixed with 3-hydroxy-2-[(1-oxohexadecyl)-oxy] propyl octadecanoate [8067-32-1]

4 Empirical Formula Molecular Weight

Glyceryl palmitostearate is a mixture of mono-, di-, and triglycerides of C_{16} and C_{18} fatty acids.

5 Structural Formula

See Sections 3 and 4.

6 Functional Category

Tablet and capsule diluent; tablet and capsule lubricant.

7 Applications in Pharmaceutical Formulation or Technology

Glyceryl palmitostearate is used in oral solid-dosage pharmaceutical formulations as a lubricant.[1,2] Disintegration times increase[3] and tablet strength decreases[4] with increase in mixing time.

It is used as a lipophilic matrix for sustained-release tablet and capsule formulations.[5,6] Tablet formulations may be prepared by either granulation or a hot-melt technique,[7] the former producing tablets that have the faster release profile. Release rate decreases with increased glyceryl palmitostearate content.[5]

Glyceryl palmitostearate may be used to form microspheres, which may be used in capsules or compressed to form tablets.[8,9] It has been used to form biodegradable injectable gels.[10] *See* Table I.

Table I: Uses of glyceryl palmitostearate.

Use	Concentration (%)
Matrix for sustained release	10–50
Tablet lubricant	0.5–5

8 Description

Glyceryl palmitostearate occurs as a fine white powder with a faint odor.

9 Pharmacopeial Specifications

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10 Typical Properties

Acid value: <6.0
Boiling point: 200°C
Color: <3 (Gardner scale)
Free glycerin content: <1.0%
Heavy metals: <10 ppm
Hydroxyl value: 60–115
Iodine value: <3
Melting point: 52–55°C
1-Monoglycerides content: 8.0–17.0%
Peroxide value: <3.0
Saponification value: 175–195
Solubility: freely soluble in chloroform and dichloromethane; practically insoluble in ethanol (95%), mineral oil, and water.
Sulfated ash: <0.1%
Unsaponifiable matter: <1.0%
Water content: <1.0%

11 Stability and Storage Conditions

Glyceryl palmitostearate should not be stored at temperatures above 35°C. For storage for periods over 1 month, glyceryl palmitostearate should be stored at a temperature of 5–15°C in an airtight container, protected from light and moisture.

12 Incompatibilities

Glyceryl palmitostearate is incompatible with ketoprofen[11] and naproxen.[12]

13 Method of Manufacture

Glyceryl palmitostearate is manufactured, without a catalyst, by the direct esterification of palmitic and stearic acids with glycerol.

14 Safety

Glyceryl palmitostearate is used in oral pharmaceutical formulations and is generally regarded as an essentially nontoxic and nonirritant material.

LD_{50} (rat, oral): >6 g/kg[13]

15 Handling Precautions

Observe normal handling precautions appropriate to the circumstances and quantity of material handled.

16 Regulatory Status

GRAS listed. Included in the FDA Inactive Ingredients Guide (oral preparations). Included in nonparenteral preparations licensed in Europe.

17 Related Substances

Glyceryl behenate; glyceryl monostearate.

18 Comments

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19 Specific References

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20 General References

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22 Date of Revision

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