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Propylene Glycol Monostearate

Octadecanoic acid, monoester with 1,2-propanediol;
1,2-Propanediol monostearate
CAS RN®: 1323-39-3.

DEFINITION

Propylene Glycol Monostearate is a mixture of the propylene glycol mono- and di-esters of stearic and palmitic acids. It contains NLT 90.0% of monoesters of saturated fatty acids, chiefly propylene glycol monostearate ($C_{21}H_{42}O_3$) and propylene glycol monopalmitate ($C_{19}H_{38}O_3$).

ASSAY

• **Propylene Glycol Monoesters**

Sample: 25 g

Analysis: Place the *Sample* in a 500-mL, round-bottom flask, and add 250 mL of alcohol and 7.5 g of potassium hydroxide. Connect the flask to a suitable condenser, reflux the mixture for 2 h, cool, and transfer to an 800-mL beaker, rinsing the flask with 100 mL of water and combining the rinsing with the mixture in the beaker. Heat on a steam bath to evaporate the alcohol, adding water occasionally to replace the alcohol, and continue the evaporation until the odor of alcohol can no longer be detected. Adjust the volume, with hot water, to 250 mL, neutralize with a mixture of equal volumes of sulfuric acid and water, noting the volume used, and add a 10% excess of the dilute acid. Heat with stirring until the fatty acid layer separates, and transfer the fatty acids to a 500-mL separator. Wash the fatty acids with four 200-mL portions of hot water, and discard the washings. Dry the fatty acids at 105° for 1 h, cool, and determine the acid value on a 1-g portion, as directed in *Fats and Fixed Oils ⟨401⟩, Acid Value (Free Fatty Acids)*.

Calculate the average molecular weight of the monoesters, in the portion of Propylene Glycol Monostearate taken:

$$M_{rAvg} = (M_{r1}/A) + M_{r2} - M_{r3}$$

M_{r1} = 1000 times the molecular weight of potassium hydroxide, 56,110

A = acid value

M_{r2} = molecular weight of propylene glycol, 76.10

M_{r3} = molecular weight of water, 18.02

Calculate F in the portion taken:

$$F = (M_{r4} \times G)/M_{r5}$$

M_{r4} = 10 times the molecular weight of potassium hydroxide, 561.1

G = content, in percentage, of glycerin and propylene glycol in propylene glycol monostearate

M_{r5} = one-half of the molecular weight of propylene glycol, 38.05

Calculate the percentage of propylene glycol monoesters:

$$\text{Result} = [(H - F) \times M_{rAvg}]/M_{r4}$$

H = hydroxyl value of propylene glycol monostearate

Acceptance criteria: NLT 90.0% of monoesters of saturated fatty acids, chiefly propylene glycol monostearate and propylene glycol monopalmitate

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.5%

• **Free Glycerin and Propylene Glycol**

Periodic acid solution: Dissolve 5.4 g of periodic acid in 100 mL of water, and add 1900 mL of glacial acetic acid. Store in a glass-stoppered bottle, protected from light.

Chloroform: Use chloroform that meets the following additional requirement. To each of three glass-stoppered, 500-mL conical flasks add 50.0 mL of *Periodic acid solution*, then add 50 mL of chloroform and 10 mL of water to two of the flasks and 50 mL of water to the third flask. To each flask add 20 mL of potassium iodide TS, mix gently, and proceed as directed for *Analysis*, beginning with "allow to stand for 1–5 min". The difference between the volumes of 0.1 N sodium thiosulfate required in the titrations with and without the chloroform does not exceed 100 µL.

Sample solution: Melt the Propylene Glycol Monostearate at a temperature NMT 55°. Transfer a 3-g portion to a 100-mL beaker, and dissolve in 25 mL of *Chloroform*.

Analysis: Transfer the *Sample solution*, with the aid of another 25-mL portion of *Chloroform*, to a separator, wash the beaker with 25 mL of water, and add the washing to the separator. Insert the stopper, shake vigorously for 30–60 s, and allow the layers to separate, adding 1–2 mL of glacial acetic acid, if necessary, to break any emulsion. Transfer the aqueous layer to a glass-stoppered, 500-mL conical flask, wash the chloroform layer with two 25-mL portions of water, combining the washings with the aqueous layer, and discard the chloroform layer. Add, with swirling, 50.0 mL of *Periodic acid solution* to the solution and to another glass-stoppered, 500-mL conical flask containing 75 mL of water to provide the blank. Allow to stand for 30–90 min. To each flask add 20 mL of potassium iodide TS, mix gently, and allow to stand for 1–5 min before titrating. Add 100 mL of water, and titrate with 0.1 N sodium thiosulfate VS until the brown iodine color fades to pale yellow, add 3 mL of starch TS, and continue the titration to the disappearance of the blue color.

Calculate the percentage of free glycerin and propylene glycol, calculated as propylene glycol, in the portion of Propylene Glycol Monostearate taken:

$$\text{Result} = [(V_B - V_S) \times M_r \times N]/W$$

V_B = volume of sodium thiosulfate consumed by the blank solution (mL)

V_S = volume of sodium thiosulfate consumed by the *Sample solution* (mL)

M_r = molecular weight of propylene glycol divided by 20, 3.805

N = actual normality of the sodium thiosulfate solution

W = weight of Propylene Glycol Monostearate taken (g)

Acceptance criteria: NMT 1.0% free glycerin and propylene glycol, calculated as propylene glycol

SPECIFIC TESTS

• **Congealing Temperature ⟨651⟩:** NLT 45°

• **Fats and Fixed Oils, *Acid Value (Free Fatty Acids)*⟨401⟩:** NMT 4

• **Fats and Fixed Oils, *Hydroxyl Value*⟨401⟩:** 160–175

• **Fats and Fixed Oils, *Iodine Value*⟨401⟩:** NMT 3

• **Fats and Fixed Oils, *Saponification Value*⟨401⟩:** 155–165

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PROPYLENE GLYCOL MONOSTEARATE	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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