



Edition: BP 2025 (Ph. Eur. 11.6 update)

Self-emulsifying Glyceryl Monostearate

[General Notices](#)

Self-emulsifying Monostearin; Self-emulsifying Mono-and Diglycerides of Food Fatty Acids

Action and use

Excipient.

DEFINITION

Self-emulsifying Glyceryl Monostearate is a mixture consisting principally of mono-, di- and triglycerides of stearic and palmitic acids and of minor proportions of glycerides of other fatty acids; it may also contain free glycerol, free fatty acids and soap. It contains not less than 30.0% of monoglycerides, calculated as $C_{21}H_{42}O_4$, not more than 7.0% of free glycerol, calculated as $C_3H_8O_3$, and not more than 6.0% of soap, calculated as sodium oleate, $C_{18}H_{33}NaO_2$, all calculated with reference to the anhydrous substance.

CHARACTERISTICS

A white to cream coloured, hard, waxy solid.

Dispersible in hot [water](#); soluble in hot [absolute ethanol](#), in hot [liquid paraffin](#) and, subject to turbidity at concentrations below 20%, in hot vegetable oils.

TESTS

[Acid value](#)

Not more than 6, [Appendix X B](#).

[Iodine value](#)

Not more than 3 ([iodine monochloride method](#)), [Appendix X E](#).

Alkalinity

Shake 1 g with 20 mL of hot [carbon dioxide-free water](#) and allow to cool with continuous shaking. The pH of the aqueous layer is 8.0 to 10.0, [Appendix V L](#).

[Water](#)

Not more than 2.0% w/w, [Appendix IX C](#). Use 0.5 g and a mixture of 10 mL of [anhydrous methanol](#) and 10 mL of anhydrous [chloroform](#) as the solvent.

ASSAY

For free glycerol

Dissolve 0.4 g in 50 mL of [dichloromethane](#) in a ground-glass-stoppered separating funnel, cool if necessary, add 25 mL of [water](#) and shake vigorously for 1 minute; add 0.2 mL of [glacial acetic acid](#), if necessary, to break the emulsion. Repeat the extraction a further three times using 25-, 20- and 20- mL quantities of [water](#) and reserve the dichloromethane solution for the Assay for monoglycerides. Filter the combined aqueous extracts through a filter paper moistened with [water](#), wash the filter with two 5 mL quantities of [water](#) and dilute the combined filtrate and washings to 100 mL with [water](#). To 50 mL of this solution add 25 mL of [periodic acetic acid solution](#), shaking cautiously, allow to stand at 25° to 30° for 30 minutes and add 100 mL of [water](#) and 12 mL of [potassium iodide solution](#). Titrate with 0.1M [sodium thiosulfate VS](#) using 1 mL of [starch solution](#) as indicator. Repeat the determination using 50 mL of [water](#) in place of the 50 mL of the solution being examined. The difference between the titrations represents the amount of sodium thiosulfate required. Each mL of 0.1M [sodium thiosulfate VS](#) is equivalent to 2.3 mg of glycerol.

For monoglycerides

Filter the reserved dichloromethane solution obtained in the Assay for free glycerol through absorbent cotton and wash the separating funnel and the filter with three 5 mL quantities of [dichloromethane](#). Dilute the combined filtrate and washings to 100 mL with [dichloromethane](#) and to 50 mL of the solution add 25 mL of [periodic acetic acid solution](#), shaking cautiously. Allow to stand at 25° to 30° for 30 minutes and add 100 mL of [water](#) and 12 mL of [potassium iodide solution](#). Titrate the liberated iodine with 0.1M [sodium thiosulfate VS](#) using 1 mL of [starch solution](#) as indicator. Repeat the determination using 50 mL of [dichloromethane](#) in place of the 50 mL of the solution of the substance being examined. The difference between the titrations represents the amount of sodium thiosulfate required. Each mL of 0.1M [sodium thiosulfate VS](#) is equivalent to 17.9 mg of 1-monoacylglycerols, calculated as $C_{21}H_{42}O_4$. The quantity of 0.1M [sodium thiosulfate VS](#) used in the assay is not less than 85% of the quantity of sodium thiosulfate used in the blank assay.

For soap

Add 10 g to a mixture of 60 mL of [acetone](#) and 0.15 mL of a 0.5% w/v solution of [bromophenol blue](#) in a mixture of 20 mL of [ethanol](#) (20%) and 80 mL of [water](#), the solvent having been previously neutralised with [0.1M hydrochloric acid VS](#) or [0.1M sodium hydroxide VS](#). Warm gently on a water bath until solution is complete and titrate with [0.1M hydrochloric acid VS](#) until the blue colour is discharged. Allow to stand for 20 minutes, warm until any solidified matter has redissolved and, if the blue colour reappears, continue the titration. Each mL of [0.1M hydrochloric acid VS](#) is equivalent to 30.45 mg of $C_{18}H_{33}NaO_2$.