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# Ethylene Glycol Stearates

## DEFINITION

Ethylene Glycol Stearates is a mixture of ethylene glycol monoesters and diesters of stearic and palmitic acids. It contains NLT 50.0% of monoesters produced from the condensation of ethylene glycol and stearic acid of vegetable or animal origin.

## IDENTIFICATION

- **A.** It meets the requirements in *Specific Tests* for *Melting Range or Temperature, Class II ⟨741⟩*.
- **B.** It meets the requirements in *Specific Tests* for *Fats and Fixed Oils, Fatty Acid Composition ⟨401⟩*.

## ASSAY

- **Procedure**

**Mobile phase:** Tetrahydrofuran

**Sample solution:** 40 mg/mL of Ethylene Glycol Stearates in tetrahydrofuran

**Chromatographic system**

(See *Chromatography ⟨621⟩, System Suitability*.)

**Mode:** LC

**Detector:** Refractive index

**Column:** 7.5-mm × 60-cm; containing 5-µm 100Å packing L21. [Note—Two or three 7.5-mm × 30-cm L21 columns may be used in place of the one 60-cm column, provided that *System suitability* requirements are met.]

**Temperatures**

**Column:** 40°. [Note—The column temperature may be lowered to ambient temperature, although working at 40° provides stable separation conditions and ensures better sample solubility.]

**Detector:** 40°

**Flow rate:** 1 mL/min

**Injection volume:** 40 µL

**System suitability**

**Sample:** *Sample solution*

[Note—The relative retention times for diesters, monoesters, and ethylene glycol are 0.76, 0.83, and 1.0, respectively.]

**Suitability requirements**

**Relative standard deviation:** NMT 2.0% for the monoesters peak

**Analysis**

**Sample:** *Sample solution*

Calculate the percentage of free fatty acids, $E$, in the portion of Ethylene Glycol Stearates taken:

$$E = I_A \times 270/561.1$$

$I_A$ = acid value, determined in *Specific Tests* for *Fats and Fixed Oils, Acid Value (Free Fatty Acids) ⟨401⟩*

Calculate the percentage of monoesters in the portion of *Sample* taken:

$$\text{Result} = [r_M/(r_M + r_D)](100 - D - E)$$

$r_M$ = peak response for the monoesters

$r_D$ = peak response for the diesters

$D$ = percentage of free ethylene glycol in the portion of Ethylene Glycol Stearates taken, as determined in *Impurities* for *Limit of Free Ethylene Glycol*

**Acceptance criteria:** NLT 50.0% of monoesters

## IMPURITIES

• **Limit of Free Ethylene Glycol**

**Mobile phase, Sample solution, Chromatographic system,** and **System suitability:** Proceed as directed in the *Assay*.

**Standard solution A:** 0.5 mg/mL of ethylene glycol in tetrahydrofuran

**Standard solution B:** 1.0 mg/mL of ethylene glycol in tetrahydrofuran

**Standard solution C:** 2.0 mg/mL of ethylene glycol in tetrahydrofuran

**Standard solution D:** 4.0 mg/mL of ethylene glycol in tetrahydrofuran

**Analysis**

**Samples:** *Sample solution* and *Standard solutions*

Plot the ethylene glycol peak responses obtained versus the concentration of ethylene glycol in the *Standard solutions*. From the standard curve so obtained, determine the ethylene glycol concentration in the *Sample solution*.

Calculate the percentage of free ethylene glycol in the portion of sample taken:

$$\text{Result} = (C/C_U) \times 100$$

$C$ = concentration of ethylene glycol, determined from the standard curve (mg/mL)

$C_U$ = concentration of the *Sample solution* (mg/mL)

**Acceptance criteria:** NMT 5.0%

## SPECIFIC TESTS

• **Melting Range or Temperature,** *Class II* ⟨741⟩**:** 54°–60°

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

**Sample:** 10.0 g

**Acceptance criteria:** NMT 3.0

• **Fats and Fixed Oils,** *Iodine Value* ⟨401⟩**:** NMT 3.0

• **Fats and Fixed Oils,** *Saponification Value* ⟨401⟩

**Sample:** 2.0 g

**Acceptance criteria:** 170–195

• **Fats and Fixed Oils,** *Fatty Acid Composition* ⟨401⟩**:** 40.0%–60.0% of stearic acid, and the sum of palmitic and stearic acids is NLT 90.0%.

• **Articles of Botanical Origin,** *Total Ash* ⟨561⟩

**Sample:** 1.0 g

**Acceptance criteria:** NMT 0.1%

## ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers. No storage requirements specified.

• **Labeling:** Label it to indicate that it is intended for topical use only.



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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| ETHYLENE GLYCOL STEARATES | Documentary Standards Support | CE2020 Complex Excipients |

**Chromatographic Database Information:** Chromatographic Database

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