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Diethylene Glycol Stearates

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click www.uspnf.com/rb-diethylene-glycol-stearates-20220527.

Change to read:

DEFINITION

Diethylene Glycol Stearates is a mixture of diethylene glycol monoesters and diesters of stearic and palmitic acids. It contains NLT 45.0% of monoesters produced from the condensation of ▲diethylene▲ (RB 1-Jun-2022) glycol and stearic acid of vegetable or animal origin.

IDENTIFICATION

- **A.** It meets the requirements in *Specific Tests* for [Melting Range or Temperature \(741\)](#), [Class II](#).
- **B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\)](#), [Fatty Acid Composition](#).

ASSAY

PROCEDURE

Mobile phase: Tetrahydrofuran

Sample solution: 40 mg/mL of Diethylene 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 60-cm column, provided that *System suitability* requirements are met.]

Temperatures

Detector: 40°

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.]

Flow rate: 1 mL/min

Injection volume: 40 μL

System suitability

Sample: *Sample solution*

[NOTE—The relative retention times for diesters, monoesters, and diethylene glycol are 0.78, 0.84, 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 Diethylene Glycol Stearates taken:

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

I_A = acid value, determined in *Specific Tests* for [Fats and Fixed Oils \(401\)](#), [Acid Value \(Free Fatty Acids\)](#).

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

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

r_M = peak response for the monoesters

r_D = peak response for the diesters

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

Acceptance criteria: NLT 45.0% of monoesters

IMPURITIES

• LIMIT OF FREE DIETHYLENE GLYCOL

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

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

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

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

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

Analysis

Samples: *Sample solution* and *Standard solutions*

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

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

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

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

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

Acceptance criteria: NMT 8.0%

SPECIFIC TESTS

• [MELTING RANGE OR TEMPERATURE \(741\), Class II](#): 43°–50°

• [FATS AND FIXED OILS \(401\), Acid Value \(Free Fatty Acids\)](#)

Sample: 10.0 g

Acceptance criteria: NMT 4.0

• [FATS AND FIXED OILS \(401\), Iodine Value](#): NMT 3.0

Change to read:

• [FATS AND FIXED OILS \(401\), Saponification value](#)

Sample: 2.0 g

Acceptance criteria: 150–▲180▲ (RB 1-Jun-2022)

• [FATS AND FIXED OILS \(401\), Fatty Acid Composition](#): 40.0%–60.0% of stearic acid, and the sum of palmitic and stearic acids is NLT 90.0%.

• [ARTICLES OF BOTANICAL ORIGIN \(561\), Total Ash](#)

Sample: 1.0 g

Acceptance criteria: NMT 0.1%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. No storage requirements are specified.

• **LABELING:** Label it to indicate that it is intended for topical and vaginal use only.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
DIETHYLENE GLYCOL STEARATES	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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