

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2020
 Document Type: USP Monographs
 DocId: GUID-8A1CB0D8-A7C0-4217-A6E9-84F327C610FD_5_en-US
 DOI: https://doi.org/10.31003/USPNF_M7189_05_01
 DOI Ref: pb9dl

© 2025 USPC
 Do not distribute

Polyethylene Glycol 3350

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click

<https://www.uspnf.com/rb-peg-3350-20201120>.

Poly(oxy-1,2-ethanediyl), α -hydro- ω -hydroxy-;

1,2-Ethanediol, homopolymer

CAS RN[®]: 25322-68-3.

DEFINITION

Polyethylene Glycol 3350 is an addition polymer of ethylene oxide and water, represented by the formula $\text{H}(\text{OCH}_2\text{CH}_2)_n\text{OH}$, in which n represents the average number of oxyethylene groups. The apparent weight-average molecular weight is 3015–3685 g/mol (Da). It contains NLT 97.0% and NMT 103.0% of polyethylene glycol 3350, calculated on the anhydrous basis. It may contain a suitable antioxidant.

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197F. Use a thin film of test specimen, melted if necessary, in the range from 4000 to 650 cm^{-1} , when the measurement is performed by using 197F.

• **B. CHROMATOGRAPHIC IDENTITY**

Analysis: Proceed as directed in the Assay.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **PROCEDURE**

Mobile phase: 50 $\mu\text{g}/\text{mL}$ of sodium azide in water

Standard solution: 20 mg/mL of [USP Polyethylene Glycol 3350 RS](#) in *Mobile phase*

Sample solution: 20 mg/mL of Polyethylene Glycol 3350 in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Differential refractive index

Columns

Guard: 6-mm $\times$ 4-cm; 6- μm packing L25

Analytical: 7.8-mm $\times$ 30-cm; 6- μm packing L25

Temperatures

Detector: 35 $\pm$ 1°

Column: 35 $\pm$ 1°

Flow rate: 0.8 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for polyethylene glycol 3350 is about 8.5 min.]

Suitability requirements

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of polyethylene glycol 3350 [$\text{H}(\text{OCH}_2\text{CH}_2)_n\text{OH}$] in the portion of Polyethylene Glycol 3350 taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Polyethylene Glycol 3350 RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Polyethylene Glycol 3350 in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#).

Sample: 2 g

Analysis: Proceed as directed, moistening the residue with 2 mL of sulfuric acid.

Acceptance criteria: NMT 0.1%

• LIMIT OF ETHYLENE OXIDE AND DIOXANE

Analysis: Proceed as directed in [Ethylene Oxide and Dioxane \(228\), Method II](#).

Acceptance criteria

Ethylene oxide: NMT 1 µg/g

Dioxane: NMT 10 µg/g

• LIMIT OF ETHYLENE GLYCOL AND DIETHYLENE GLYCOL

Mobile phase: 50 µg/mL of sodium azide in water

Eluant: Water

Standard stock solution: 10 mg/g of [USP Diethylene Glycol RS](#) and 10 mg/g of [USP Ethylene Glycol RS](#) in *Eluant*

Standard solution: Transfer 0.1 g of *Standard stock solution* to a 100-mL volumetric flask. Dilute with water to volume. The *Standard solution* contains 0.01 mg/mL of [USP Diethylene Glycol RS](#) and 0.01 mg/mL of [USP Ethylene Glycol RS](#).

Sample solution: 10 mg/mL of Polyethylene Glycol 3350 in *Eluant*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: Differential refractive index

Column: 7.8-mm × 30-cm; 7-µm packing L89, 125-Å pore size

Temperatures

Detector: 35 ± 1°

Column: 35 ± 1°

Flow rate: 0.5 mL/min

Injection volume: 100 µL

Run time: 30 min

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for diethylene glycol and ethylene glycol are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 0.9 between diethylene glycol and ethylene glycol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of diethylene glycol (or ethylene glycol) in the portion of Polyethylene Glycol 3350 taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of diethylene glycol (or ethylene glycol) from the *Sample solution*

r_S = peak response of diethylene glycol (or ethylene glycol) from the *Standard solution*

C_S = concentration of [USP Diethylene Glycol RS](#) (or [USP Ethylene Glycol RS](#)) in the *Standard solution* (mg/mL)

C_U = concentration of Polyethylene Glycol 3350 in the *Sample solution* (mg/mL)

Acceptance criteria

Ethylene glycol: NMT 0.062%