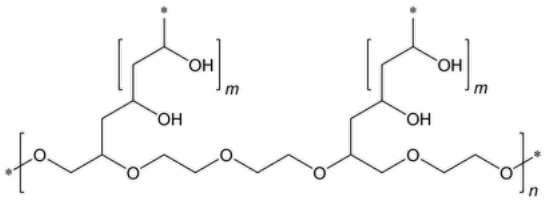
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Ethylene Glycol and Vinyl Alcohol Graft Copolymer



Polyethylene glycol-graft-polyvinyl alcohol;
Graft-copoly(ethylene glycol-vinyl alcohol)
CAS RN®: 121786-16-1.

DEFINITION

Ethylene Glycol and Vinyl Alcohol Graft Copolymer is a graft copolymer of ethylene glycol and vinyl alcohol. It consists of about 75% of vinyl alcohol ($-CH_2CH(OH)-$) units and 25% of ethylene glycol ($-CH_2CH_2O-$) units. The Copolymer is produced by using polyethylene glycol and vinyl acetate as starting materials. Polyethylene glycol forms the polymer backbone on which polyvinyl acetate is grafted. Hydrolysis of polyvinyl acetate side chains leads to formation of polyvinyl alcohol grafted chains. Ethylene Glycol and Vinyl Alcohol Graft Copolymer may contain glidant to improve flowability.

IDENTIFICATION

• **Infrared Absorption**

Sample: 200 mg of Ethylene Glycol and Vinyl Alcohol Graft Copolymer

Analysis: Dissolve the *Sample* in 5–10 mL of water. Spread 1 mL of this solution on a thallium bromoiodide window.[1] Totally moisten the surface area of the window. Dry the window at 110° for approximately 30 min, and allow the window to cool to room temperature.

Acceptance criteria: The IR absorption spectrum of Ethylene Glycol and Vinyl Alcohol Graft Copolymer exhibits maxima corresponding to the same wavelengths as those of a similar preparation of USP Ethylene Glycol and Vinyl Alcohol Graft Copolymer RS treated in the same manner.

IMPURITIES

Inorganic Impurities

• **Residue on Ignition ⟨281⟩**

Sample: 10.0 g

Acceptance criteria: NMT 3.0%

Change to read:

Organic Impurities

• **Procedure 1: Ethylene Oxide and Dioxane**

[Caution—Ethylene oxide is toxic and flammable. Prepare these solutions in a well-ventilated fume hood, using great care. Protect both hands and face by wearing polyethylene protective gloves and an appropriate face mask. Store all solutions in hermetic containers, and refrigerate at a temperature between 4° and 8°.]

[Note—Before using polyethylene glycol 200 in this test, remove any volatile components from it by placing 500 mL of polyethylene glycol 200 in a 1000-mL round-bottom flask, and attaching the flask to a rotary evaporator maintained at a temperature of 60° and under a vacuum of 10–20 mm Hg for 6 h.]

Acetaldehyde solution: 10 µg/mL of acetaldehyde. [Note—Prepare the *Acetaldehyde solution* immediately before use.]

Ethylene oxide stock solution: Introduce 300 µL (corresponding to 250 mg) of gaseous ethylene oxide to the polyethylene glycol 200. Determine the absorbed mass of ethylene oxide via the weight of the solution before and after the absorption. Dilute the solution with the polyethylene glyol 200 to 100 g. This stock solution contains 2.5 mg/g of ethylene oxide.
[Note—Prepare this stock solution immediately before use, and store in a refrigerator after preparation.]

Ethylene oxide solution: 100 µg/g of ethylene oxide in polyethylene glycol 200 from *Ethylene oxide stock solution*. Transfer 5 g of 100 µg/g ethylene oxide in polyethylene glycol 200 to a 50-mL volumetric flask filled with 30 mL of water. Dilute with water to volume, and mix to

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obtain a solution containing 10 µg/mL of ethylene oxide. [NOTE—Prepare this solution immediately before use, and use the solution directly after preparation.]

Dioxane solution: 500 µg/mL of dioxane

Standard solution A: Transfer 0.1 mL of *Ethylene oxide solution* to a 10-mL pressure headspace vial. [NOTE—Other sizes, such as 22-mL, may be used, depending on the operating conditions; however, the same size must be used for *Standard solution A*, *Standard solution B*, and the *Sample solution*.] Add 0.1 mL of *Acetaldehyde solution* and 0.1 mL of *Dioxane solution*, seal the vial, and mix.

Standard solution B: Transfer 1.0 g of Ethylene Glycol and Vinyl Alcohol Graft Copolymer to a 10-mL pressure headspace vial. Add 0.1 mL of *Ethylene oxide solution*, 0.1 mL of *Dioxane solution*, and 1.0 mL of *N*,*N*-dimethylacetamide, seal the vial, and mix.

Sample solution: Transfer 1.0 g of Ethylene Glycol and Vinyl Alcohol Graft Copolymer to a 10-mL pressure headspace vial. Add 1.0 mL of *N*,*N*-dimethylacetamide and 0.2 mL of water, seal the vial, and mix.

Chromatographic system

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

[NOTE—Use a headspace apparatus that automatically transfers a measured amount of headspace.]

Mode: GC

Detector: Flame ionization

Detector temperature: 250°

Column: 0.25-mm × 30-m glass or quartz capillary column; 1.0-µm layer of phase G1

Column temperature: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (min)	Hold Time at Final Temperature (min)
50	—	50	5
50	5	180	—
180	30	230	5

Carrier gas: Helium

Flow rate: 0.8 mL/min

Injection size: 1 mL (the gaseous headspace)

Injection type: Split ratio 20:1

Injection port temperature: 250°

Headspace sampler

Equilibration time: 45 min

Equilibration temperature

Standard solution A: 70°

Standard solution B: 90°

Sample solution: 90°

Transfer line temperature: 150°

Pressurization time: 1 min

Final headspace pressure: 0.7 bar

Injection time: 12 s

System suitability

Sample: *Standard solution A*

[NOTE—The relative retention times for acetaldehyde and ethylene oxide are 0.94 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between acetaldehyde and ethylene oxide

Signal-to-noise: NLT 5 determined from the dioxane peak

Relative standard deviation: NMT 15%

Analysis

Samples: *Standard solution B* and *Sample solution*

Calculate the content of ethylene oxide, in ppm, in the portion of Ethylene Glycol and Vinyl Alcohol Graft Copolymer taken:

$$\text{Result} = A_E \times r_U / [(r_S \times W_U) - (r_U \times W_S)]$$

A_E = quantity of ethylene oxide added to *Standard solution B* (µg)

r_U = ethylene oxide peak response from the *Sample solution*

r_S = ethylene oxide peak response from *Standard solution B*

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