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Polyoxyl 15 Hydroxystearate

12-Hydroxyoctadecanoic acid polymer with α -hydro- ω -hydroxypoly(oxy-1,2-ethanediyl);
 Polyethylene glycol 15 hydroxystearate
 CAS RN[®]: 70142-34-6.

DEFINITION

Polyoxyl 15 Hydroxystearate results from the reaction of about 15 moles of ethylene oxide with 1 mole of 12-hydroxystearic acid. The product consists mainly of 12-hydroxystearic acid polyethoxylated at both the carboxyl and the hydroxyl groups with polyethylene glycol. It contains free polyethylene glycols.

IDENTIFICATION

Change to read:

• **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F](#) • ▲ (CN 1-MAY-2020) If the sample is solid or too viscous for thin film formation, the sample should be gently warmed to achieve a mobile liquid, which may then be used to prepare the thin film.

• **B.** [THIN-LAYER CHROMATOGRAPHIC IDENTIFICATION TEST \(201\)](#)

Sample solution: To 1.0 g of Polyoxyl 15 Hydroxystearate add 100 mL of a 100-mg/mL solution of potassium hydroxide, and boil under a reflux condenser for 30 min. Acidify the warm solution with 20 mL of hydrochloric acid, and cool to room temperature. Shake the mixture with 50 mL of ether, and allow to stand until a separation of the layers is visible. Separate the clear upper layer, add 5 g of anhydrous sodium sulfate, wait for 30 min, filter, and evaporate to dryness on a water bath. Dissolve 50 mg of the residue in 25 mL of ether.

Standard solution: 2 mg/mL of [USP 12-Hydroxystearic Acid RS](#) in methylene chloride

Plate: Octadecylsilyl silica gel for chromatography as the coating substance

Application volume: 2 μ L

Developing solvent system: Acetone, methylene chloride, and glacial acetic acid (50:10:40)

Spray reagent: Prepare a solution of 80 mg/mL of phosphomolybdic acid in 2-propanol.

Analysis: Proceed as directed in the chapter. Develop over two-thirds of the plate, and dry in a current of cold air. Then spray the plate with *Spray reagent*, heat the plate at 120° for 1–2 min, and locate the spots on the plate.

Acceptance criteria: The R_f value and color of the principal spot of the *Sample solution* correspond to those of the *Standard solution*.

• **C.** It meets the requirements of the test for *Free Polyethylene Glycols*.

COMPOSITION

• FREE POLYETHYLENE GLYCOLS

Mobile phase: Methanol and water (8:2)

Standard solution A: 1.6 mg/mL of [USP Polyethylene Glycol 1000 RS](#) in *Mobile phase*

Standard solution B: 0.8 mg/mL of [USP Polyethylene Glycol 1000 RS](#) in *Mobile phase*, diluted from *Standard solution A* in *Mobile phase*

Sample solution: 4.8 mg/mL of Polyoxyl 15 Hydroxy stearate in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: Refractive index

Columns: 7.8-mm $\times$ 30-cm analytical column; 6- μ m packing L39 and a 12-nm pore size; two 4-mm $\times$ 12.5-cm precolumns; 5- μ m packing L1 and a 10-nm pore size.

Connect both precolumns to the analytical column using a 3-way valve, and switch the *Mobile phase* flow according to the following program. [NOTE—Shown in [Figure 1](#), the analysis is started with precolumn 2 and an analytical column in series. After about 1.45 min, the valves, controlled by the detector program, switch over such that the eluent flows past precolumn 2, and direct to precolumn 1 and the

analytical column. The columns are switched when the components to be determined, but not the interfering matrix, are ready to reach the analytical column. Simultaneously, precolumn 2 is washed out in the reverse direction by a second pump to remove the unwanted matrix components.]

Time (s)	Program
0–114	Precolumn 2 and analytical column
115–end	Precolumn 1 and analytical column
115–420	Reverse flow of precolumn 2

Temperature

Column: Room temperature

Detector: Room temperature

Flow rate: 1.1 mL/min

Injection size: 50 µL

System suitability

Sample: Standard solution A

Suitability requirements

Relative standard deviation: NMT 3.0%

Analysis

Samples: Standard solution A, Standard solution B, and Sample solution

Calculate the percentage of polyethylene glycols in the portion of Polyoxyl 15 Hydroxystearate taken:

Result = 2 × (C_s/C_u)[r_u/(r_{s1} + 2r_{s2})] × 100

C_s = concentration of [USP Polyethylene Glycol 1000 RS](#) in Standard solution A (mg/mL)

C_u = concentration of Polyoxyl 15 Hydroxystearate in the Sample solution (mg/mL)

r_u = peak response of polyethylene glycol from the Sample solution

r_{s1} = peak response of polyethylene glycol 1000 from Standard solution A

r_{s2} = peak response of polyethylene glycol 1000 from Standard solution B

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