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Polyoxyl Stearyl Ether

Polyethylene glycol monostearyl ether
 $\text{CH}_3(\text{CH}_2)_{17}(\text{OCH}_2\text{CH}_2)_n\text{OH}$, $n = 2-20$ CAS RN®: 9005-00-9.

DEFINITION

Polyoxyl Stearyl Ether is a mixture of the monostearyl ethers of mixed polyethylene glycols, the average polymer length being equivalent to NLT 2 and NMT 20 oxyethylene units (nominal value). It may contain various amounts of free stearyl alcohol and some free polyethylene glycol.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F](#) [▲](#) (CN 1-MAY-2020) Use a thin film of melted Polyoxyl Stearyl Ether.
- **B. PROCEDURE**
Sample: 0.1 g
Analysis: Dissolve or disperse the *Sample* in alcohol. Add 10 mL of diluted hydrochloric acid, 5 mL of barium chloride TS, and 10 mL of phosphomolybdic acid solution (1 in 10).
Acceptance criteria: A precipitate is formed.
- **C.** It meets the requirements in the test for [Fats and Fixed Oils, Hydroxyl Value \(401\)](#).

IMPURITIES

Organic Impurities

- **PROCEDURE: LIMIT OF FREE ETHYLENE OXIDE AND DIOXANE**
Analysis: Proceed as directed in [Ethylene Oxide and Dioxane \(228\), Method I](#).
Acceptance criteria
Ethylene oxide: NMT 1 µg/g (ppm)
Dioxane: NMT 10 µg/g (ppm)

SPECIFIC TESTS

- **FATS AND FIXED OILS, Acid Value (401):** NMT 1.0, determined on 5.0 g
- **FATS AND FIXED OILS, Hydroxyl Value (401):** Within the ranges specified in the table below

Oxyethylene Units/Molecule (Nominal Value)	Hydroxyl Value
2	150–180
10	75–90
20	40–60

- **FATS AND FIXED OILS, Iodine Value (401):** NMT 2.0
- **FATS AND FIXED OILS, Saponification Value (401):** NMT 3.0, determined on 10.0 g
- **ALKALINITY**
Sample: 2.0 g of Polyoxyl Stearyl Ether
Analysis: Dissolve the *Sample* to a hot mixture of 10 mL of alcohol and 10 mL of water. Add 0.05 mL of bromothymol blue TS. Titrate with 0.1 N hydrochloric acid to a yellow endpoint.

Acceptance criteria: NMT 0.5 mL of 0.1 N hydrochloric acid is required.

- **WATER DETERMINATION, Method I (921):** NMT 3.0%
- **APPEARANCE OF SOLUTION:** 5.0 g of Polyoxyl Stearyl Ether in 50.0 mL of alcohol. The solution is not more intensely colored than a solution prepared immediately before use by mixing 12.0 mL of ferric chloride CS, 5.0 mL of cobaltous chloride CS, and 2.0 mL of cupric sulfate CS with dilute hydrochloric acid (10 g/L) to make 50.0 mL, and diluting 12.5 mL of this solution with dilute hydrochloric acid (10 g/L) to make 100.0 mL. Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see [Color and Achromicity \(631\)](#)).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, and store in a cool, dry place.
- **LABELING:** Label it to indicate the average nominal number of oxyethylene units.
- **USP REFERENCE STANDARDS (11).**
[USP Polyoxyl 2 Stearyl Ether RS](#)
[USP Polyoxyl 10 Stearyl Ether RS](#)
[USP Polyoxyl 20 Stearyl Ether RS](#)

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

Topic/Question	Contact	Expert Committee
POLYOXYL STEARYL ETHER	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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