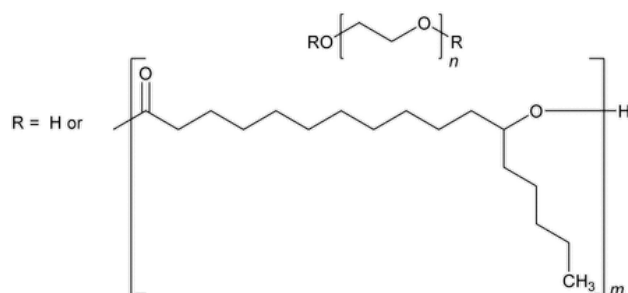


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Add the following:

## ▲Polyethylene Glycol 30 Dipolyhydroxystearate 5



$n = 30-35$  (average),  $m = 5$  (average)  
 Octadecanoic acid, 12-hydroxy-, polymer with oxirane, triblock.  
 Polyoxyethylene 30 dipolyhydroxystearate 5  
 CAS RN®: 827596-80-5.

### DEFINITION

Polyethylene Glycol 30 Dipolyhydroxystearate 5 is the polyethylene glycol (PEG) diester of poly(12-hydroxystearic acid) containing a polyethylene glycol backbone, with both the terminal hydroxyl groups linked by ester bonds to branched oligomers, based on hydroxystearic acid. It is obtained by esterification of polyethylene glycol with 12-hydroxystearic acid. The average number of units of ethylene oxide in the polyethylene glycol chain is in the range of 30–35. The size of each polyhydroxystearic acid group is about 5 monomer units.

### IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A
- **B.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\), Procedures, Saponification Value](#).
- **C.** It meets the requirements in *Specific Tests* for [Fats and Fixed Oils \(401\), Procedures, Hydroxyl Value](#).

### IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.5%
- [ETHYLENE OXIDE AND DIOXANE \(228\), Method II](#)

#### Acceptance criteria

- For ethylene oxide:** NMT 1 ppm
- For dioxane:** NMT 10 ppm

### SPECIFIC TESTS

- [FATS AND FIXED OILS \(401\), Procedures, Hydroxyl Value](#)

**Pyridine–acetic anhydride reagent:** Just before use, mix 3 volumes of freshly opened or freshly distilled pyridine with 1 volume of freshly opened or freshly distilled acetic anhydride.

**Analysis:** Transfer about 4.0 g of accurately weighed sample to a glass-stoppered 250-mL conical flask. Add 5.0 mL of *Pyridine–acetic anhydride reagent*. Heat in a steam bath for 1 h, keeping the level of the water about 2.5 cm above the level of the liquid in the flask. Add 5 mL of water through the condenser. If the solution appears cloudy, add a sufficient amount of [pyridine](#) to clear it. Shake the flask and heat in the water bath for 10 min. Cool and add 5 mL of [alcohol](#), previously neutralized to [phenolphthalein TS](#). Add 1 mL of [phenolphthalein TS](#) and titrate with [0.5 N alcoholic potassium hydroxide VS](#), recording the volume, in milliliters, consumed by the residual acid in the test solution. Carry out a blank test under the same conditions.

**Acceptance criteria:** 12–30

- **FATS AND FIXED OILS** (401), *Procedures, Acid Value*

[NOTE—[Petroleum ether](#) with a 100°–120° boiling range can be used to replace [ether](#) in the test.]

**Acceptance criteria:** NMT 10.0

- **FATS AND FIXED OILS** (401), *Procedures, Saponification Value*

**Analysis:** Accurately weigh about 2.0 g of Polyethylene Glycol 30 Dipolyhydroxystearate 5 and add to it 30.0 mL of [0.5 N alcoholic potassium hydroxide](#). Heat the flask in a steam bath, under a suitable condenser to maintain reflux for 60 min, frequently rotating the contents. Add 50 mL of [dehydrated alcohol](#) before carrying out the titration.

**Acceptance criteria:** 125–150

- **FATS AND FIXED OILS** (401), *Procedures, Iodine Value*

**Analysis:** Accurately weigh 1.0 g of Polyethylene Glycol 30 Dipolyhydroxystearate 5 into a 250-mL iodine flask, dissolve it in 15 mL of [chloroform](#), add 25.0 mL of [iodobromide TS](#). Insert the stopper in the vessel securely, and allow it to stand for 30 min protected from light, with occasional shaking. Add 10 mL of a 100-g/L solution of [potassium iodide TS](#) and 100 mL of water. Titrate the liberated iodine with [0.1 N sodium thiosulfate VS](#), shaking thoroughly after each addition of [thiosulfate](#). When the color of the iodine becomes quite pale, add 5 mL of [starch TS](#), and continue the titration with [0.1 N sodium thiosulfate VS](#) until the blue color is discharged. Perform a blank test at the same time with the same quantities of the same reagents and in the same manner.

**Acceptance criteria:** NMT 10.0

- **FATS AND FIXED OILS** (401), *Procedures, Peroxide Value*: NMT 5.0
- **WATER DETERMINATION** (921), *Method I*: NMT 1.0%

#### ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, in a cool place.
- **USP REFERENCE STANDARDS** (11)  
[USP Polyethylene Glycol 30 Dipolyhydroxystearate 5 RS](#)

▲ (NF 1-Aug-2023)

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

| Topic/Question                                    | Contact                                                                     | Expert Committee          |
|---------------------------------------------------|-----------------------------------------------------------------------------|---------------------------|
| POLYETHYLENE GLYCOL 30<br>DIPOLYHYDROXYSTEARATE 5 | <a href="#">Documentary Standards Support</a>                               | CE2020 Complex Excipients |
| REFERENCE STANDARD SUPPORT                        | RS Technical Services<br><a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a> | CE2020 Complex Excipients |

**Chromatographic Database Information:** [Chromatographic Database](#)

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