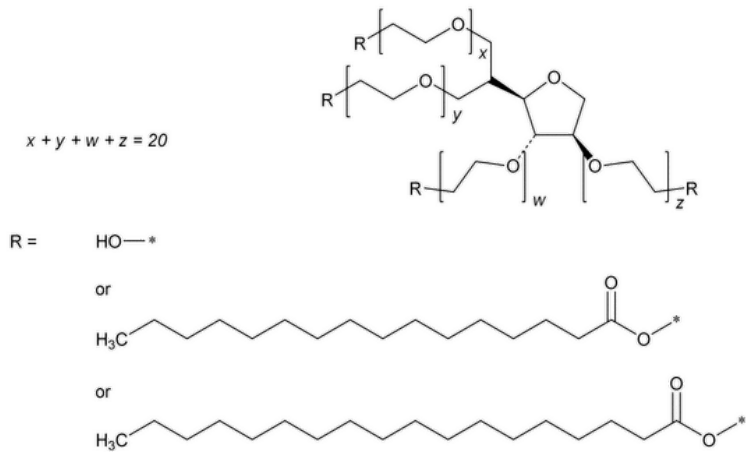


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Polysorbate 60



The ratio of OH group to the sum of C₁₅H₃₁COO and C₁₇H₃₅COO groups is mainly 3:1.
Polyethylene glycol 20 sorbitan ether monostearate;
Polyoxyethylene 20 sorbitan monooleadecanoate;
Polyoxyethylene 20 sorbitan monostearate
CAS RN®: 9005-67-8.

DEFINITION

Polysorbate 60 is a mixture of stearate and palmitate esters of sorbitol and its anhydrides copolymerized with about 20 moles of ethylene oxide for each mole of sorbitol and sorbitol anhydrides. The fatty acids may be of vegetable, animal, or synthetic origin.

IDENTIFICATION

Change to read:

- A. [▲SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F](#) ▲ (CN 1-MAY-2020)
- B. It meets the requirements in the Assay for *Composition of Fatty Acids*.

ASSAY

• COMPOSITION OF FATTY ACIDS

Polysorbate 60 exhibits the composition profiles of fatty acids shown in [Table 1](#), as determined in [Fats and Fixed Oils \(401\), Fatty Acid Composition](#).

Table 1

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
18	0	40.0–60.0
Sum of stearic acid (C18:0) and palmitic acid (C16:0)		≥90.0

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.25%

- [ETHYLENE OXIDE AND DIOXANE, Method II \(228\)](#).

Acceptance criteria

Ethylene oxide: NMT 1 ppm

Dioxane: NMT 10 ppm

SPECIFIC TESTS

- [FATS AND FIXED OILS, Acid Value \(401\)](#).

Sample: 10.0 g of Polysorbate 60

Analysis: Transfer the *Sample* to a wide-mouth, 250-mL conical flask, and add 50 mL of neutralized alcohol. Heat on a steam bath nearly to boiling, shaking thoroughly occasionally while heating. Invert a beaker over the mouth of the flask, cool under running water, and add 5 drops of phenolphthalein TS. Titrate with 0.1 N sodium hydroxide VS. Calculate the acid value as directed in the chapter.

Acceptance criteria: NMT 2.0

- [FATS AND FIXED OILS, Hydroxyl Value \(401\)](#): 81–96

- [FATS AND FIXED OILS, Peroxide Value \(401\)](#).

Sample: 10.0 g

Saturated potassium iodide solution: Prepare a saturated solution of potassium iodide in carbon dioxide-free water. Make sure the solution remains saturated as indicated by the presence of undissolved crystals.

Analysis: Introduce the *Sample* into a 100-mL beaker, and dissolve with 20 mL of glacial acetic acid. Add 1 mL of *Saturated potassium iodide solution*, mix, and allow to stand for 1 min. Add 50 mL of carbon dioxide-free water and a magnetic stirring bar. Titrate with 0.01 M sodium thiosulfate VS, determining the endpoint potentiometrically (see [Titrimetry \(541\)](#)). Perform a blank titration.

Calculate the peroxide value as directed in the chapter.

Acceptance criteria: NMT 10.0

- [FATS AND FIXED OILS, Saponification Value \(401\)](#): 45–55

- [WATER DETERMINATION, Method I \(921\)](#): NMT 3.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light and moisture. Store at room temperature.

- **LABELING:** Label to indicate whether the fatty acids are derived from animal, vegetable, or synthetic sources.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Polysorbate 60 RS](#)

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

Topic/Question	Contact	Expert Committee
POLYSORBATE 60	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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