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Polyoxyl Oleate

Polyethylene glycol monooleate

CAS RN®: 9004-96-0.

DEFINITION

Polyoxyl Oleate is a mixture of the monoesters and diesters of oleic acid and mixed polyethylene glycols. It may be obtained by ethoxylation of oleic acid or by esterification of polyethylene glycols with oleic acid of animal or vegetable origin. It may contain free polyethylene glycol. The average polymer length is equivalent to either 5–6 or 10 oxyethylene units (nominal values). A suitable antioxidant may be added.

IDENTIFICATION

Change to read:

• **A. ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197F ▲** (CN 1-May-2020)

Sample: Undried specimen

Acceptance criteria: Meets the requirements

IMPURITIES

• **Limit of Free Ethylene Oxide and Dioxane**

Analysis: Proceed as directed in *Ethylene Oxide and Dioxane ⟨228⟩, Method 1*.

Acceptance criteria

Ethylene oxide: NMT 1 µg/g

Dioxane: NMT 10 µg/g

SPECIFIC TESTS

• **Fats and Fixed Oils,** *Acid Value ⟨401⟩*

Sample: 10.0 g

Acceptance criteria: NMT 1.0

• **Fats and Fixed Oils,** *Peroxide Value ⟨401⟩*: NMT 12.0

• **Fats and Fixed Oils,** *Hydroxyl Value ⟨401⟩*: See *Table 1*.

• **Fats and Fixed Oils,** *Iodine Value ⟨401⟩*: See *Table 1*.

• **Fats and Fixed Oils,** *Saponification Value ⟨401⟩*: See *Table 1*.

Table 1

	5–6 Ethylene Oxide Units	10 Ethylene Oxide Units
Hydroxyl value	50–70	65–90
Iodine value	50–60	27–34
Saponification value	105–120	68–85

• **Fats and Fixed Oils,** *Fatty Acid Composition ⟨401⟩*: Polyoxyl Oleate exhibits the composition profile of fatty acids shown in *Table 2*.

Table 2

Carbon-Chain Length	Number of Double Bonds	Percentage (%)
14	0	≤5.0
16	0	≤16.0
18	0	≤6.0
16	1	≤8.0
18	1	65.0–88.0
18	2	≤18.0
18	3	≤4.0
>18	—	≤4.0

• **Alkalinity**

Sample solution: 100 mg/mL of Polyoxyl Oleate in alcohol

Analysis: To 2 mL of the *Sample solution* add 0.05 mL of phenol red TS.

Acceptance criteria: The solution is not red.

• **Articles of Botanical Origin,** *Total Ash* ⟨561⟩

Sample: 1.0 g

Acceptance criteria: NMT 0.3%

• **Water Determination,** *Method I* ⟨921⟩**:** NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers, and store in a cool, dry place. Protect from moisture.

• **Labeling:** Label it to indicate the number of ethylene oxide units per molecule (nominal value), and the name and concentration of any added antioxidant.

• **USP Reference Standards** ⟨11⟩

USP Polyoxyl Oleate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POLYOXYL OLEATE	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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