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Polyoxyl 35 Castor Oil

Polyethylene glycol 35 castor oil;
Polyoxyethylene 35 castor oil
CAS RN®: 61791-12-6.

DEFINITION

Polyoxyl 35 Castor Oil contains mainly the triricinoleate ester of ethoxylated glycerol with smaller amounts of polyethylene glycol ricinoleate and the corresponding free glycols. It results from the reaction of glycerol ricinoleate with 35 mol of ethylene oxide.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197F ▲](#) (CN 1-May-2020)
- **B. CONSTITUTING FATTY ACIDS**
Sample: 0.1 g
Analysis: Dissolve the *Sample* in 10 mL of potassium hydroxide TS, alcoholic; boil for 3 min; and evaporate to dryness. Mix the residue with 5 mL of water.
Acceptance criteria: The residue dissolves, yielding a clear solution. Add a few drops of glacial acetic acid. A white precipitate is formed.

Change to read:

- **C. IDENTITY BY FATTY ACID COMPOSITION**
Diluent: *n*-Heptane
Standard solution 1: 0.2 mg/mL each of methyl palmitate, methyl stearate, methyl oleate, methyl linoleate, methyl *cis*-11-eicosenoate, and methyl ricinoleate, from [USP Methyl Palmitate RS](#), [USP Methyl Stearate RS](#), [USP Methyl Oleate RS](#), [USP Methyl Linoleate RS](#), methyl *cis*-11-eicosenoate, and [USP Methyl Ricinoleate RS](#), in *Diluent*
Standard solution 2: 4 mg/mL each of methyl stearate and methyl ricinoleate from [USP Methyl Stearate RS](#) and [USP Methyl Ricinoleate RS](#) in *Diluent*
Sample solution: Transfer 140 mg of Polyoxyl 35 Castor Oil to a 10-mL screw-cap test tube, add 3.0 mL of *Diluent*, and mix well. Add 0.5 mL of 0.5 M sodium methoxide in methanol,¹ and mix with the sample. Allow the reaction to proceed at room temperature for 2 h. After 2 h, add 5 mL of water, and mix. Centrifuge the test tube at 1000 × g for 10–15 min until a clear upper layer forms. Separate the organic layer (the upper layer), and remove the lower layer. Place an aliquot of the organic layer into an autosampler vial.

Chromatographic system

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

- Mode:** GC
Detector: Flame ionization
Column: 0.25-mm × 15-m fused silica capillary; bonded with a 0.25-μm layer of phase [G7](#)
Temperatures
Injection port: 240°
Detector: 250°
Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)	Total Time (min)
80	0	80	1	1
80	30	140	0	3
140	3	150	0	6.3
150	1	155	0	11.3
155	2	165	0	16.3
165	3	220	10	45

Column mode: See [Table 2](#) for the pressure program.

Table 2

Pressure (psi)	Pressure Ramp (psi/min)	Hold Time (min)	Total Time (min)
10	0	16	16
4	5	9 or 0 ^a	26.2 or 17.2
3	10	19 or 28	45

^a If considerable discrimination of late eluting compounds is observed, the hold time can be adjusted from 9 to 0 min. Thus the total time should be 17.2 min. Then the next step of the hold time should be 28 min.

Carrier gas: Hydrogen

Injection volume: 0.5 µL

Injection type: Split ratio, 60:1

Liner: Single taper, low-pressure drop liner with deactivated wool

Run time: 45 min

System suitability

Sample: Standard solution 1

[NOTE—See [Table 3](#) for relative retention times.]

Table 3

Component	Relative Retention Time
Methyl palmitate (C16:0)	0.61
Methyl stearate (C18:0)	0.98
Methyl oleate (C18:1)	1.00
Methyl linoleate (C18:2)	1.02
Methyl cis-11-eicosenoate (C20:1)	1.70

Component	Relative Retention Time
Methyl ricinoleate	2.30

Suitability requirements

Resolution: NLT 1.5 between methyl stearate and methyl oleate peaks

Relative standard deviation: NMT 2.0% for the peak area ratio of methyl ricinoleate to methyl linoleate (ERR 1-May-2020)

Analysis

Samples: *Standard solution 1, Standard solution 2, and Sample solution*

The peak of methyl *cis*-11-octadecenoate, which is an isomer of methyl oleate, can be resolved from the methyl oleate peak with a resolution of about 1 and a relative retention time of 1.01 with respect to methyl oleate.

Calculate the relative response factor, F , for methyl ricinoleate:

$$F = (r_S/r_R) \times (C_R/C_S)$$

r_S = peak area of methyl stearate from *Standard solution 2*

r_R = peak area of methyl ricinoleate from *Standard solution 2*

C_R = concentration of [USP Methyl Ricinoleate RS](#) in *Standard solution 2* (mg/mL)

C_S = concentration of [USP Methyl Stearate RS](#) in *Standard solution 2* (mg/mL)

Correct the peak area of methyl ricinoleate in the *Sample solution* by multiplying by F .

Calculate the percentage of each fatty acid component in the portion of Polyoxyl 35 Castor Oil taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of each individual fatty acid methyl ester, except for the uncorrected peak area of methyl ricinoleate (or the corrected peak area of methyl ricinoleate), from the *Sample solution*

r_T = sum of all the peak areas, excluding the solvent and methyl ricinoleate peaks and including the corrected peak area of methyl ricinoleate, from the *Sample solution*

Acceptance criteria: Polyoxyl 35 Castor Oil exhibits the composition profile of fatty acids shown in [Table 4](#).

Table 4

Component	Percentage (%)
Palmitic acid (C16:0)	≤4.0
Stearic acid (C18:0)	≤5.0
Oleic acid (C18:1)	4.0–10.0
Linoleic acid (C18:2)	≤5.0
<i>cis</i> -11-Eicosenoic acid (C20:1)	≤1.0
Ricinoleic acid	45.0–75.0

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.3%
- [ETHYLENE OXIDE AND DIOXANE \(228\)](#), [Method I](#)

Acceptance criteria

Ethylene oxide: NMT 1 µg/g

Dioxane: NMT 10 µg/g

- [ETHYLENE GLYCOL, DIETHYLENE GLYCOL, AND TRIETHYLENE GLYCOL IN ETHOXYLATED SUBSTANCES \(469\)](#).

Acceptance criteria

Ethylene glycol: NMT 620 µg/g

Sum of diethylene glycol and ethylene glycol: NMT 2500 µg/g

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#): 1.05–1.06
- [VISCOSITY—CAPILLARY METHODS \(911\)](#): 600–850 mPa · s at 25°, using a capillary viscometer
- [FATS AND FIXED OILS \(401\), Procedures, Acid Value](#): NMT 2.0
- [FATS AND FIXED OILS \(401\), Procedures, Hydroxyl Value](#): 65–80
- [FATS AND FIXED OILS \(401\), Procedures, Iodine Value](#): 25–35
- [FATS AND FIXED OILS \(401\), Procedures, Saponification Value](#): 60–75
- [WATER DETERMINATION \(921\), Method I](#): NMT 3.0%

ADDITIONAL REQUIREMENTS

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

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

[USP Methyl Linoleate RS](#)

[USP Methyl Oleate RS](#)

[USP Methyl Palmitate RS](#)

[USP Methyl Ricinoleate RS](#)

[USP Methyl Stearate RS](#)

[USP Polyoxyl 35 Castor Oil RS](#)

¹ 0.5 M sodium methoxide in methanol is available from Sigma-Aldrich (www.sigmaaldrich.com), product #403067. Any other equivalent reagent can be used as well.

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

Topic/Question	Contact	Expert Committee
POLYOXYL 35 CASTOR OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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