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Add the following:

^Polyethylene Glycol 40 Castor Oil

Polyoxyl 40 castor oil;
Polyoxyethylene 40 castor oil
CAS RN®: 61791-12-6.

DEFINITION

Polyethylene Glycol 40 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 castor oil with 40 mol of ethylene oxide.

IDENTIFICATION

- A. TEST FOR PRESENCE OF 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.

- B. IDENTITY BY FATTY ACID COMPOSITION**

Diluent: [n-Heptane](#)

Standard solution 1: 0.2 mg/mL of each of [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 [USP Methyl Stearate RS](#) and [USP Methyl Ricinoleate RS](#) in *Diluent*

Sample solution: Transfer 140 mg of Polyethylene Glycol 40 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 methanol¹ 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 15 min until a clear upper layer forms. Remove the lower layer.

Place an aliquot of the organic layer (the upper layer) into an autosampler vial.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 15-cm 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

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)	Total Time (min)
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	26.2
3	10	19	45.3

Carrier gas: Hydrogen

Injection volume: 0.5 µL

Injection type: Split, 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
Methyl ricinoleate	2.30

Suitability requirements

Resolution: NLT 1.5 between the methyl stearate and methyl oleate peaks

Relative standard deviation: NMT 2.0% for the peak area ratio of methyl ricinoleate to methyl linoleate

Analysis

Samples: 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 Polyethylene Glycol 40 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: Polyethylene Glycol 40 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

For ethylene oxide: NMT 1 µg/g

For dioxane: NMT 10 µg/g

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

Acceptance criteria

For ethylene glycol: NMT 620 µg/g

For diethylene glycol: NMT 1000 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 1.0

- [FATS AND FIXED OILS \(401\), Procedures, Hydroxyl Value](#): 60–75
- [FATS AND FIXED OILS \(401\), Procedures, Iodine Value](#): 29–33
- [FATS AND FIXED OILS \(401\), Procedures, Saponification Value](#): 57–70
- [WATER DETERMINATION \(921\), Method I, Method Ic](#): 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](#)▲ (NF 1-Dec-2024)

¹ 0.5 M sodium methoxide in methanol is available from Sigma-Aldrich (www.sigmaaldrich.com), catalog #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
POLYETHYLENE GLYCOL 40 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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