

Status: Currently Official on 14-Feb-2025

Official Date: Official as of 01-Mar-2019

Document Type: USP Monographs

DocId: GUID-E7B5913F-01A6-4C24-B4E2-457F16E6EA4C_3_en-US

DOI: https://doi.org/10.31003/USPNF_M13790_03_01

DOI Ref: oo6k2

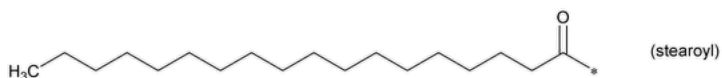
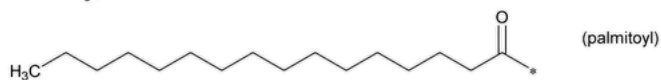
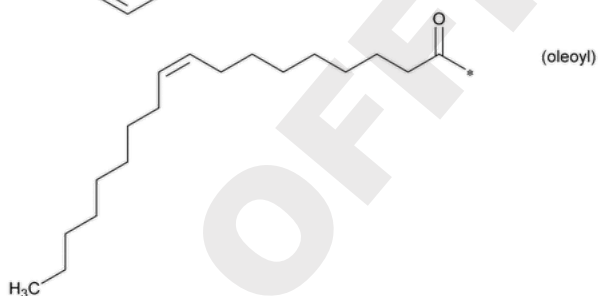
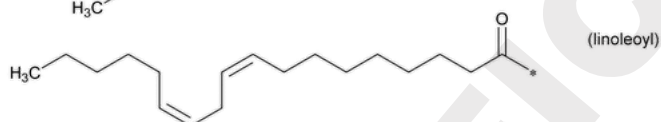
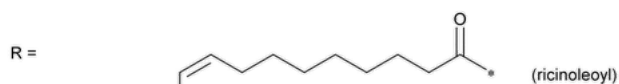
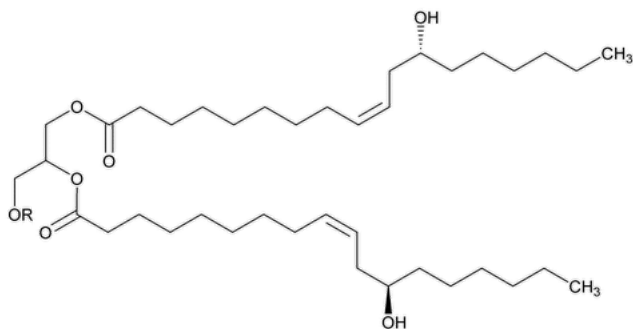
© 2025 USPC

Do not distribute

Castor Oil

Add the following:

▲



Triricinolein (glyceryl triricinoleate or triricinoleoyl-glycerol) predominates

CAS RN[®]: 8001-79-4].▲_{2S} (USP41)

Change to read:

DEFINITION

Castor Oil is the fixed oil obtained from the seed of *Ricinus communis* L. (Family Euphorbiaceae). ▲Castor Oil consists of NLT 90.0% of the triglyceride of ricinoleic acid.▲_{2S} (USP41) It contains no added substances.

IDENTIFICATION

Add the following:

▲• A. 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 linolenate, methyl *cis*-11-eicosenoate, and methyl ricinoleate from, respectively, [USP Methyl Palmitate RS](#), [USP Methyl Stearate RS](#), [USP Methyl Oleate RS](#), [USP Methyl Linoleate RS](#), [USP Methyl Linolenate 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 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. 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](#) for the oven program.

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. 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 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)	0.62
Methyl stearate (C18:0)	0.98
Methyl oleate (C18:1)	1.00
Methyl linoleate (C18:2)	1.08
Methyl linolenate (C18:3)	1.19
Methyl <i>cis</i> -11-eicosenoate (C20:1)	1.63
Methyl ricinoleate	2.68

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 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 sample taken:

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

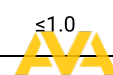
r_U = peak area of each individual fatty acid methyl ester, except for the uncorrected peak area of methyl ricinoleate (or corrected peak area of methyl ricinoleate) in the *Sample solution*

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

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

Table 4

Component	Percentage (%)
Palmitic acid (C16:0)	≤2.0
Stearic acid (C18:0)	≤2.5
Oleic acid (C18:1)	2.5–6.0
Linoleic acid (C18:2)	2.5–7.0
Linolenic acid (C18:3)	≤1.0



Documents

Document Sharing Hub