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Castor Oil Emulsion

DEFINITION
Castor Oil Emulsion contains NLT 90.0% and NMT 120.0% of the labeled amount of Castor Oil.

IDENTIFICATION

• **A.**

Sample: 10 mL of Emulsion well shaken

Analysis: Transfer the *Sample* to a 125-mL separator. Add 10 mL of 1 N hydrochloric acid and 20 mL of solvent hexane. Shake vigorously for 2–3 min, allow the layers to separate, discard the aqueous phase, and filter the upper layer through anhydrous sodium sulfate into a small beaker. Evaporate the solvent on a steam bath, and to the residue add 1–2 drops of sulfuric acid.

Acceptance criteria: A red color indicates the presence of castor oil.

ASSAY

• **Procedure**

Internal standard solution: 12 mg/mL of di(2-ethylhexyl)phthalate in chloroform

Standard solution: Transfer 100 mg of castor oil to a 100-mL boiling flask equipped with a suitable reflux condenser connected by a ground-glass joint. Add 30 mL of a mixture of 300 mL of methanol and 3.7 mL of sulfuric acid, reflux in a water bath maintained at 75°–80° for 2.5 h, cool, and rinse down the condenser with 10 mL of water. Transfer the contents of the flask to a 125-mL separator with the aid of 10 mL of water. Rinse the condenser and the flask with 25 mL of solvent hexane, and transfer to the separator. Shake the separator for 2 min, and draw off the aqueous layer into a second 125-mL separator. Add 20 mL of solvent hexane to the second separator, shake for 2 min, discard the aqueous layer, and transfer the solvent hexane layer to the first separator with the aid of 10 mL of solvent hexane. Wash the combined extracts with three 5-mL portions of water, discarding the washings, and transfer the washed extract to a 125-mL conical flask through a funnel containing anhydrous sodium sulfate, with the aid of 25 mL of solvent hexane. Place the flask in a hot water bath, and evaporate with the aid of a current of air to dryness. To the residue add 10.0 mL of *Internal standard solution*, and mix until solution is complete.

Sample solution: Transfer an amount of Emulsion, well-shaken and nominally equivalent to 100 mg of castor oil, to a long-neck, round-bottom 100-mL boiling flask equipped with a suitable reflux condenser connected by a ground-glass joint. Prepare as directed in *Standard solution*, beginning with “Add 30 mL of a mixture of 300 mL of methanol and 3.7 mL of sulfuric acid”.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 1.8-m × 4-mm; packed with 4% liquid phase G25 on support S1

Column conditioning: Flush with helium for 2–5 min, then heat without further flushing at 250° for NLT 30 min, then cool to room temperature, and finally heat while helium is flowing through it at 250° for NLT 60 min.

Temperature

Column: 245°

Injector: 300°

Detector: 300°

Flow rate: Adjust to obtain a peak due to castor oil 5.5 min after introduction of the specimen and an internal standard peak 8 min after introduction of the specimen.

Carrier gas: Helium

Injection size: 5 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Measure the heights of the peaks due to castor oil and the internal standard.

Calculate the percentage of castor oil in the portion of Emulsion taken:

$$\text{Result} = (R_U/R_S) \times (W_S/W_U) \times 100$$

R_U = ratio of the heights of the peaks due to castor oil and internal standard, *Sample solution*

R_S = ratio of the heights of the peaks due to castor oil and internal standard, *Standard solution*

W_S = weight of castor oil taken to prepare the *Standard solution* (mg)

W_U = nominal weight of castor oil in the amount of Emulsion taken to prepare the *Sample solution* (mg)

Acceptance criteria: 90.0%–120.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

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

Topic/Question	Contact	Expert Committee
CASTOR OIL EMULSION	Nam-Cheol Kim Scientific Liaison	BDSHM2020 Botanical Dietary Supplements and Herbal Medicines

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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