

## U.S. PHARMACOPEIA

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Castor Oil

» Castor Oil is the fixed oil obtained from the seed of *Ricinus communis* Linné (Fam. Euphorbiaceae). It contains no added substances.

**Packaging and storage**— Preserve in tight containers, and avoid exposure to excessive heat.

**Specific gravity** [〈 841 〉](#): between 0.957 and 0.961.

**Distinction from most other fixed oils**— It is only partly soluble in solvent hexane ([distinction from most other fixed oils](#)), but it yields a clear liquid with an equal volume of alcohol (*foreign fixed oils*).

**Heavy metals, Method II** [〈 231 〉](#): 0.001%.

**Free fatty acids** [〈 401 〉](#)— The free fatty acids in 10 g require for neutralization not more than 3.5 mL of 0.10 N sodium hydroxide.

**Hydroxyl value** [〈 401 〉](#)— Transfer 2 g, accurately weighed, to a glass-stoppered, 250-mL conical flask, add 5.0 mL of a freshly prepared mixture of 1 volume of acetic anhydride and 3 volumes of pyridine, and swirl to mix. Connect the flask to a reflux condenser, and heat on a steam bath for 2 hours. Add 10 mL of water through the condenser, swirl to mix, heat on a steam bath for an additional 10 minutes, and allow to cool to room temperature. Add through the condenser 15 mL of normal butyl alcohol that previously has been neutralized to phenolphthalein, remove the condenser, and wash the tip of the condenser and the sides of the flask with an additional 10 mL of neutralized normal butyl alcohol. Add 1 mL of phenolphthalein TS, and titrate with 0.5 N alcoholic potassium hydroxide VS to a faint pink endpoint. Perform a blank determination on a 5.0 mL portion of the acetic anhydride-pyridine mixture. To determine the amount of free acid in the Oil, weigh accurately 10 g into a 250-mL conical flask, add 10 mL of pyridine that previously has been neutralized to phenolphthalein, swirl to mix, add 1 mL of phenolphthalein TS, and titrate with 0.5 N alcoholic potassium hydroxide VS to a faint pink endpoint. Calculate the hydroxyl value taken by the formula:

$$56.1N[A+(BW/D) - C]/W,$$

in which *N* is the normality determined for the alcoholic potassium hydroxide solution; *A* is the volume, in mL, of 0.5 *N* alcoholic potassium hydroxide consumed by the blank; *B* is the volume, in mL consumed in the free-acid titration; *W* is the weight, in g, of Oil taken, *D* is the weight, in g, of Oil used in the free-acid titration; and *C* is the volume, in mL, consumed in the sample titration. The hydroxyl value is between 160 and 168.

**Iodine value** [〈 401 〉](#): between 83 and 88.

**Saponification value** [〈 401 〉](#): between 176 and 182.

**Residual solvents** [〈 467 〉](#): meets the requirements.

(Official January 1, 2007)

**Auxiliary Information**— *Staff Liaison*: [Hong Wang, Ph.D., Senior Scientific Associate](#)

*Expert Committee*: (EM205) Excipient Monographs 2

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