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Castor Oil Capsules

DEFINITION

Castor Oil Capsules contain NLT 90.0% and NMT 110.0% of the labeled amount of castor oil, calculated from the tests for *Weight Variation* and *Specific Gravity*.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197S](#) ▲ (CN 1-MAY-2020)

Standard solution: 40 mg/mL of Castor Oil in chloroform

Sample solution: 40 mg/mL of the oil from Capsules in chloroform

Acceptance criteria: Meet the requirements

PERFORMANCE TESTS

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

SPECIFIC TESTS

- [SPECIFIC GRAVITY \(841\)](#).

Sample: Capsule contents

Acceptance criteria: 0.957–0.961

- [FATS AND FIXED OILS, Free Fatty Acids \(401\)](#): The free fatty acids in 10 g require NMT 3.5 mL of 0.10 N sodium hydroxide for neutralization.

- [FATS AND FIXED OILS, Hydroxyl Value \(401\)](#).

Free acid determination: Determine the amount of free acid in the Capsule contents.

Sample: 10 g of Capsule contents

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.5 N alcoholic potassium hydroxide VS

Endpoint detection: Visual

Analysis 1: Transfer the *Sample* to a 250-mL conical flask, add 10 mL of pyridine that has been neutralized previously to phenolphthalein, and swirl to mix. Add 1 mL of phenolphthalein TS, and titrate with *Titrant* to a faint pink endpoint. Record the volume of *Titrant* consumed.

Hydroxyl value determination: Determine the hydroxyl value of the Capsule contents.

Sample: 2 g from the Capsule contents

Blank: 5.0 mL of a freshly prepared mixture of 1 volume of acetic anhydride and 3 volumes of pyridine

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Residual titration

Titrant: 0.5 N alcoholic potassium hydroxide VS

Endpoint detection: Visual

Analysis 2: Transfer the *Sample* 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 h. Add 10 mL of water through the condenser, swirl to mix, heat on a steam bath for an additional 10 min, 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 *Titrant* to a faint pink endpoint.

Calculate the hydroxyl value in the portion of Capsule contents taken:

$$\text{Result} = (M_r \times N/W) \times [B + (W \times A/C) - T]$$

M_r = milliequivalent weight of potassium hydroxide, 56.11 mg/mEq

N = actual normality of the *Titrant*

W = *Sample* weight for the hydroxyl determination (g)

B = Titrant volume consumed by the Blank (mL)

A = Titrant volume consumed by the Sample in the free acid determination (mL)

C = Sample weight for the free acid determination (g)

T = Titrant volume consumed by the *Sample* in the hydroxyl determination (mL)

Acceptance criteria: 160–168 in mg of KOH/g of Capsule content or hydroxyl value

- **FATS AND FIXED OILS, Iodine Value(401).**

Sample: Capsule contents

Acceptance criteria: 83–88

- **FATS AND FIXED OILS, Saponification Value**(401).

Sample: Capsule contents

Acceptance criteria: 176–182

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, preferably at controlled room temperature.

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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