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Compound Orange Spirit

DEFINITION

Compound Orange Spirit contains NLT 25 mL and NMT 30 mL of the mixed oils in 100 mL of Spirit.

Prepare Compound Orange Spirit as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Orange Oil	200 mL
Lemon Oil	50 mL
Coriander Oil	20 mL
Anise Oil	5 mL
Alcohol, a sufficient quantity to make	1000 mL

Mix the oils with sufficient *Alcohol* to make the product measure 1000 mL.

ASSAY

• **Procedure**

Sample solution: Transfer 2.0 mL of Compound Orange Spirit and 1.0 mL of kerosene to a Babcock bottle, graduated to 8%, and mix.

Analysis: To the *Sample solution* add sufficient saturated calcium chloride solution, acidified with hydrochloric acid, to almost fill the bulb of the bottle. Rotate the bottle vigorously to ensure mixing, then add a sufficient quantity of the calcium chloride solution to bring the separated oil into the neck of the bottle. Centrifuge for 5 min at 1500 rpm, and read the volume of oil in the stem. Subtract five divisions on the volumetric flask for the kerosene added, and multiply the remaining number of divisions by 10.5 to obtain the volume, in mL, of mixed oils in 100 mL of the Compound Orange Spirit.

Acceptance criteria: 25–30 mL

OTHER COMPONENTS

• **Alcohol Determination,** *Method I* ⟨611⟩**:** 65.0%–70.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight containers, protected from light, and store in a cold place.

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

Topic/Question	Contact	Expert Committee
COMPOUND ORANGE SPIRIT	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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