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# Orange Syrup

## DEFINITION

Orange Syrup contains NLT 0.45% and NMT 0.55% of citric acid ( $C_6H_8O_7$ ).

Prepare Orange Syrup as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Sweet Orange Peel Tincture	50 mL
Anhydrous Citric Acid	5 g
Talc	15 g
Sucrose	820 g
Purified Water, a sufficient quantity to make	1000 mL

Triturate *Talc* with *Sweet Orange Peel Tincture* and *Anhydrous Citric Acid*, and gradually add 400 mL of *Purified Water*. Filter, returning the first portions of the filtrate until it becomes clear, and wash the mortar and the filter with sufficient *Purified Water* to make the filtrate measure 450 mL. Dissolve *Sucrose* in this filtrate by agitation, without heating, and add *Purified Water* to make the product measure 1000 mL. Mix, and strain. [NOTE—Do not use Orange Syrup that has a terebinthine odor or taste or shows other indications of deterioration.]

## ASSAY

• **CITRIC ACID**

**Sample:** 20 mL

**Titrimetric system**

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

**Mode:** Direct titration

**Titrant:** 0.1 N sodium hydroxide VS

**Endpoint detection:** Visual

**Analysis:** To the *Sample* add 20 mL of water and add phenolphthalein TS. Titrate with *Titrant*. Each mL of *Titrant* is equivalent to 6.404 mg of citric acid ( $C_6H_8O_7$ ).

**Acceptance criteria:** 0.45%–0.55%

## OTHER COMPONENTS

- [ALCOHOL DETERMINATION, Method I \(611\)](#): 2.0%–5.0%

## ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight containers, and store in a cold place.
- **LABELING:** The label states the Latin binomial and, following the official name, the part of the plant source from which the article was derived. The label indicates that Syrup is not to be used if it has a terebinthine odor or taste or shows other indications of deterioration.

Topic/Question	Contact	Expert Committee
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