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Add the following:

^Star Anise Oil

CAS RN®: 68952-43-2.

DEFINITION

Star Anise Oil is the volatile oil distilled with steam from the dried, ripe fruit of *Illicium verum* Hook. f. It contains NLT 86% and NMT 93% of *trans*-anethole.

[NOTE—If solid material has separated, carefully warm the Star Anise Oil until it is completely liquefied, and mix before using.]

IDENTIFICATION

• A. CHROMATOGRAPHIC IDENTITY

Peak identification and sensitivity solution: 60 mg/mL of [USP Anethole RS](#), 1 mg/mL of [USP Foeniculin RS](#), and 0.1 mg/mL each of [USP Pseudoisoeugenyl 2-methylbutyrate RS](#) and [USP Safrole RS](#) in *n*-hexane

Standard: [USP Star Anise Oil RS](#)

Sample: Star Anise Oil

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m; coated with a 0.25-μm film of phase [G16](#)

Temperatures

Injection port: 200°

Detector: 220°

Column: See [Table 1](#).

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	—	60	5
60	2	210	15

Carrier gas: Helium

Flow rate: 1.0 mL/min

Injection volume: 0.4 μL

Injection type: Split; split ratio, 100:1

System suitability

Sample: Peak identification and sensitivity solution

[NOTE—The relative retention times for the *trans*-anethole, safrole, foeniculin, and pseudoisoeugenyl 2-methylbutyrate peaks are 1.0, 1.04, 1.5, and 1.7, respectively.]

Suitability requirements

Signal-to-noise ratio: NLT 10 for the pseudoisoeugenyl 2-methylbutyrate and safrole peaks

Analysis

Samples: Peak identification and sensitivity solution, Standard, and Sample

Identify the safrole, foeniculin, and pseudoisoeugenyl 2-methylbutyrate peaks in the chromatogram of the *Sample* based on those in the chromatogram of the *Peak identification and sensitivity solution*.

Calculate the percentage of safrole, foeniculin, and pseudoisoeugenyl 2-methylbutyrate in the portion of Star Anise Oil taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of safrole or foeniculin or pseudoisoeugenyl 2-methylbutyrate from the *Sample*

r_T = sum of all the peak areas, excluding the solvent peak

Acceptance criteria

Chromatographic similarity: Examine the chromatograms of the *Sample* and the *Standard*. The chromatogram of the *Sample* is similar to that of the *Standard*. [NOTE—The chromatogram of the *Standard* is similar to the reference chromatogram provided with the lot of USP Star Anise Oil RS being used.]

Safrole: NMT 0.01%

Foeniculin: NLT 0.10%

Pseudoisoeugenyl 2-methylbutyrate: NMT 0.01%

- **B. REFRACTIVE INDEX:** Meets the requirements for *Refractive Index* in *Specific Tests*

ASSAY

- **CONTENT OF trans-ANETHOLE**

Peak identification and sensitivity solution, Sample, and Chromatographic system: Proceed as directed in *Identification A*.

Analysis

Samples: Peak identification and sensitivity solution and *Sample*

Identify the *trans-anethole* peak in the chromatogram of the *Sample* based on that in the chromatogram of the *Peak identification and sensitivity solution*.

Calculate the percentage of *trans-anethole* in the portion of Star Anise Oil taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area of *trans-anethole* from the *Sample*

r_T = sum of all the peak areas, excluding the solvent peak

Acceptance criteria: 86%–93%

IMPURITIES

- **LIMIT OF PHENOLS**

Sample solution: Recently distilled Star Anise Oil in 90% alcohol (1 in 3)

Acceptance criteria: The *Sample solution* is neutral to moistened neutral litmus paper, and no blue or brownish color develops upon the addition of 1 drop of [ferric chloride TS](#) to 5 mL of the *Sample solution*.

SPECIFIC TESTS

- **SOLUBILITY IN 90% ALCOHOL:** 1 volume dissolves in 3 volumes of 90% alcohol.

- **REFRACTIVE INDEX (831):** 1.553–1.556 at 20°

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-filled, tight containers, and protect from light. Avoid exposure to excessive heat.

LABELING: The label states the Latin binomial name and, following the official name, the part of the plant source from which the article was derived. The label also states that if solid material has separated, carefully warm the oil until it is completely liquefied, and mix before using.

- **USP REFERENCE STANDARDS (11).**

[USP Anethole RS](#)

[USP Foeniculin RS](#)

[USP Pseudoisoeugenyl 2-methylbutyrate RS](#)

[USP Safrole RS](#)

[USP Star Anise Oil RS](#) ▲ (NF 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
STAR ANISE OIL	Documentary Standards Support	CE2020 Complex Excipients
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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